

국민 안심이 기준입니다  
YOUR SAFETY IS OUR STANDARD



기능성 원료  
안전성 확인을 위한  
국가별 원료 정보  
검색 가이드

2025. 7.



식품의약품안전처  
식품의약품안전평가원



이 가이드는 건강기능식품 기능성 원료 인정을 위한 제출자료 작성 시 도움을 주고자, 기능성 원료의 안전성 확인을 위한 국가별 원료 정보 검색 방법을 안내하는 참고 자료입니다.

본 자료는 2024년 11월 기준으로 작성되었으며, 원료를 검색할 수 있는 모든 DB가 포함된 것이 아니므로 참고로만 활용하시기 바랍니다.

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※ 본 가이드에 대한 의견이나 문의사항이 있을 경우  
식품의약품안전평가원 식품위해평가부 영양기능연구과로 문의하시길 바랍니다.

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건강기능식품 · 식품	안전성	미국	식품의약품청(FDA)	신규식이성분 신고 목록(List of NDINs)	<a href="https://www.fda.gov/food/new-dietary-ingredient-ndi-notification-process/submitted-75-day-premarket-notifications-new-dietary-ingredients">https://www.fda.gov/food/new-dietary-ingredient-ndi-notification-process/submitted-75-day-premarket-notifications-new-dietary-ingredients</a>	4	
				GRAS 물질 선택 위원회 데이터베이스 (SCOGS Database)	<a href="https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=SCOGS">https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=SCOGS</a>	12	
				식품에 첨가하는 물질 인벤토리 (Substances Added to Food Inventory)	<a href="https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=FoodSubstances">https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=FoodSubstances</a>	21	
				GRAS 신고(GRAS Notices)	<a href="https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&amp;sort=GRN_No&amp;order=DESC&amp;startrow=51&amp;type=basic&amp;search=">https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&amp;sort=GRN_No&amp;order=DESC&amp;startrow=51&amp;type=basic&amp;search=</a>	28	
			국립보건원(NIH)	메디라인플러스(MedlinePlus)	<a href="https://medlineplus.gov/">https://medlineplus.gov/</a>	36	
			캐나다	캐나다 보건부(HC)	안전성 평가 완료된 신소재 식품(유전자 변형 식품 포함) 목록	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html">https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html</a>	39
			유럽연합	유럽위원회(EC)/ 유럽식품안전청(EFSA)	식품, 사료 정보 포털 데이터베이스(신소재 식품)	<a href="https://eur-lex.europa.eu/eli/reg_impl/2017/2470/oj">https://eur-lex.europa.eu/eli/reg_impl/2017/2470/oj</a>	42
			호주	호주뉴질랜드 식품기준청 (FSANZ)	호주뉴질랜드 식품기준 코드-별표 25- 허용된 신규식품 목록	<a href="https://www.legislation.gov.au/F2015L00440/latest/text">https://www.legislation.gov.au/F2015L00440/latest/text</a>	46
			인도	식품안전기준청(FSSAI)	비정의 식품	<a href="https://fssai.gov.in/cms/non-specified-food.php">https://fssai.gov.in/cms/non-specified-food.php</a>	50
		식품 안전 및 기준(식품 또는 건강보조식품, 뉴트리슈터컬, 특수식이 목자식품, 특수의료목적식품, 기능성 식품, 신소재식품) 규정			<a href="https://fssai.gov.in/cms/product-standards.php">https://fssai.gov.in/cms/product-standards.php</a>	55	

대분류	중분류	국가명	관리기관	DB명칭	접속 주소	페이지
건강기능식품 · 식품	안전성	일본	국립건강영양연구소	「건강식품」의 안전성·유효성 정보	<a href="https://hfnet.nibiohn.go.jp/">https://hfnet.nibiohn.go.jp/</a>	61
			식품안전위원회	식품 위험 허브 정보 - 수돗물·청량음료 내 화학물질 목록	<a href="https://www.fsc.go.jp/foodsafetyinfo_map/foodhazinfohub/foodhazinfohub_drink.html">https://www.fsc.go.jp/foodsafetyinfo_map/foodhazinfohub/foodhazinfohub_drink.html</a>	65
				식품 위험 허브 정보 - 영양성분 및 식품 구성성분 목록	<a href="https://www.fsc.go.jp/foodsafetyinfo_map/foodhazinfohub/foodhazinfohub_others.html">https://www.fsc.go.jp/foodsafetyinfo_map/foodhazinfohub/foodhazinfohub_others.html</a>	69
		베트남	보건부 식품안전국(VFA)	건강보호식품 생산, 영업 간 사용이 금지된 물질 목록 규정(No.10/2021/TT-BYT)	<a href="https://vfa.gov.vn/van-ban.html">https://vfa.gov.vn/van-ban.html</a>	72
	섭취근거	미국	United Natural Products Alliance(UMPA)	기존 식이 성분 목록 (Old Dietary Ingredient List)	<a href="https://blog.priceplow.com/wp-content/uploads/unpa-old_dietary_ingredients_list-1999.pdf">https://blog.priceplow.com/wp-content/uploads/unpa-old_dietary_ingredients_list-1999.pdf</a>	75
		캐나다	캐나다 보건부(HC)	천연건강제품 원료 데이터베이스(NHPID)	<a href="https://webprod.hc-sc.gc.ca/nhpid-bdipsn/">https://webprod.hc-sc.gc.ca/nhpid-bdipsn/</a>	78
		유럽연합	유럽위원회(EC)/ 유럽식품안전청(EFSA)	식품, 사료 정보 포털 데이터베이스(영양성분)	<a href="https://ec.europa.eu/food/food-feed-portal/screen/nutrients/search">https://ec.europa.eu/food/food-feed-portal/screen/nutrients/search</a>	87
		호주	연방의료제품청(TGA)	의약품(허용 성분) 결정	<a href="https://www.legislation.gov.au/F2024L01196/asmade/text">https://www.legislation.gov.au/F2024L01196/asmade/text</a>	92
			호주뉴질랜드 식품기준청(FSANZ)	호주식품성분데이터베이스	<a href="https://www.foodstandards.gov.au/science-data/monitoring-nutrients/afcd">https://www.foodstandards.gov.au/science-data/monitoring-nutrients/afcd</a>	96
		중국	식품화반넷	식품원료 검색데이터베이스	<a href="http://dbxinshipin.foodmate.net/">http://dbxinshipin.foodmate.net/</a>	100
			국가약전위원회	중국약전	<a href="https://ydz.chp.org.cn/#/main">https://ydz.chp.org.cn/#/main</a>	104
		일본	소비자청	특정 보건용 식품 일람	<a href="https://www.caa.go.jp/policies/policy/food_labeling/foods_for_specified_health_uses/">https://www.caa.go.jp/policies/policy/food_labeling/foods_for_specified_health_uses/</a>	108
		대만	위생복지부 식품약품관리서	식품원료 통합 조회 플랫폼	<a href="https://consumer.fda.gov.tw/Food/Material.aspx?nodeID=160">https://consumer.fda.gov.tw/Food/Material.aspx?nodeID=160</a>	112
	기준규격	호주	호주뉴질랜드 식품기준청(FSANZ)	호주뉴질랜드 식품기준 코드-별표 23-금지된 식물 및 곰팡이	<a href="https://www.legislation.gov.au/F2015L00435/latest/text">https://www.legislation.gov.au/F2015L00435/latest/text</a>	119
				호주뉴질랜드 식품기준 코드-별표 24-제한된 식물 및 곰팡이	<a href="https://www.legislation.gov.au/F2015L00438/latest/text">https://www.legislation.gov.au/F2015L00438/latest/text</a>	123

대분류	중분류	국가명	관리기관	DB명칭	접속 주소	페이지
건강기능식품 · 식품	기준규격	인도	식품안전기준청(FSSAI)	식품 안전 및 기준(오염물질, 독소 및 잔류물질) 규정	<a href="https://fssai.gov.in/cms/product-standards.php">https://fssai.gov.in/cms/product-standards.php</a>	127
		일본	식품안전위원회	식품 위험 허브 정보	<a href="https://www.fsc.go.jp/foodsafetyinfo_map/foodhazinfohub/foodhazinfohub_poll.html">https://www.fsc.go.jp/foodsafetyinfo_map/foodhazinfohub/foodhazinfohub_poll.html</a>	132
의약품	의약품	호주	연방의료제품청(TGA)	TGA eBusiness Services	<a href="https://www.ebs.tga.gov.au/">https://www.ebs.tga.gov.au/</a>	138
		일본	후생노동성	무승인 무허가 의약품 정보(의약품적 효능효과를 표방하지 않는 경우에는 의약품이라고 판단하지 않는 원재료 목록)	<a href="https://www.mhlw.go.jp/content/001318303.pdf">https://www.mhlw.go.jp/content/001318303.pdf</a>	142
				무승인 무허가 의약품 정보(오로지 의약품으로서 사용되는 성분 원재료 목록)	<a href="https://www.mhlw.go.jp/content/001318302.pdf">https://www.mhlw.go.jp/content/001318302.pdf</a>	146
생약	생약	유럽연합	유럽의약품청(EMA)	유럽연합 약초 모노그래프	<a href="https://www.ema.europa.eu/en/search?f%5B0%5D=ema_search_categories%3A85&amp;f%5B1%5D=herbal_outcome%3A256">https://www.ema.europa.eu/en/search?f%5B0%5D=ema_search_categories%3A85&amp;f%5B1%5D=herbal_outcome%3A256</a>	152
		일본	독립행정법인 의약품의료기기종합기구	생약 목록	<a href="https://www.pmda.go.jp/rs-std-jp/standards-development/jp/0192.html">https://www.pmda.go.jp/rs-std-jp/standards-development/jp/0192.html</a>	157
			국립건강영양연구소	약용식물 종합 데이터베이스	<a href="https://www.wts9.nibiohn.go.jp/mpdb.html">https://www.wts9.nibiohn.go.jp/mpdb.html</a>	161
		대만	위생복지부 중의약사	대만중약전		<a href="https://dep.mohw.gov.tw/DOCMAP/cp-759-63293-108.html">https://dep.mohw.gov.tw/DOCMAP/cp-759-63293-108.html</a>
식품에 동시 사용 가능한 중약재 품목				<a href="https://dep.mohw.gov.tw/DOCMAP/cp-754-39873-108.html">https://dep.mohw.gov.tw/DOCMAP/cp-754-39873-108.html</a>	172	
첨가물	첨가물	미국	식품의약품청(FDA)	색소첨가물 규제 상태 (Regulatory Status of Color Additives)	<a href="https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=ColorAdditives">https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=ColorAdditives</a>	180
		캐나다	캐나다 보건부(HC)	허용 식품첨가물(고결방지제) 목록	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/1-anticaking-agents.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/1-anticaking-agents.html</a>	188
				허용 식품첨가물(밀가루 개량제) 목록	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/2-bleaching-maturing-dough-conditioning-agents.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/2-bleaching-maturing-dough-conditioning-agents.html</a>	193

대분류	중분류	국가명	관리기관	DB명칭	접속 주소	페이지
첨가물	첨가물	캐나다	캐나다 보건부(HC)	허용 식품첨가물(색소) 목록	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/3-colouring-agents.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/3-colouring-agents.html</a>	197
				허용 식품첨가물(유화제, 겔화제, 안정제 및 증점제) 목록	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/4-emulsifying-gelling-stabilizing-thickening-agents.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/4-emulsifying-gelling-stabilizing-thickening-agents.html</a>	201
				허용 식품첨가물(효소제제) 목록	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/5-enzymes.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/5-enzymes.html</a>	206
				허용 식품첨가물(경화제) 목록	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/6-firming-agents.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/6-firming-agents.html</a>	210
				허용 식품첨가물(광택제) 목록	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/7-glazing-polishing-agents.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/7-glazing-polishing-agents.html</a>	214
				허용 식품첨가물(기타) 목록	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/8-other-accepted-uses.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/8-other-accepted-uses.html</a>	218
				허용 식품첨가물(감미료) 목록	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/9-sweeteners.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/9-sweeteners.html</a>	222
				허용 식품첨가물(산도조절제) 목록	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/10-adjusting-agents.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/10-adjusting-agents.html</a>	226

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첨가물	첨가물	캐나다	캐나다 보건부(HC)	허용 식품첨가물(보존제) 목록	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/11-preservatives.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/11-preservatives.html</a>	230
				허용 식품첨가물(제조용제) 목록	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/12-sequestering-agents.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/12-sequestering-agents.html</a>	234
				허용 식품첨가물(변성전분 제제) 목록	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/13-starch-modifying-agents.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/13-starch-modifying-agents.html</a>	238
				허용 식품첨가물(효모식품) 목록	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/14-yeast-foods.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/14-yeast-foods.html</a>	243
				허용 식품첨가물(용매) 목록	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/15-carrier-extraction-solvents.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/15-carrier-extraction-solvents.html</a>	247
	유럽연합	유럽연합	유럽위원회(EC)/ 유럽식품안전청(EFSA)	식품, 사료 정보 포털 데이터베이스(식품첨가물)	<a href="https://ec.europa.eu/food/food-feed-portal/screen/food-additives/search">https://ec.europa.eu/food/food-feed-portal/screen/food-additives/search</a>	251
				식품, 사료 정보 포털 데이터베이스(향미증진제)	<a href="https://ec.europa.eu/food/food-feed-portal/screen/food-flavourings/search">https://ec.europa.eu/food/food-feed-portal/screen/food-flavourings/search</a>	255
				비타민, 미네랄 및 기타 물질의 식품 첨가에 관한 규정(Regulation(EC) No 1925/2006)	<a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R1925&amp;qid=1731237974212">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R1925&amp;qid=1731237974212</a>	259
				식품에 사용되거나 사용될 목적으로 제조된 혼제 향료에 관한 규정 (Regulation(EC) No 2065/2003)	<a href="http://data.europa.eu/eli/reg/2003/2065/oj">http://data.europa.eu/eli/reg/2003/2065/oj</a>	263
				식품첨가물에 관한 규정 (Regulation(EC) No 1333/2008)	<a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R1333&amp;qid=1731242495915">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R1333&amp;qid=1731242495915</a>	272
				식품 및 식품첨가물로 사용되는 향료 및 특정 향미증진제에 관한 규정 (Regulation(EC) No 1334/2008)	<a href="http://data.europa.eu/eli/reg/2008/1334/oj">http://data.europa.eu/eli/reg/2008/1334/oj</a>	275

대분류	중분류	국가명	관리기관	DB명칭	접속 주소	페이지
첨가물	첨가물	호주	호주뉴질랜드 식품기준청 (FSANZ)	호주뉴질랜드 식품기준 코드-별표 15-식품첨가물로 사용될 수 있는 물질	<a href="https://www.legislation.gov.au/F2015L00439/latest/text">https://www.legislation.gov.au/F2015L00439/latest/text</a>	278
		인도	식품안전기준청(FSSAI)	식품 안전 및 기준(식품 기준 및 식품첨가물) 규정	<a href="https://fssai.gov.in/cms/product-standards.php">https://fssai.gov.in/cms/product-standards.php</a>	282
		중국	식품화반넷	GB 2760-2024 식품첨가물 사용표준	<a href="https://gb2760.cfsa.net.cn/">https://gb2760.cfsa.net.cn/</a>	287
				GB 14880-2012 식품영양강화제 사용표준	<a href="http://14880.foodvip.net/">http://14880.foodvip.net/</a>	291
		일본	후생노동성	식품첨가물 리스트	<a href="https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_jryou/shokuhin/syokuten/index.html">https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_jryou/shokuhin/syokuten/index.html</a>	295
			소비자청	식품첨가물공정서	<a href="https://www.caa.go.jp/policies/policy/standards_evaluation/food_additives/official_documents_002">https://www.caa.go.jp/policies/policy/standards_evaluation/food_additives/official_documents_002</a>	300
		일본	일본식품화학연구진흥재단	기존첨가물 명부	<a href="https://www.ffcr.or.jp/tenka/list/post-12.html?OpenDocument">https://www.ffcr.or.jp/tenka/list/post-12.html?OpenDocument</a>	304
				지정첨가물 명부	<a href="https://www.ffcr.or.jp/tenka/list/post-12.html?OpenDocument">https://www.ffcr.or.jp/tenka/list/post-12.html?OpenDocument</a>	307
				천연향료 기원 물질 리스트	<a href="https://www.ffcr.or.jp/tenka/list/post-13.html">https://www.ffcr.or.jp/tenka/list/post-13.html</a>	310
				일반첨가물 리스트	<a href="https://www.ffcr.or.jp/tenka/list/post-14.html">https://www.ffcr.or.jp/tenka/list/post-14.html</a>	313
				유전자 재조합 첨가물 목록	<a href="https://www.ffcr.or.jp/tenka/list/post-15.html">https://www.ffcr.or.jp/tenka/list/post-15.html</a>	316
		베트남	보건부 식품안전국(VFA)	식품첨가물 사용, 관리에 관한 규정 (No.09/VBHN-BYT)	<a href="https://vfa.gov.vn/van-ban.html">https://vfa.gov.vn/van-ban.html</a>	319
		대만	위생복지부 식품약물관리서	식품첨가물 사용범위 및 제한량, 규격표준	<a href="https://consumer.fda.gov.tw/Law/FoodAdditivesList.aspx?nodeID=521">https://consumer.fda.gov.tw/Law/FoodAdditivesList.aspx?nodeID=521</a>	322
				천연식용색소 위생표준	<a href="https://consumer.fda.gov.tw/Law/Detail.aspx?nodeID=518&amp;lawid=139">https://consumer.fda.gov.tw/Law/Detail.aspx?nodeID=518&amp;lawid=139</a>	328
기타	표시	미국	국립보건원(NIH)	식이보충제 라벨 정보 데이터베이스 (Dietary Supplement Label Database)	<a href="https://dssl.od.nih.gov/browse-ingredients/by_letter/A/0/20">https://dssl.od.nih.gov/browse-ingredients/by_letter/A/0/20</a>	336
		유럽연합	유럽위원회(EC)/ 유럽식품안전청(EFSA)	식품, 사료 정보 모델 데이터베이스(건강강조표시)	<a href="https://food.ec.europa.eu/food-safety/labelling-and-nutrition/nutrition-and-health-claims_en">https://food.ec.europa.eu/food-safety/labelling-and-nutrition/nutrition-and-health-claims_en</a>	340

대분류	중분류	국가명	관리기관	DB명칭	접속 주소	페이지
기타	표시	유럽연합	유럽위원회(EC)/ 유럽식품안전청(EFSA)	식품에 사용하는 영양 및 건강강조표시 관련 규정(Regulation(EC) No 1924/2006)	<a href="http://data.europa.eu/eli/reg/2006/1924/2014-12-13">http://data.europa.eu/eli/reg/2006/1924/2014-12-13</a>	345
		호주	연방의료제품청(TGA)	의약품(허용 기능표시) 결정	<a href="https://www.legislation.gov.au/F2021L00056/latest/text">https://www.legislation.gov.au/F2021L00056/latest/text</a>	350
	규정	유럽연합	유럽위원회(EC)/ 유럽식품안전청(EFSA)	식품보충제와 관련된 회원국 법률의 조화를 위한 지침(Directive 2002/46/EC)	<a href="https://eur-lex.europa.eu/eli/dir/2002/46/oj">https://eur-lex.europa.eu/eli/dir/2002/46/oj</a>	354
				신소재 식품에 관한 규정 (Regulation(EU) NO 2015/2283)	<a href="http://data.europa.eu/eli/reg/2015/2283/oj">http://data.europa.eu/eli/reg/2015/2283/oj</a>	358
		인도	식품안전기준청(FSSAI)	식품 안전 및 기준(유기농 식품) 규정	<a href="https://fssai.gov.in/cms/product-standards.php">https://fssai.gov.in/cms/product-standards.php</a>	366
				식품 안전 및 기준(알코올 음료) 규정	<a href="https://fssai.gov.in/cms/product-standards.php">https://fssai.gov.in/cms/product-standards.php</a>	371
				식품 안전 및 기준(강화식품) 규정	<a href="https://fssai.gov.in/cms/product-standards.php">https://fssai.gov.in/cms/product-standards.php</a>	376
				식품 안전 및 기준(독자적 식품) 규정	<a href="https://fssai.gov.in/cms/proprietary-food.php">https://fssai.gov.in/cms/proprietary-food.php</a>	381
		베트남	보건부 식품안전국(VFA)	기능성식품 관리규정(No.11/VBHN-BYT)	<a href="https://vfa.gov.vn/van-ban.html">https://vfa.gov.vn/van-ban.html</a>	386
				식품에 사용되는 미량영양소 목록을 정하는 시행규칙(No.44/2015/TT-BYT)	<a href="https://vfa.gov.vn/van-ban.html">https://vfa.gov.vn/van-ban.html</a>	389
	기타	유럽연합	유럽위원회(EC)/ 유럽식품안전청(EFSA)	식품, 사료 정보 포털 데이터베이스(유아용 조제분유 및 성장기 조제분유)	<a href="https://ec.europa.eu/food/food-feed-portal/screen/iffof/search">https://ec.europa.eu/food/food-feed-portal/screen/iffof/search</a>	392
				영유아용 식품, 특수의료목적 식품, 체중 조절용 완전 대체식품에 관한 규정	<a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R0609&amp;qid=1731237974212">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R0609&amp;qid=1731237974212</a>	396
		호주	호주농수산임업국(DAFF)	호주 검역검사국(BICON) 수입 요건 검색	<a href="https://bicon.agriculture.gov.au">https://bicon.agriculture.gov.au</a>	400
		일본	소비자청	제조업체 고유 기호 제도 신고 데이터베이스	<a href="https://www.caa.go.jp/policies/policy/food_labeling/unique_code">https://www.caa.go.jp/policies/policy/food_labeling/unique_code</a>	406
		대만	위생복지부 식품약물관리서	건강식품 검사등록허가증 정보 조회	<a href="https://consumer.fda.gov.tw/Food/InfoHealthFood.aspx?nodeID=162">https://consumer.fda.gov.tw/Food/InfoHealthFood.aspx?nodeID=162</a>	410
				수입 정제·캡슐형태 식품 검사등록 허가 문서 정보 조회	<a href="https://consumer.fda.gov.tw/Food/CapsuleAuditQuery.aspx?nodeID=165">https://consumer.fda.gov.tw/Food/CapsuleAuditQuery.aspx?nodeID=165</a>	416

대분류	중분류	국가명	관리기관	DB명칭	접속 주소	페이지
기타	기타	대만	위생복지부 식품약물관리서	대만산 비타민류 정제·캡슐형태 식품 검사등록증 정보 조회	<a href="https://consumer.fda.gov.tw/Food/DomesticFormulationsQuery.aspx?nodeID=166">https://consumer.fda.gov.tw/Food/DomesticFormulationsQuery.aspx?nodeID=166</a>	422

안전성DB	미국	Therapeutic Research Center	Food, Herbs & Supplements	<a href="https://naturalmedicines.therapeuticresearch.com/databases/food,-herbs-supplements.aspx">https://naturalmedicines.therapeuticresearch.com/databases/food,-herbs-supplements.aspx</a>	430
		AHP(American Herbal Pharmacopoeia)	AHP(American Herbal Pharmacopoeia)- Order Monographs	<a href="https://herbal-ahp.org/">https://herbal-ahp.org/</a>	432
		AMR(Alternative Medicine Review)	AMR ARCHIVE	<a href="https://altmedrev.com/resources/">https://altmedrev.com/resources/</a>	434
		Council for Responsible Nutrition(CRN)	Vitamin and Mineral Safety	<a href="https://www.crnusa.org/sites/default/files/files/resources/CRN-SafetyBook-3rdEdition-2014-fullbook.pdf">https://www.crnusa.org/sites/default/files/files/resources/CRN-SafetyBook-3rdEdition-2014-fullbook.pdf</a>	441
	캐나다	캐나다 보건부(HC)	Pre-Cleared information	<a href="https://webprod.hc-sc.gc.ca/nhpid-bdipsn/monosReq">https://webprod.hc-sc.gc.ca/nhpid-bdipsn/monosReq</a>	447
	유럽연합	European Scientific Cooperative on Phytotherapy (ESCOP)	ESCOP Monograph-List of online Monograph	<a href="https://www.escop.com/escop-products/online-monographs/">https://www.escop.com/escop-products/online-monographs/</a>	458
	영국	Expert Group on Vitamins and Minerals(EVM)	Safe Upper Levels for Vitamins and Minerals	<a href="https://cot.food.gov.uk/sites/default/files/vitmin2003.pdf">https://cot.food.gov.uk/sites/default/files/vitmin2003.pdf</a>	460
	WHO	World Health Organization	WHO monographs on selected medicinal plants	<a href="https://www.who.int/publications/i/item/9241545178">https://www.who.int/publications/i/item/9241545178</a>	464
WHO 산하 International Agency for Research on Cancer(IARC)	SOME DRUGS AND HERBAL PRODUCTS VOLUME 108	<a href="https://monographs.iarc.who.int/cards_page/publications-monographs/">https://monographs.iarc.who.int/cards_page/publications-monographs/</a>	474		

● Ministry of Food and Drug Safety



## Part I.



# 기능성 원료 국외 사용 현황 확인 DB

1. 건강기능식품·식품 · 3
2. 의약품 · 137
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4. 첨가물 · 179
5. 기타 · 335







# 1. 건강기능식품 · 식품

1-1 안전성 · 4

1-2 섭취 근거 · 75

1-3 기준·규격 · 119

## 1-1. 안전성

### ■ 미국

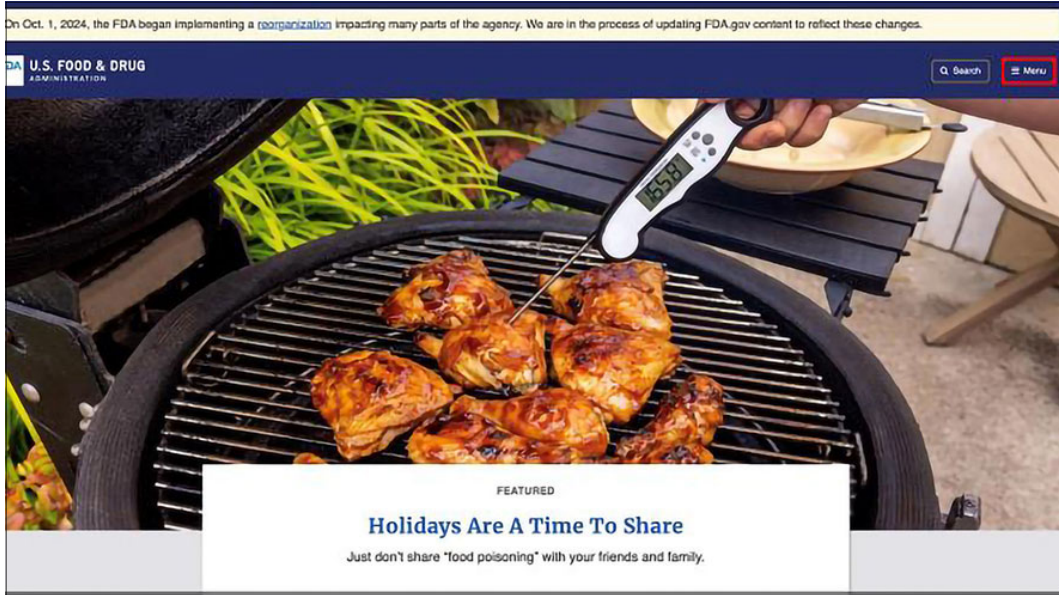
#### [ 신규식이성분 신고 목록(List of NDINs) ]

##### ● 개요

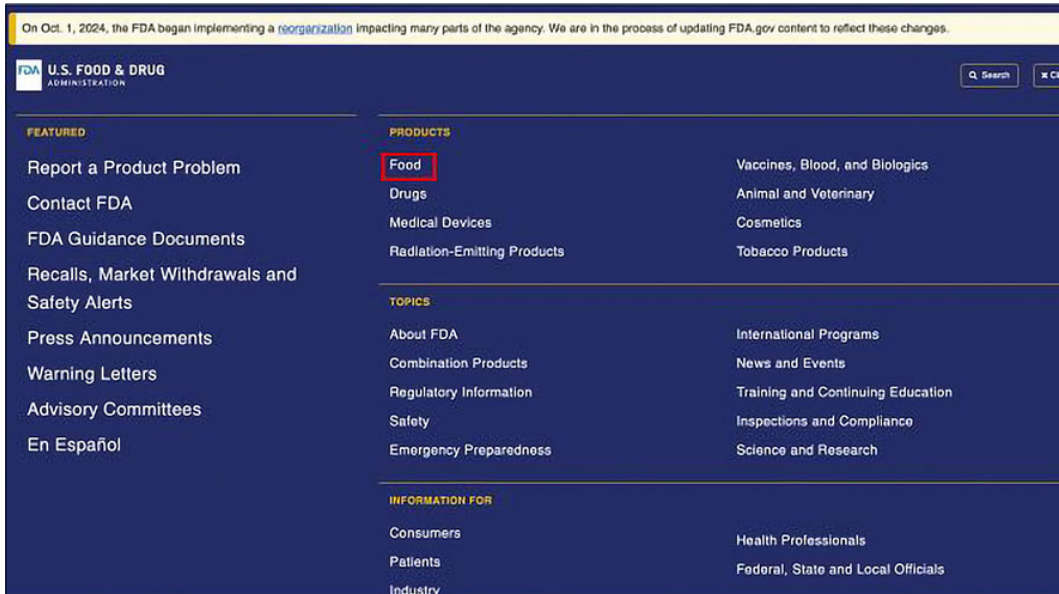
DB명	신규식이성분 신고 목록(List of NDINs)
관리기관	식품의약품청(FDA)
DB 내용	식이보충제에 사용하는 신규식이원료(NDI) 신고 정보
제공 정보	▲ NDI 신고(NDIN) 번호, ▲ 성분명, ▲ 신고서 제출업체명, ▲ 제출일, ▲ FDA 답변일
접속 주소	<a href="https://www.fda.gov/food/new-dietary-ingredient-ndi-notification-process/submitted-75-day-premarket-notifications-new-dietary-ingredients">https://www.fda.gov/food/new-dietary-ingredient-ndi-notification-process/submitted-75-day-premarket-notifications-new-dietary-ingredients</a>
정보 제공 건수	1,243건('24.11. 기준)
기타	엑셀(XLSX) 파일과 PDF 파일 형태로 제공

● DB 접속 방법

○ FDA 홈페이지 메인 우측 상단 'Menu' 클릭



○ 'Menu' 화면으로 이동 후 'Food' 항목 클릭



- 'Food' 화면에서 '식이보충제(Dietary Supplements)' 항목 클릭

NAVIGATE THE FOOD SECTION

<p><b>Labeling &amp; Nutrition</b></p> <p>Nutrition Facts Label, Label Claims, Menu &amp; Vending Machine Labeling, Gluten-Free Labeling</p>	<p><b>Ingredients &amp; Packaging</b></p> <p>Food &amp; Color Additives, GRAS, Food Allergens, Food Contact Substances, New Plant Varieties</p>	<p><b>Food Defense</b></p> <p>Protecting the Food Supply, Intentional Adulteration, Food Defense Plan Builder</p>	<p><b>Dietary Supplements</b></p> <p>Products &amp; Ingredients, New Dietary Ingredients Notification Process, Structure/Function Claim Notifications</p>
<p><b>Science &amp; Research</b></p> <p>Laboratory Methods, Whole Genome Sequencing, Risk Analysis, Total Diet Study, Consumer Research</p>	<p><b>Compliance &amp; Enforcement</b></p> <p>Reportable Food Registry, Warning Letters, Inspections, Compliance Programs, Adverse Event Reporting</p>	<p><b>International &amp; Interagency Coordination</b></p> <p>International Outreach, Visitor's Program, Trade Agreements, Interagency Agreements</p>	<p><b>Chemical Contaminants &amp; Pesticides</b></p> <p>Acrylamide, Arsenic, Chemical Contaminants, Toxins &amp; Pesticides in Food</p>

INDUSTRY GUIDANCE & REGULATION

<p><b>Guidance for Industry by Topic</b></p> <p><b>Food Safety Modernization Act (FSMA)</b></p>	<p><b>Imports &amp; Exports</b></p> <p><b>Hazard Analysis Critical Control Point (HACCP)</b></p>	<p><b>Registration of Food Facilities/Other Submissions</b></p> <p><b>Current Good Manufacturing Practices (CGMPs)</b></p>	<p><b>Retail Food Protection</b></p> <p><b>Federal/State Food Programs</b></p>
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↑ Top

- '식이보충제(Dietary Supplements)' 화면에서 '신규식이원료 신고 절차[New Dietary Ingredient(NDI) Notification Process]' 항목 클릭


Home / Food / Dietary Supplements

**Dietary Supplements**

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**Dietary Supplements**

- How to Report a Problem with Dietary Supplements
- Information for Consumers on Using Dietary Supplements
- Information for Industry on Dietary Supplements
- Information on Select Dietary Supplement Ingredients and Other Substances
- New Dietary Ingredient (NDI) Notification Process**



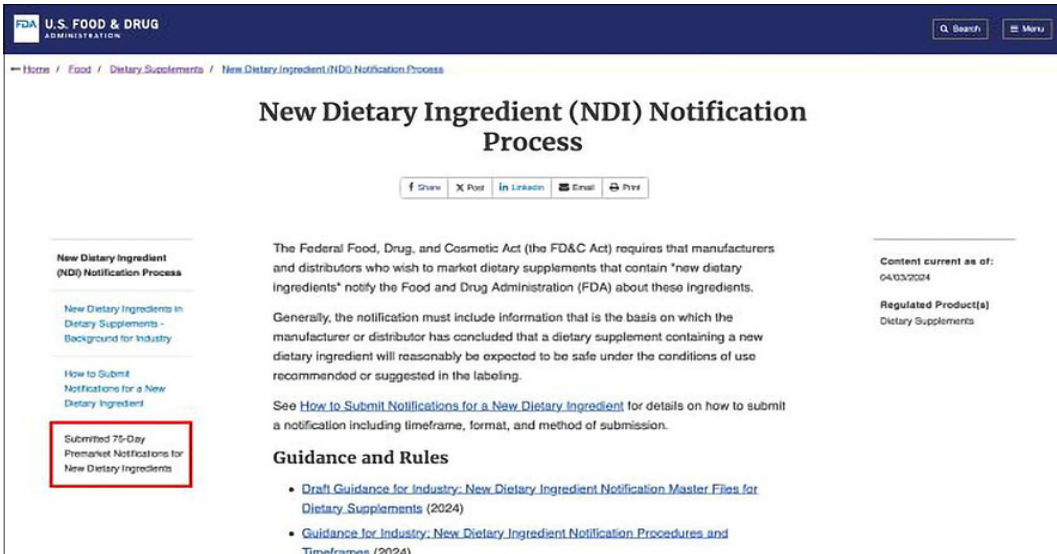
The work of the FDA for dietary supplement oversight is coordinated by the [Human Foods Program's Office of Food Chemical Safety, Dietary Supplements, and Innovation](#).

FDA regulates both finished dietary supplement products and dietary ingredients. FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products. Under the Dietary Supplement Health and Education Act (DSHEA),

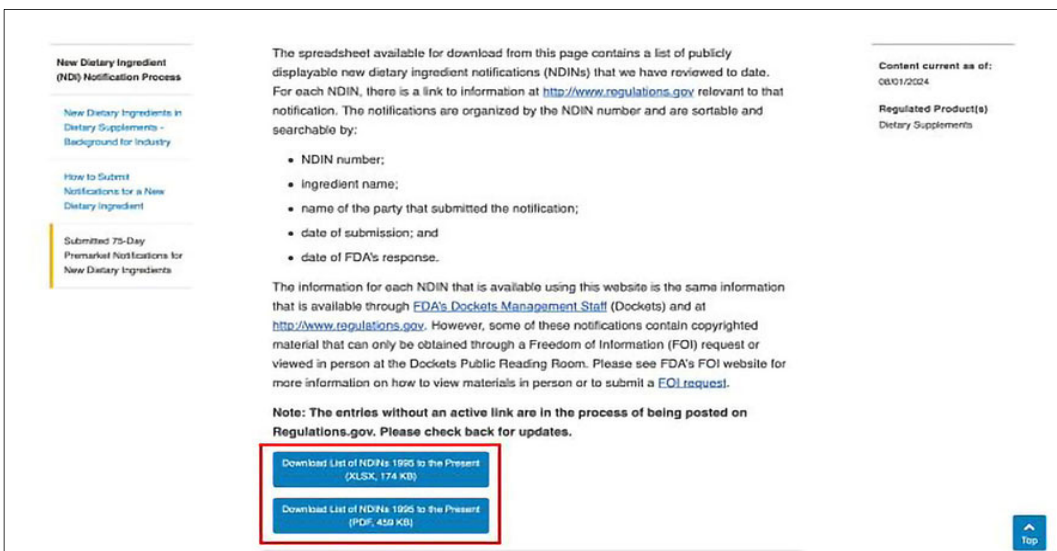
Content current as of: 10/01/2024

**Regulated Product(s)**  
Dietary Supplements

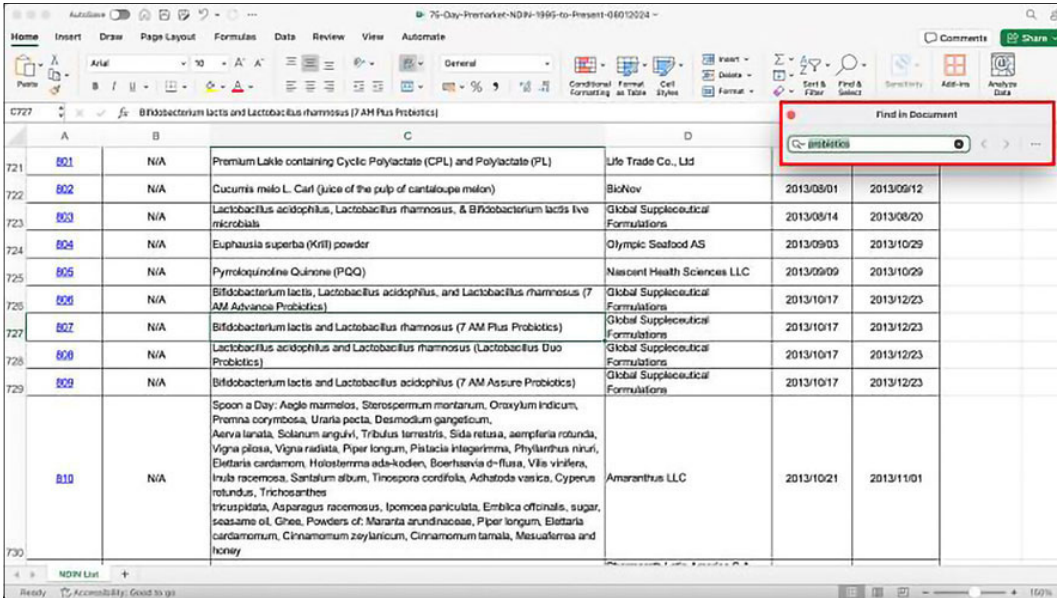
- ‘신규식이원료 신고 절차[New Dietary Ingredient(NDI) Notification Process]’ 화면에서 ‘제출된 신규식이원료 75일 시판전 신고(Submitted 75-Day Premarket Notifications for New Dietary Ingredients)’ 항목 클릭



- ‘제출된 신규식이원료 75일 시판전 신고(Submitted 75-Day Premarket Notifications for New Dietary Ingredients)’ 화면에서 신고 데이터를 엑셀 / PDF 파일로 조회 가능



- 자체 검색 기능을 제공하지 않는 관계로 찾기 기능(Ctrl+F)을 활용한 검색 필요



## ● 정보 제공 범위

- 엑셀 또는 PDF 파일에서 ▲ NDI 신고(NDIN) 번호, ▲ 신규식이원료 보고서 번호 (Regulations.gov), ▲ 성분명, ▲ 신고서 제출업체명, ▲ 제출일, ▲ FDA 답변일 정보를 제공

New Dietary Ingredient Notification #	New Dietary Ingredient Report # Regulations.gov	Name of New Dietary Ingredient	Firm	Date of Submission	Date of FDA's Response
1	Memo 2	<i>Stevia rebaudiana</i> Bertoni (stevia or stevia leaf)	Sunrider International Inc	7/7/1995	8/16/1995
2	Memo 3	Protein nutraceutical Lab #PS-30	Foodsmith Corporation	7/10/1995	9/25/1995
3	Rpt/NDI 1	Theobromine	Tinos LLC	1/22/1996	4/6/1996
4	Rpt/NDI 2	Tepozan ( <i>Buddleja americana</i> L.) white sapote ( <i>Casimiroa edulis</i> )	Malabar Productos Naturales S.A. De C.V	2/7/1996	3/16/1996
5	Rpt/NDI 3	Lo Han Kuo Extract (fruit extract of <i>Siraitia grosvenorii</i> S.) (HerbaSvy™ Cucurbitaceae Fruit Extract)	HerbaSvy Laboratories, Inc.	3/4/1996	4/17/1996
6	Rpt/NDI 4	Peptidase (enzyme derived from bacteria in the genus <i>Serratia</i> ) ( <i>Serratiopeptidase</i> ™)	Specialty Enzymes and Biochemicals Company	5/17/1996	7/30/1996
7	Rpt/NDI 5	Bark extract of the Pao Pereira tree, <i>Geissospermum vellosii</i> (Pao V™)	Natural Source International, Ltd. Formerly called VIVA (USA) Inc.	9/11/1996	11/13/1996

- PDF 파일에서 NDIN 신고번호 클릭 시 미국 정부 공식 웹사이트로 연결되며, 해당 번호의 신고서, FDA/식품안전응용영양센터(CFSAN)의 서한 등 관련 문서 확인 가능



**예시 | 원료명: Probiotics**

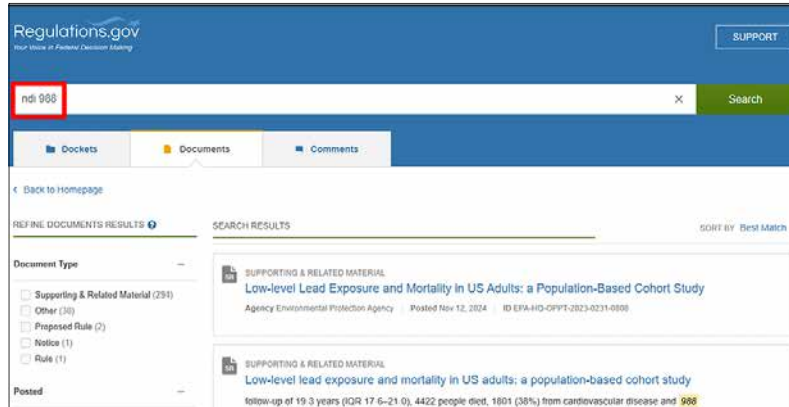
	A	B	C	D	E	F	G
720	800	N/A	Incarvillea sinensis	Infrinium Health LLC	2013/06/24	2013/07/01	
721	801	N/A	Premium Lake containing Cyclic Polylactate (CPL) and Polylactate (PL)	Life Trade Co., Ltd	2013/07/24	2013/09/12	
722	802	N/A	Cucumis melo L. Carl (juice of the pulp of cantaloupe melon)	BioNov	2013/08/01	2013/09/12	
723	803	N/A	Lactobacillus acidophilus, Lactobacillus rhamnosus, & Bifidobacterium lactis live microbials	Global Suppleceutical Formulations	2013/08/14	2013/08/20	
724	804	N/A	Euphasia superba (Krit) powder	Olympic Seafood AS	2013/09/03	2013/10/29	
725	① 805	② N/A	③ Pyrroloquinoline Quinone (PQQ)	④ Nascent Health Sciences LLC	⑤ 2013/09/09	⑥ 2013/10/29	
726	806	N/A	Bifidobacterium lactis, Lactobacillus acidophilus, and Lactobacillus rhamnosus (7 AM Advance Probiotics)	Global Suppleceutical Formulations	2013/10/17	2013/12/23	
727	807	N/A	Bifidobacterium lactis and Lactobacillus rhamnosus (7 AM Plus Probiotics)	Global Suppleceutical Formulations	2013/10/17	2013/12/23	
728	808	N/A	Lactobacillus acidophilus and Lactobacillus rhamnosus (Lactobacillus Duo Probiotics)	Global Suppleceutical Formulations	2013/10/17	2013/12/23	

- ① NDI 신고번호: 806
- ② 보고서 번호: N/A(해당 사항 없음)
- ③ 성분명: Bifidobacterium lactis, Lactobacillus acidophilus, and Lactobacillus rhamnosus(7 AM Advance Probiotics)
- ④ 신고서 제출업체명: Global Suppleceutical Formulations
- ⑤ 제출일: 2013/10/17
- ⑥ FDA 답변일: 2013/12/23

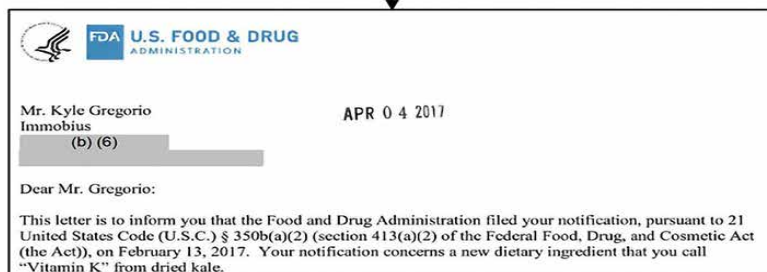
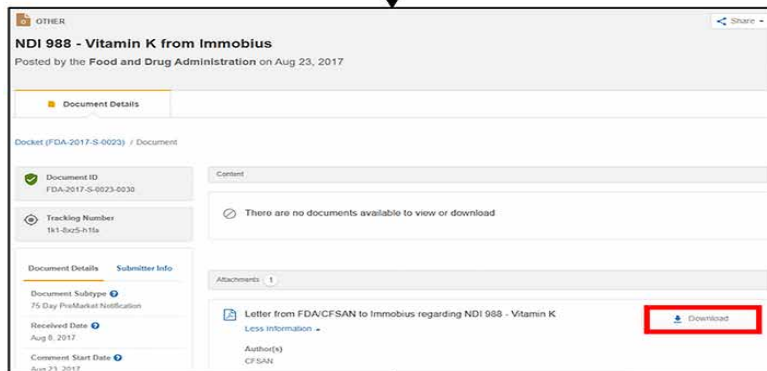
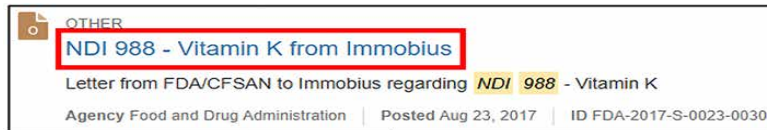


## 예시 | 988번 건조 케일 유래 비타민 K

988	N/A	Vitamin K from dried kale	Immobius	2/13/2017	4/4/2017
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### ① NDI 988 비타민 K에 대한 FDA/CFSAN의 서한



② NDI 988 - 비타민 K - NDI 신고서

**SUPPORTING & RELATED MATERIAL**

**NDI 988 - Vitamin K - Original NDI Notification**

Agency Food and Drug Administration | Posted Aug 23, 2017 | ID FDA-2017-S-0023-0031

↓

**SUPPORTING & RELATED MATERIAL**

**NDI 988 - Vitamin K - Original NDI Notification**

Posted by the Food and Drug Administration on Aug 23, 2017

**Document Details**

Docket (FDA-2017-S-0023) / Document

<p><b>Document ID</b> FDA-2017-S-0023-0031</p> <p><b>Tracking Number</b> 1K1-8xz5-dg5</p>	<p><b>Content</b></p> <p style="text-align: right;"><a href="#">Download File</a> <span style="border: 2px solid red; padding: 2px;">Download</span></p>
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↓

**View Notification**

NDI Number	Filing Date	Category of Compound
2017000988	02/13/2017	Vitamin

**Section 1: Contact Information**

Contacts List

Type	Name	Address
Submitter	IMMCGIUS	(b) (6)
Owner	IMMCGIUS	
Primary	Kyle Gregorio	

<p><b>Submitter</b></p> <p>Type of Submitter Distributor of Dietary Supplement Containing NDI</p>	<p><b>Owner</b></p> <p>Type of Submitter Distributor of Dietary Supplement Containing NDI</p>
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## [ GRAS 물질 선택 위원회 데이터베이스 ]

### ● 개요

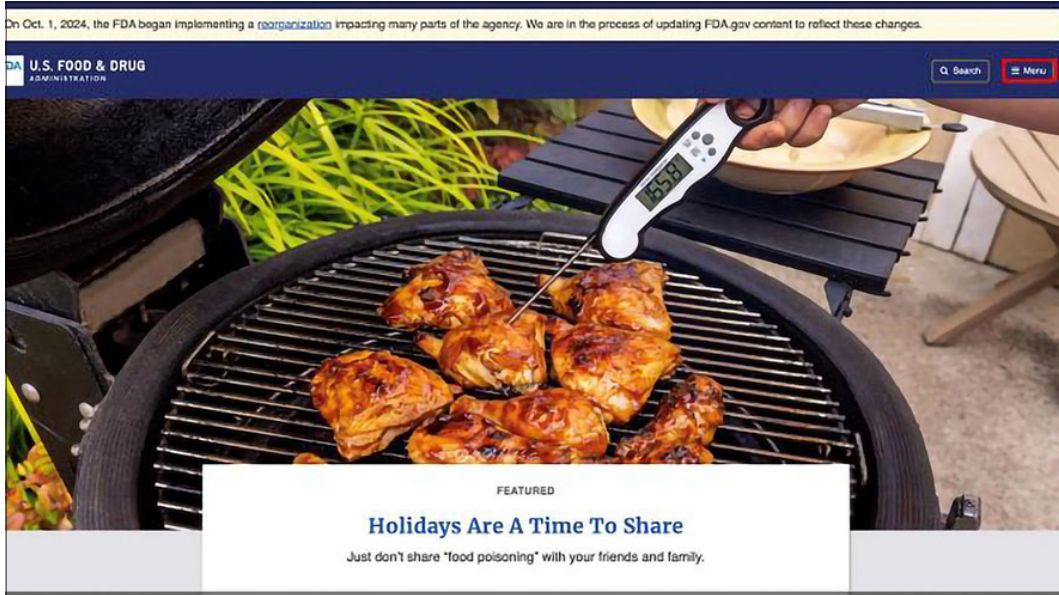
<b>DB명</b>	GRAS 물질 선택 위원회 데이터베이스(SCOGS Database)
<b>관리기관</b>	식품의약품청(FDA)
<b>DB 내용</b>	식품첨가물 또는 식품 원료로 사용되는 물질에 대해 안전하다고 공식적으로 인정된 원료 및 성분인 GRAS에 대한 SCOGS의 분석보고서를 제공하며 안전성에 따라 Type 1~5로 분류함 * SCOGS: Select Committee on GRAS Substances
<b>접속 주소</b>	<a href="https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=SCOGS">https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=SCOGS</a>
<b>정보 제공 건수</b>	381건('24.11. 기준)

\* Type1은 가장 안전하다고 평가된 등급으로, 등급 분포는 다음과 같음

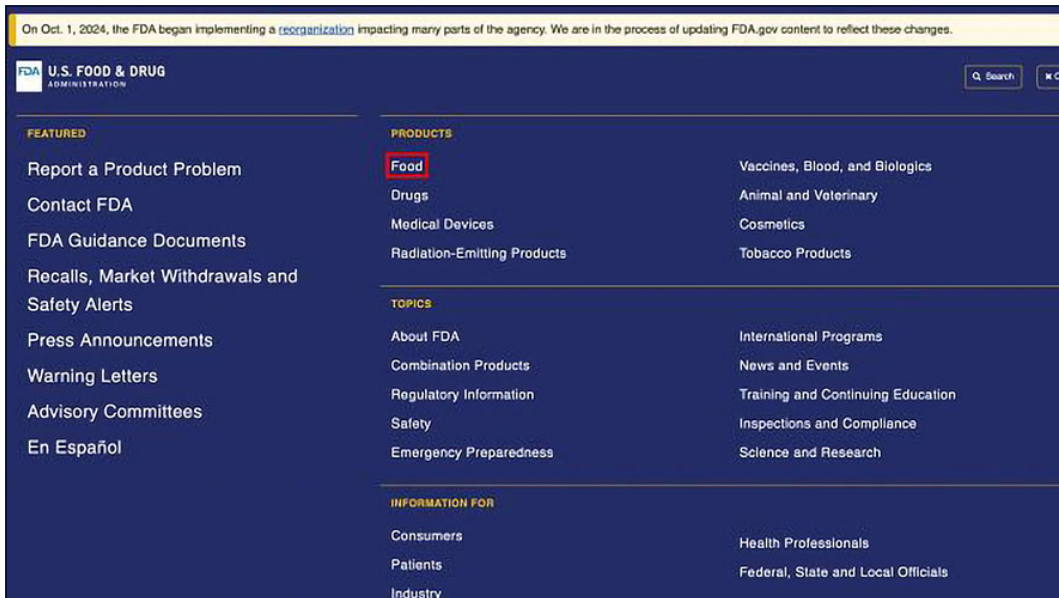
Type1	Type2	Type3	Type4	Type5	중복 Type	미평가
272	69	13	4	16	4	3

● DB 접속 방법

○ FDA 홈페이지 메인 우측 상단 'Menu' 클릭



○ 'Menu' 화면으로 이동 후 'Food' 항목 클릭



- ‘Food’ 화면에서 ‘성분&포장(Ingredients & Packaging)’ 항목 클릭

NAVIGATE THE FOOD SECTION

<p><b>Labeling &amp; Nutrition</b></p> <p>Nutrition Facts Label, Label Claims, Menu &amp; Vending Machine Labeling, Gluten-Free Labeling</p>	<p><b>Ingredients &amp; Packaging</b></p> <p>Food &amp; Color Additives, GRAS, Food Allergens, Food Contact Substances, New Plant Varieties</p>	<p><b>Food Defense</b></p> <p>Protecting the Food Supply, Intentional Adulteration, Food Defense Plan Builder</p>	<p><b>Dietary Supplements</b></p> <p>Products &amp; Ingredients, New Dietary Ingredients Notification Process, Structure/Function Claim Notifications</p>
<p><b>Science &amp; Research</b></p> <p>Laboratory Methods, Whole Genome Sequencing, Risk Analysis, Total Diet Study, Consumer Research</p>	<p><b>Compliance &amp; Enforcement</b></p> <p>Reportable Food Registry, Warning Letters, Inspections, Compliance Programs, Adverse Event Reporting</p>	<p><b>International &amp; Interagency Coordination</b></p> <p>International Outreach, Visitor's Program, Trade Agreements, Interagency Agreements</p>	<p><b>Chemical Contaminants &amp; Pesticides</b></p> <p>Acrylamide, Arsenic, Chemical Contaminants, Toxins &amp; Pesticides in Food</p>

INDUSTRY GUIDANCE & REGULATION

<p><b>Guidance for Industry by Topic</b></p>	<p><b>Imports &amp; Exports</b></p>	<p><b>Registration of Food Facilities/Other Submissions</b></p>	<p><b>Retail Food Protection</b></p>
<p><b>Food Safety Modernization Act (FSMA)</b></p>	<p><b>Hazard Analysis Critical Control Point (HACCP)</b></p>	<p><b>Current Good Manufacturing Practices (CGMPs)</b></p>	<p><b>Federal/State Food Program</b></p>

[↑ Top](#)

- ‘성분&포장(Ingredients & Packaging)’ 화면에서 ‘일반적으로 안전하다고 인정되는 물질[Generally Recognized as Safe(GRAS)]’ 클릭

# / Food / Food Ingredients & Packaging

## Food Ingredients & Packaging

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**Food Ingredients & Packaging**

- Determining the Regulatory Status of a Food Ingredient
- Food Chemical Safety
- Food Ingredient & Packaging Terms
- Food Additives & Petitions
- Generally Recognized as Safe (GRAS)**
- Color Additives - Information for Consumers



Content current as of: 07/06/2023

**Regulated Product(s)**  
Food & Beverages  
Food & Color Additives

The FDA regulates the safety of ingredients added directly to food and substances that come into contact with food, such as those added to packaging materials, cookware or containers that store food.

Food manufacturers are responsible for marketing safe foods. Ingredients added directly

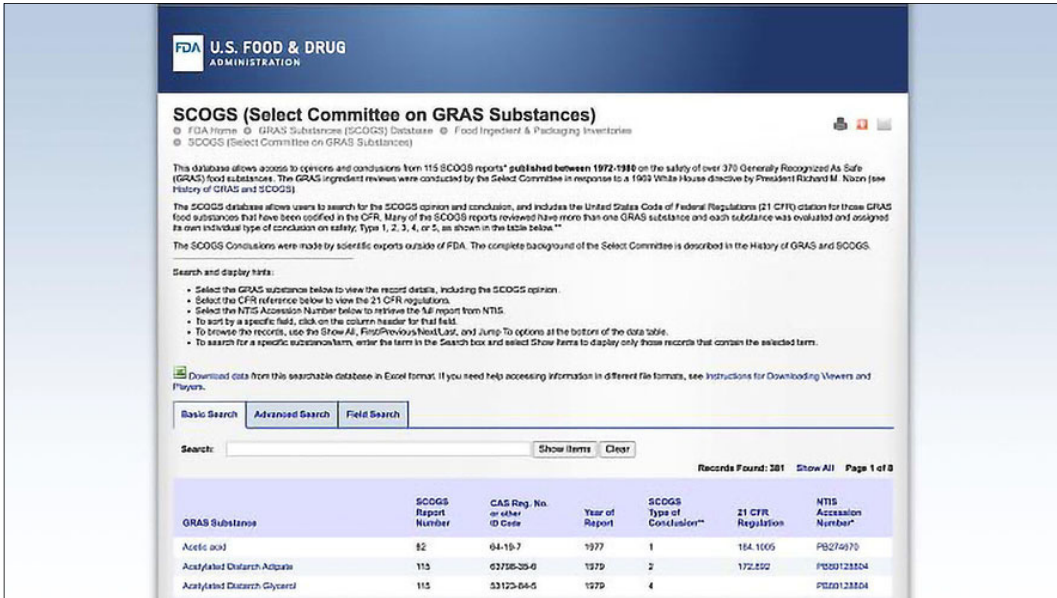
- ‘일반적으로 안전하다고 인정되는 물질[Generally Recognized as Safe(GRAS)]’ 화면에서 ‘GRAS 물질 SCOGS 데이터베이스[GRAS Substances(SCOGS) Databases]’ 클릭



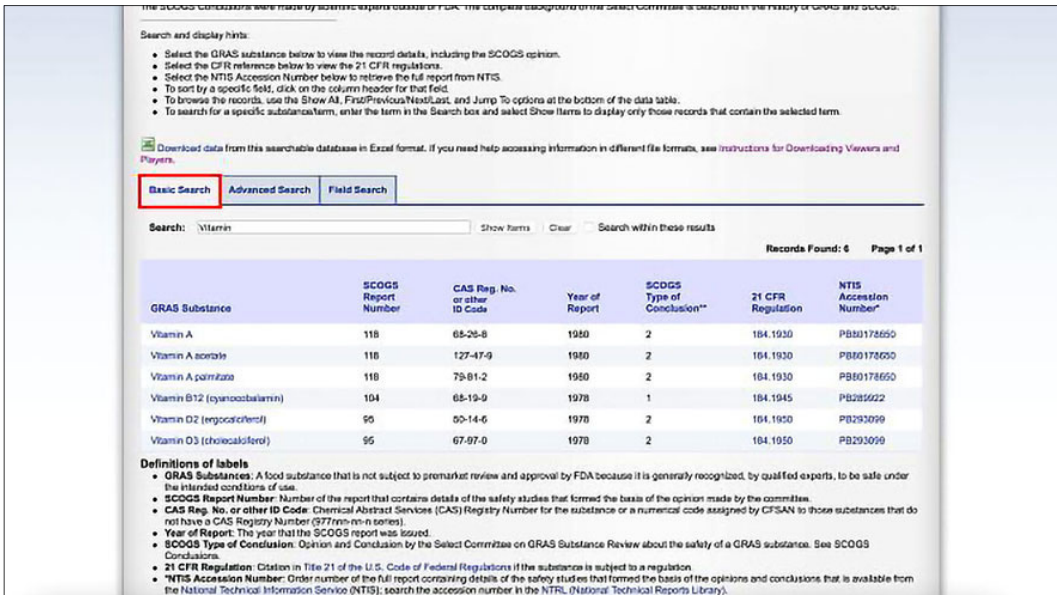
- GRAS 물질 SCOGS 데이터베이스[GRAS Substances (SCOGS) Databases]’ 화면에서 ‘SCOGS Database’ 클릭



○ SCOGS 데이터베이스 접근완료



○ ‘기본검색(Basic Search)’, ‘고급검색(Advanced Search)’, ‘범주검색(Field Search)’ 기능 제공



- ‘고급검색(Advanced Search)’에서는 완전 일치어구(This Exact Phrase), 모든 단어 포함(All of this words), 하나라도 포함(Any of these words), 포함 시 제외(None of these words) 등의 기능 사용 가능

Search and display hints:

- Select the GRAS substance below to view the record details, including the SCOGS opinion.
- Select the CFR reference below to view the 21 CFR regulations.
- Select the NTIS Accession Number below to retrieve the full report from NTIS.
- To sort by a specific field, click on the column header for that field.
- To browse the records, use the Show All, First/Previous/Next/Last, and Jump To options at the bottom of the data table.
- To search for a specific substance/term, enter the term in the Search box and select Show Items to display only those records that contain the selected term.

Download data from this searchable database in Excel format. If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Basic Search **Advanced Search** Field Search

Fill in one or more of the criteria to search for. Separate multiple word (or character string) entries with spaces.  
(Character strings may be whole or partial words or numbers, and may include common punctuation as is found in chemical names.)

This Exact phrase:  
 ALL of these words:  
 ANY of these words:  
 NONE of these words:

Show Items Clear Search within these results

Records Found: 6 Page 1 of 1

GRAS Substance	SCOGS Report Number	CAS Reg. No. or other ID Code	Year of Report	SCOGS Type of Conclusion**	21 CFR Regulation	NTIS Accession Number*
Vitamin A	118	68-26-8	1980	2	184.1930	PB80178650
Vitamin A acetate	118	127-47-9	1980	2	184.1930	PB80178650
Vitamin A palmitate	118	79-81-2	1980	2	184.1930	PB80178650
Vitamin B12 (cyanocobalamin)	104	68-19-9	1978	1	184.1945	PB289922
Vitamin D2 (ergocalciferol)	95	50-14-6	1978	2	184.1950	PB293099
Vitamin D3 (cholecalciferol)	95	67-97-0	1978	2	184.1950	PB293099

Definitions of labels

- GRAS Substances:** A food substance that is not subject to premarket review and approval by FDA because it is generally recognized, by qualified experts, to be safe under the intended conditions of use.
- SCOGS Report Number:** Number of the report that contains details of the safety studies that formed the basis of the opinion made by the committee.
- CAS Reg. No. or other ID Code:** Chemical Abstract Services (CAS) Registry Number for the substance or a numerical code assigned by CFSAN to those substances that do not have a CAS Registry Number (977mm-mm series).

- ‘범주검색(Field Search)’에서는 제공범위 범주를 선택해 검색 가능

The SCOGS Conclusions were made by scientific experts outside of FDA. The complete background of the Select Committee is described in the History of GRAS and SCOGS.

Search and display hints:

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Basic Search Advanced Search **Field Search**

Choose a field to search. (An asterisk (\*) indicates that the field is found on an individual record's detail page and is not shown below.)

Field:  Show Items Clear Search within these results

Records Found: 6 Page 1 of 1

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Vitamin A palmitate	118	79-81-2	1980	2	184.1930	PB80178650
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- Year of Report:** The year that the SCOGS report was issued.
- SCOGS Type of Conclusion:** Opinion and Conclusion by the Select Committee on GRAS Substance Review about the safety of a GRAS substance. See SCOGS Conclusions.

- ‘검색(Search)’에 검색하고자 하는 원료의 영문 명칭 입력 후 ‘결과보기(Show Item)’ 버튼 클릭

The SCOGS Conclusions were made by scientific experts outside of FDA. The complete background on the Select Committee's decisions is available in the history of GRAS and SCOGS.

Search and display hints:

- Select the GRAS substance below to view the record details, including the SCOGS opinion.
- Select the CFR reference below to view the 21 CFR regulations.
- Select the NTIS Accession Number below to retrieve the full report from NTIS.
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Download data from this searchable database in Excel format. If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Basic Search   **Advanced Search**   Field Search

Search: Vitamin   Show Items   Clear   Search within these results

Records Found: 6   Page 1 of 1

GRAS Substance	SCOGS Report Number	CAS Reg. No. or other ID Code	Year of Report	SCOGS Type of Conclusion**	21 CFR Regulation	NTIS Accession Number*
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- **CAS Reg. No. or other ID Code:** Chemical Abstract Services (CAS) Registry Number for the substance or a numerical code assigned by CFSAN to those substances that do not have a CAS Registry Number (977xxxx-n series).
- **Year of Report:** The year that the SCOGS report was issued.
- **SCOGS Type of Conclusion:** Opinion and Conclusion by the Select Committee on GRAS Substance Review about the safety of a GRAS substance. See SCOGS Conclusions.
- **21 CFR Regulation:** Citation in Title 21 of the U.S. Code of Federal Regulations if the substance is subject to a regulation.
- **NTIS Accession Number:** Order number of the full report containing details of the safety studies that formed the basis of the opinions and conclusions that is available from the National Technical Information Service (NTIS); search the accession number in the NTRL (National Technical Reports Library).

- 해당 원료의 상세 정보 확인, 해당 원료의 명칭(하이퍼링크) 클릭 시 SCOGS 리포트 확인 가능

The SCOGS Conclusions were made by scientific experts outside of FDA. The complete background on the Select Committee's decisions is available in the history of GRAS and SCOGS.

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- Select the GRAS substance below to view the record details, including the SCOGS opinion.
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Basic Search   **Advanced Search**   Field Search

Search: Vitamin   Show Items   Clear   Search within these results

Records Found: 6   Page 1 of 1

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<a href="#">Vitamin A</a>	118	68-26-8	1980	2	184.1930	PB80178650
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Vitamin A palmitate	118	79-81-2	1980	2	184.1930	PB80178650
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- **Year of Report:** The year that the SCOGS report was issued.
- **SCOGS Type of Conclusion:** Opinion and Conclusion by the Select Committee on GRAS Substance Review about the safety of a GRAS substance. See SCOGS Conclusions.
- **21 CFR Regulation:** Citation in Title 21 of the U.S. Code of Federal Regulations if the substance is subject to a regulation.
- **NTIS Accession Number:** Order number of the full report containing details of the safety studies that formed the basis of the opinions and conclusions that is available from the National Technical Information Service (NTIS); search the accession number in the NTRL (National Technical Reports Library).

○ SCOGS의 해당 원료에 대한 의견서

GRAS Substances (SCOGS) Database

## Select Committee on GRAS Substances (SCOGS) Opinion: Vitamin A, Vitamin A acetate, Vitamin A palmitate

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The GRAS Substances (SCOGS) Database allows access to opinions and conclusions from 175 SCOGS reports published between 1972-1980 on the safety of over 370 Generally Recognized As Safe (GRAS) food substances. The GRAS ingredient reviews were conducted by the Select Committee in response to a 1969 White House directive by President Richard M. Nixon.

### Vitamin A, Vitamin A acetate, and Vitamin A palmitate

SCOGS Report Number: 118  
NHS Accession Number: P0601786042  
Year of Report: 1980

GRAS Substance	ID Code	21 CFR Section
Vitamin A	69-36-4	184.1000
Vitamin A acetate	127-47-9	184.1000
Vitamin A palmitate	79-41-2	184.1000

**SCOGS Opinion:**

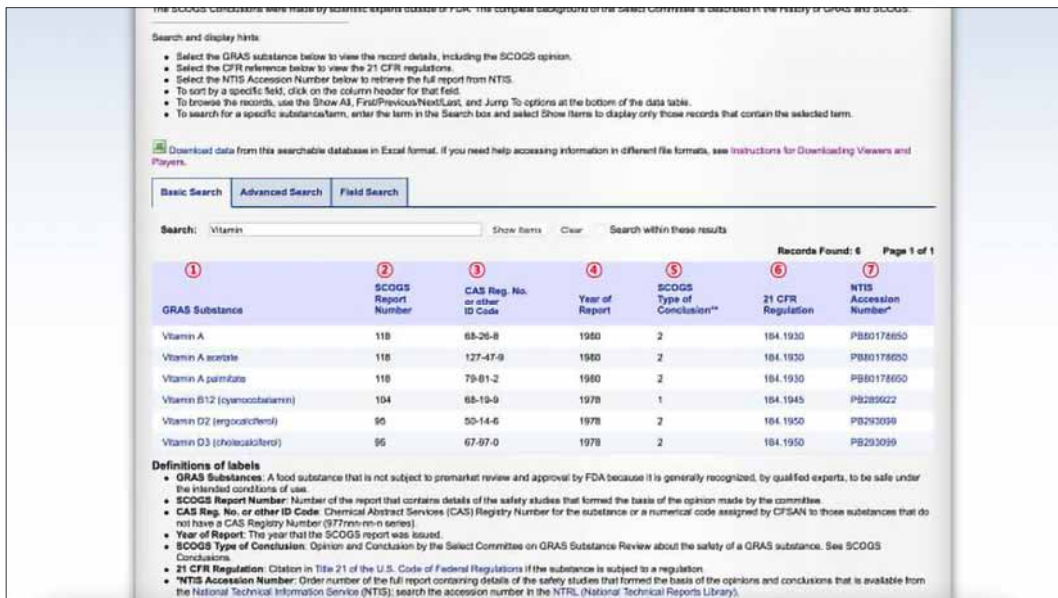
Vitamin A is an essential nutrient for man and other animals. Deficiency of vitamin A causes at least four physiologically distinct and clinically recognized states: loss of night vision; defects in bone growth; defects in reproduction; and defects in the growth and differentiation of epithelial tissues. The recommended dietary allowance of vitamin A for adults is about 3,300 International Units (IU) daily. A daily intake of 3,300 IU would amount to about 50 IU per kg for an adult.

Dietary vitamin A activity is supplied by animal products (preformed vitamin A), plant products (provitamin A, such as carotene), and by the addition of vitamin A (retinol) and/or its esters (retinyl acetate and retinyl palmitate) to fortify certain foods. Mean daily intake of vitamin A from all food sources (excluding vitamin preparations) was approximately 5,000 IU in 1971 to 1974. However, some 47 percent of young adults were found to consume no more than 3,500 IU daily. Nevertheless, there is no clear evidence that Vitamin A nutrition is a problem of public health significance in the United States. Per capita daily intake of vitamin A used for the fortification of foods is assumed to be about 800 IU (about 13 IU per kg body weight in adults). However, accurate data on the amounts

● 정보 제공 범위

- SCOGS 보고서 번호, CAS 등록번호, 보고서 발행연도, SCOGS 결론 유형, 관련 21 CFR 규정, NTIS 접근 번호 등의 정보 제공하며 상세 정보에서는 SCOGS의 해당 원료에 대한 의견서를 제공

 예시 | 원료명: Vitamin A



① GRAS Substance	② SCOGS Report Number	③ CAS Reg. No. or other ID Code	④ Year of Report	⑤ SCOGS Type of Conclusion**	⑥ 21 CFR Regulation	⑦ NTIS Accession Number*
Vitamin A	118	68-26-8	1980	2	184.1930	PB80178650
Vitamin A ascorbate	118	127-47-9	1980	2	184.1930	PB80178650
Vitamin A palmitate	118	79-81-2	1980	2	184.1930	PB80178650
Vitamin B12 (cyanocobalamin)	104	68-19-9	1978	1	184.1945	PB285622
Vitamin D2 (ergocalciferol)	95	50-14-6	1978	2	184.1950	PB293059
Vitamin D3 (cholecalciferol)	95	67-97-0	1978	2	184.1950	PB293059

**Definitions of labels**

- **GRAS Substances:** A food substance that is not subject to premarket review and approval by FDA because it is generally recognized, by qualified experts, to be safe under the intended conditions of use.
- **SCOGS Report Number:** Number of the report that contains details of the safety studies that formed the basis of the opinion made by the committee.
- **CAS Reg. No. or other ID Code:** Chemical Abstract Services (CAS) Registry Number for the substance or a numerical code assigned by CFSAN to those substances that do not have a CAS Registry Number (977xxx-min series).
- **Year of Report:** The year that the SCOGS report was issued.
- **SCOGS Type of Conclusion:** Opinion and Conclusion by the Select Committees on GRAS Substance Review about the safety of a GRAS substance. See SCOGS Conclusions.
- **21 CFR Regulation:** Citation in Title 21 of the U.S. Code of Federal Regulations if the substance is subject to a regulation.
- **NTIS Accession Number:** Order number of the full report containing details of the safety studies that formed the basis of the opinions and conclusions that is available from the National Technical Information Service (NTIS); search the accession number in the NTRL (National Technical Reports Library).

- ① GRAS 성분: Vitamin A
- ② SCOGS 보고서 번호: 118
- ③ CAS 등록번호/타 ID 코드: 68-26-8
- ④ 보고서 발행연도: 1980
- ⑤ SCOGS 결론 유형(Type 부여등급): Type 2
- ⑥ 관련 21 CFR\* 규정: 184.1930
- ⑦ NTIS\*\* 접근 번호: PB80178650

\* 21 CFR: Code of Federal Regulations Title 21

\*\* NTIS: National Technical Information Service

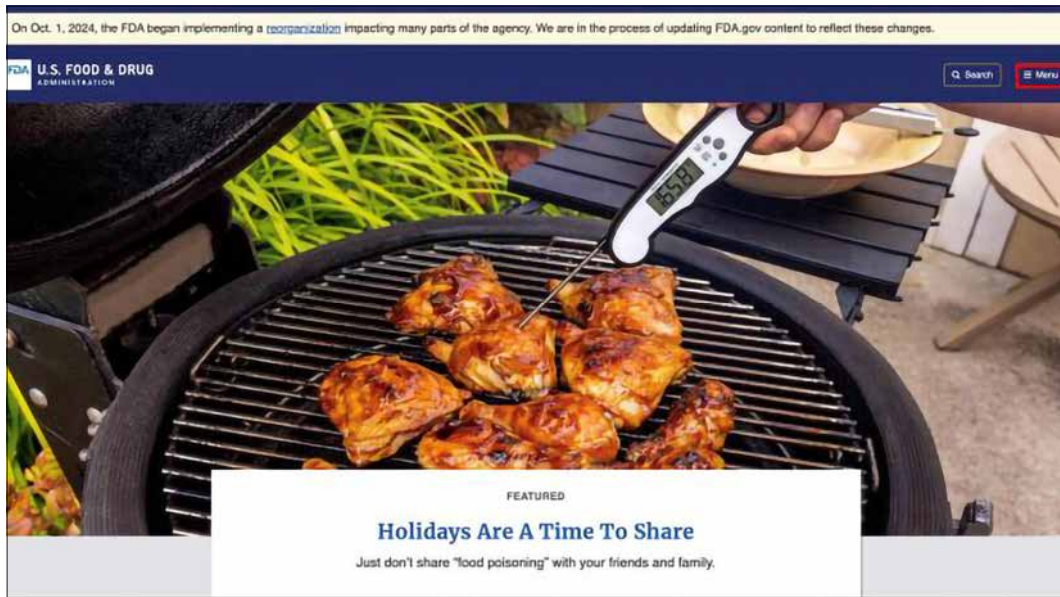
## [ 식품에 첨가하는 물질 인벤토리 ]

### ● 개요

<b>DB명</b>	식품에 첨가하는 물질 인벤토리(Substances Added to Food Inventory)
<b>관리기관</b>	미국 식품의약품청(FDA)
<b>DB 내용</b>	<p>▲ FDA 규정에 등재된 식품 및 색소첨가물, ▲ FDA 규정에 등재된 GRAS 물질, ▲ 1958년 9월 6일 이전 식품에 특정 용도로 승인된 물질, ▲ 과거 사용했으나 현재 금지된 물질(FDA 규정에 등재된 금지 물질, FDA 규정에서 삭제된 색소첨가물, FEMA* GRAS 분류에서 제외된 물질) 등 다양한 물질의 목록</p> <p>* FEMA: Flavor and Extract Manufacturers Association</p>
<b>접속 주소</b>	<a href="https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=FoodSubstances">https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=FoodSubstances</a>
<b>정보 제공 건수</b>	<p>3,971건('24.11. 기준)</p> <p>- 사용이 금지되거나 예외 규정을 둔 사용금지물질 21건</p>

● DB 접속 방법

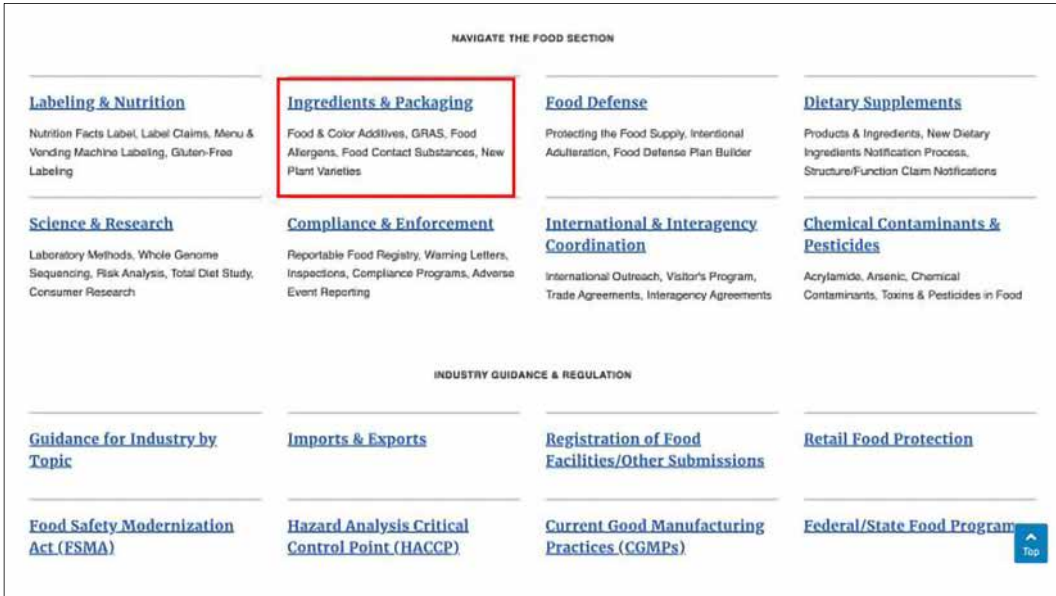
- ‘FDA’ 메인 홈페이지 접속 후 우측 상단의 ‘메뉴(Menu)’ 클릭



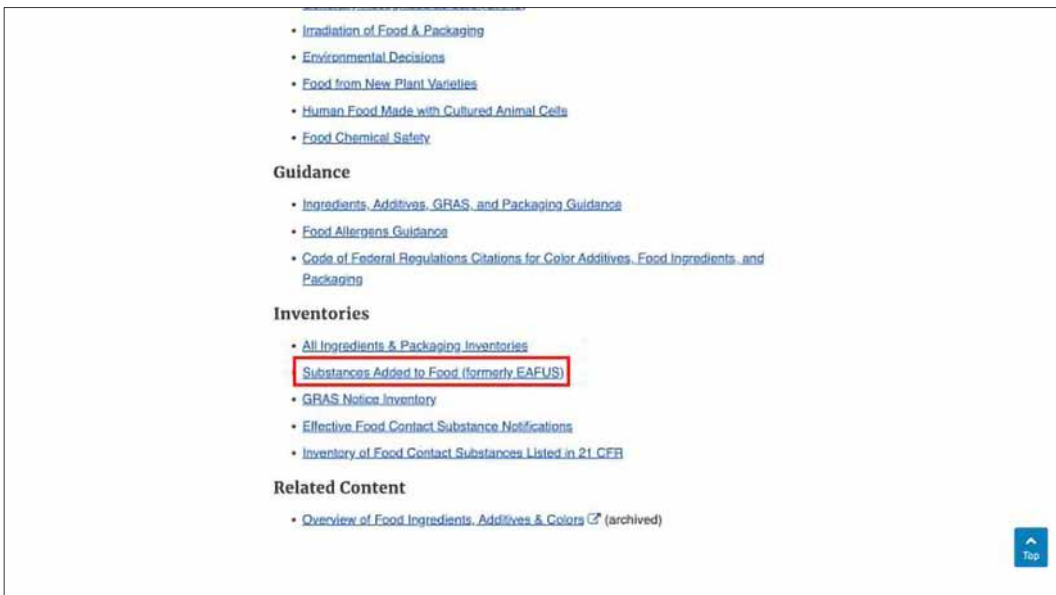
- ‘메뉴(Menu)’ 화면으로 이동 후 ‘Food’ 항목 클릭



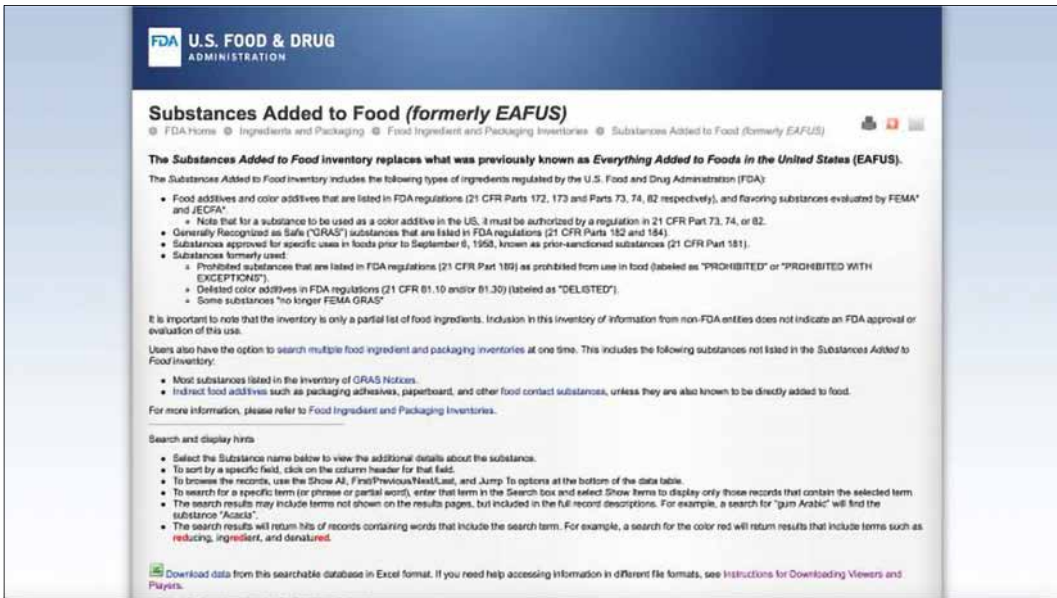
- ‘Food’ 화면에서 ‘성분&포장(Ingredients & Packaging)’ 항목 클릭



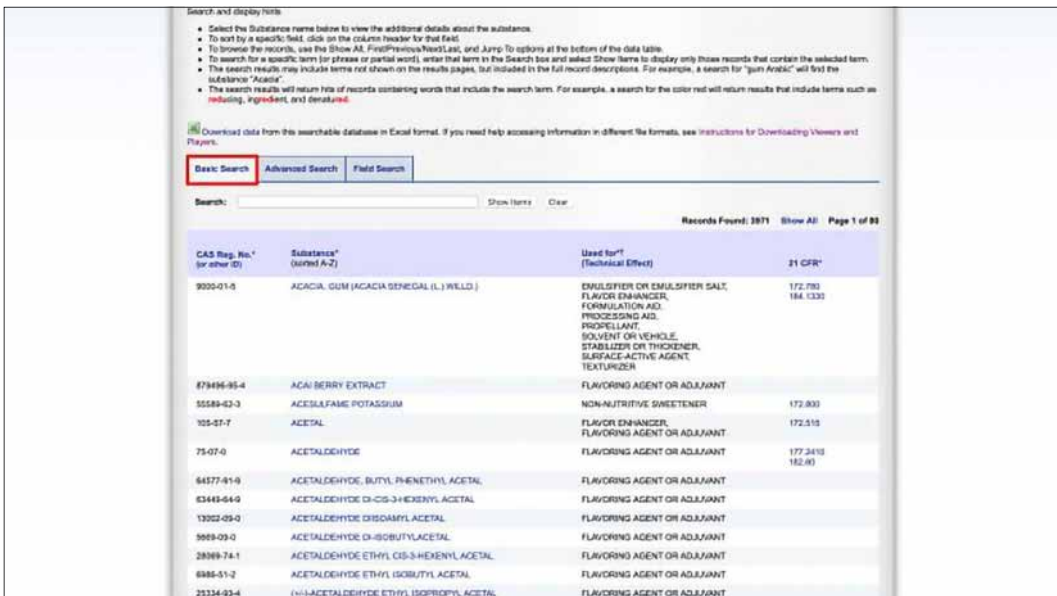
- ‘성분&포장(Ingredients & Packaging)’ 화면에서 ‘식품에 첨가하는 물질 (Substances Added to Food, Formerly EAFUS)’ 항목 클릭



○ 식품에 첨가하는 물질 인벤토리(Substances Added to Food Inventory) 접속 완료



○ ‘기본검색(Basic Search)’, ‘고급검색(Advanced Search)’, ‘범주검색(Field Search)’ 기능을 제공



- ‘고급검색(Advanced Search)’에서는 완전 일치어구(This Exact Phrase), 모든 단어 포함(All of these words), 하나라도 포함(Any of these words), 포함 시 제외(None of these words) 등의 기능 사용 가능

Search and display hints

- Select the Substance name below to view the additional details about the substance.
- To sort by a specific field, click on the column header for that field.
- To browse the records, use the Show All, First/Previous/Next/Last, and Jump To options at the bottom of the data table.
- To search for a specific term (or phrase or partial word), enter that term in the Search box and select Show Items to display only those records that contain the selected term.
- The search results may include terms not shown on the results pages, but included in the full record descriptions. For example, a search for "guar Acacia" will find the substance "Acacia".
- The search results will return hits of records containing words that include the search term. For example, a search for the color red will return results that include terms such as reduting, ingredient, and derantene.

Download data from this searchable database in Excel format. If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Basic Search **Advanced Search** Field Search

Fill in one or more of the criteria to search for. Separate multiple word (or character string) entries with spaces.  
(Character string) may be whole or partial words or numbers, and may include common punctuation as is found in chemical names.)

This Exact phrase:

ALL of these words:

ANY of these words:

NONE of these words:

Show Items Clear

Records Found: 3871 Show All Page 1 of 86

CAS Reg. No.* (or other ID)	Substance* (sorted A-Z)	Used for† (Technical Effect)	21 CFR*
9000-01-6	ACACIA, GUM (ACACIA SENEGAL (L.) WILDL.)	EMULSIFIER OR EMULSIFIER GALT, FLAVOR ENHANCER, FORMULATION AID, PROCESSING AID, PROPELLANT, SOLVENT OR VEHICLE, STABILIZER OR THICKENER, SURFACE-ACTIVE AGENT, TEXTURIZER	172.780 184.1330
879496-95-4	ACAI BERRY EXTRACT	FLAVORING AGENT OR ADJUVANT	
55589-82-3	ACESULFAME POTASSIUM	NON-NUTRITIVE SWEETENER	172.800
105-87-7	ACETAL	FLAVOR ENHANCER, FLAVORING AGENT OR ADJUVANT	172.515
75-07-0	ACETALDEHYDE	FLAVORING AGENT OR ADJUVANT	177.2410 182.00
64577-91-9	ACETALDEHYDE, BUTYL PHENETHYL ACETAL	FLAVORING AGENT OR ADJUVANT	
83448-64-9	ACETALDEHYDE DI-CIS-3-HEXENYL ACETAL	FLAVORING AGENT OR ADJUVANT	
13302-09-0	ACETALDEHYDE DISOMYL ACETAL	FLAVORING AGENT OR ADJUVANT	

- ‘범주검색(Field Search)’에서는 제공범위 범주를 선택해 검색 가능

Search and display hints

- Select the Substance name below to view the additional details about the substance.
- To sort by a specific field, click on the column header for that field.
- To browse the records, use the Show All, First/Previous/Next/Last, and Jump To options at the bottom of the data table.
- To search for a specific term (or phrase or partial word), enter that term in the Search box and select Show Items to display only those records that contain the selected term.
- The search results may include terms not shown on the results pages, but included in the full record descriptions. For example, a search for "guar Acacia" will find the substance "Acacia".
- The search results will return hits of records containing words that include the search term. For example, a search for the color red will return results that include terms such as reduting, ingredient, and derantene.

Download data from this searchable database in Excel format. If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Basic Search Advanced Search **Field Search**

Choose a field to search. (An asterisk (\*) indicates that the field is found on an individual record's detail page and is not shown below)

Field:  Show Items Clear

Records Found: 3871 Show All Page 1 of 86

CAS Reg. No.* (or other ID)	Substance* (sorted A-Z)	Used for† (Technical Effect)	21 CFR*
9000-01-6	ACACIA, GUM (ACACIA SENEGAL (L.) WILDL.)	EMULSIFIER OR EMULSIFIER GALT, FLAVOR ENHANCER, FORMULATION AID, PROCESSING AID, PROPELLANT, SOLVENT OR VEHICLE, STABILIZER OR THICKENER, SURFACE-ACTIVE AGENT, TEXTURIZER	172.780 184.1330
879496-95-4	ACAI BERRY EXTRACT	FLAVORING AGENT OR ADJUVANT	
55589-82-3	ACESULFAME POTASSIUM	NON-NUTRITIVE SWEETENER	172.800
105-87-7	ACETAL	FLAVOR ENHANCER, FLAVORING AGENT OR ADJUVANT	172.515
75-07-0	ACETALDEHYDE	FLAVORING AGENT OR ADJUVANT	177.2410 182.00
64577-91-9	ACETALDEHYDE, BUTYL PHENETHYL ACETAL	FLAVORING AGENT OR ADJUVANT	
83448-64-9	ACETALDEHYDE DI-CIS-3-HEXENYL ACETAL	FLAVORING AGENT OR ADJUVANT	
13302-09-0	ACETALDEHYDE DISOMYL ACETAL	FLAVORING AGENT OR ADJUVANT	
8889-09-0	ACETALDEHYDE DI-ISOBUTYL ACETAL	FLAVORING AGENT OR ADJUVANT	
28089-74-1	ACETALDEHYDE ETHYL CIS-3-HEXENYL ACETAL	FLAVORING AGENT OR ADJUVANT	
9388-51-2	ACETALDEHYDE ETHYL ISOBUTYL ACETAL	FLAVORING AGENT OR ADJUVANT	

- ‘검색(Search)’에 검색하고자 하는 원료의 영문 명칭 입력 후 ‘결과보기(Show Item)’ 버튼 클릭

- Select the Substance name below to view the additional details about the substance.
- To sort by a specific field, click on the column header for that field.
- To browse the records, use the Show All, First/Previous/Next/Last, and Jump To options at the bottom of the data table.
- To search for a specific term (or phrase or partial word), enter that term in the Search box and select Show Items to display only those records that contain the selected term.
- The search results may include terms not shown on the results pages, but included in the full record descriptions. For example, a search for "gum Arabic" will find the substance "Acacia".
- The search results will return hits of records containing words that include the search term. For example, a search for the color red will return results that include terms such as reducing, ingredient, and saturated.

[Download data from this searchable database in Excel format.](#) If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Basic Search   **Advanced Search**   Field Search

Search: Vitamin C   Show Items   Clear   Search within these results

Records Found: 3   Page 1 of 1

CAS Reg. No. <sup>a</sup> (or other ID)	Substance <sup>b</sup> (sorted A-Z)	Used for <sup>c</sup> (Technical Effect)	21 CFR <sup>d</sup>
50-81-7	ASCORBIC ACID	ANTIMICROBIAL AGENT, ANTIOXIDANT, COLOR OR COLORING ADJUNCT, DOUGH STRENGTHENER, FLAVOR ENHANCER, FLAVORING AGENT OR ADJUVANT, NUTRIENT SUPPLEMENT, PH CONTROL AGENT, SEQUESTRANT, STABILIZER OR THICKENER	172.260 182.2012 183.8012
89-65-8	ERYTHRORIC ACID	ANTIMICROBIAL AGENT, ANTIOXIDANT, COLOR OR COLORING ADJUNCT, CURING OR POLING AGENT, FLAVOR ENHANCER, FLAVORING AGENT OR ADJUVANT	175.166 182.2041
13443-2	SODIUM ASCORBATE	ANTIOXIDANT, COLOR OR COLORING ADJUNCT, DOUGH STRENGTHENER, FLOUR TREATING AGENT, LEAVENING AGENT, NUTRIENT SUPPLEMENT, OXIDING OR REDUCING AGENT, PROCESSING AID, SURFACE-FINISHING AGENT	182.2721

**Definitions**

- **CAS Reg. No. (or other ID):** Chemical Abstract Service (CAS) Registry Number<sup>®</sup> for the substance or a numerical code assigned by HFP to those substances that do not have a CAS Registry Number (HTF items only).
- **Substance:** The name of the ingredient as recognized by HFP.
- **Used for<sup>c</sup> (Technical Effect):** The (physical or technical effect(s)) the substance has in (or on food, see 21 CFR 170.33) for definitions.
- **21 CFR:** Title 21 of the Code of Federal Regulations.

● 정보 제공 범위

- CAS 등록번호, 물질명, 사용목적 관련 21 CFR 규정 등의 정보 제공



예시 | 원료명: Vitamin C(ASCORBIC ACID)

Most substances listed in the inventory of GRAS Notices.  
Indirect food additives such as packaging adhesives, paperboard, and other food contact substances, unless they are also known to be directly added to food.  
For more information, please refer to Food Ingredient and Packaging Inventories.

Search and display items

- Select the Substance name below to view the additional details about the substance.
- To sort by a specific field, click on the column header for that field.
- To browse the records, use the Show All, First/Previous/Next/Last, and Jump To options at the bottom of the data table.
- To search for a specific term (or phrase or partial word), enter that term in the Search box and select Show Items to display only those records that contain the selected term.
- The search results may include terms not shown on the results pages, but included in the full record descriptions. For example, a search for "gum Arabic" will find the substance "Acacia".
- The search results will return hits of records containing words that include the search term. For example, a search for the color red will return results that include terms such as reducing, ingredient, and denatured.

Download data from the searchable database in Excel format. If you need help accessing information in different file formats, see [Instructions for Downloading Views and Pages](#).

Basic Search | **Advanced Search** | Field Search

Search:  Show Items Clear Search within these results

Records Found: 3 Page 1 of 1

CAS Reg. No. <sup>a</sup> (or other ID)	Substance <sup>b</sup> (sorted A-Z)	Used for <sup>c</sup> (Technical Effect)	21 CFR <sup>d</sup>
50-81-7	ASCORBIC ACID	ANTIMICROBIAL AGENT, ANTIOXIDANT, COLOR OR COLORING ADJUNCT, DOUGH STRENGTHENER, FLAVOR ENHANCER, FLAVORING AGENT OR ADJUVANT, NUTRIENT SUPPLEMENT, PH CONTROL AGENT, SEQUESTRANT, STABILIZER OR THICKENER	172.280 182.3013 182.8013
89-05-6	ERYTHRIBIC ACID	ANTIMICROBIAL AGENT, ANTIOXIDANT, COLOR OR COLORING ADJUNCT, CURING OR PICKLING AGENT, FLAVOR ENHANCER, FLAVORING AGENT OR ADJUVANT	175.105 182.3041
134-03-2	SODIUM ASCORBATE	ANTIOXIDANT, COLOR OR COLORING ADJUNCT, DOUGH STRENGTHENER, FLAVOR ENHANCER, LEAVENING AGENT, NUTRIENT SUPPLEMENT, OXIDIZING OR REDUCING AGENT, PROCESSING AID	182.3731

- ① CAS 등록번호: 50-81-7
- ② 물질명: ASCORBIC ACID
- ③ 사용목적: ANTIMICROBIAL AGENT, ANTIOXIDANT, COLOR OR COLORING ADJUNCT, DOUGH STRENGTHENER, FLAVOR ENHANCER, FLAVORING AGENT OR ADJUVANT, NUTRIENT SUPPLEMENT, PH CONTROL AGENT, SEQUESTRANT, STABILIZER OR THICKENER
- ④ 관련 21 CFR 규정: 172.280, 182.3013, 182.8013

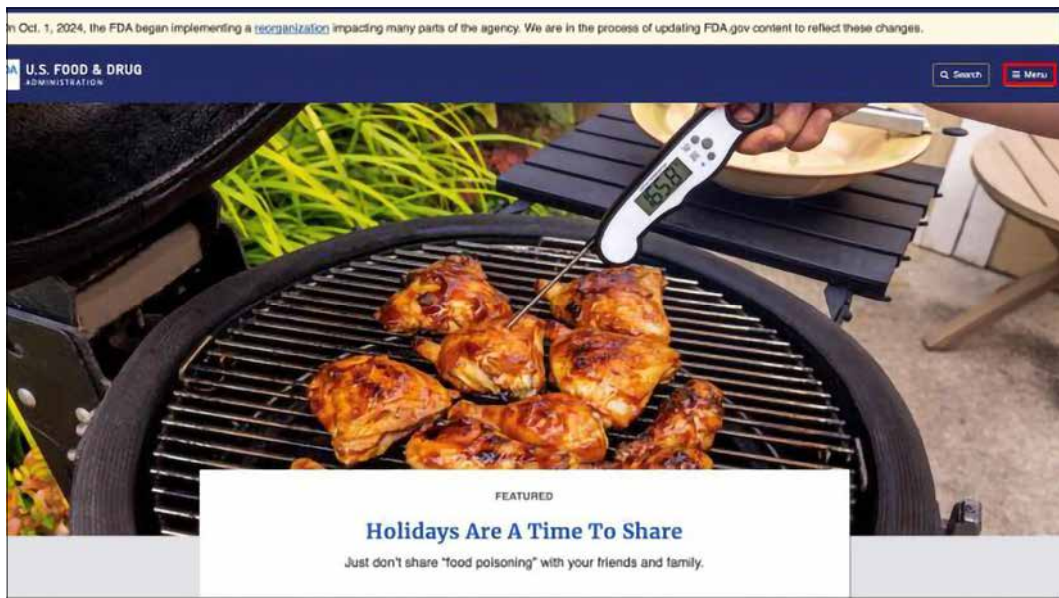
## [ GRAS 신고 ]

### ● 개요

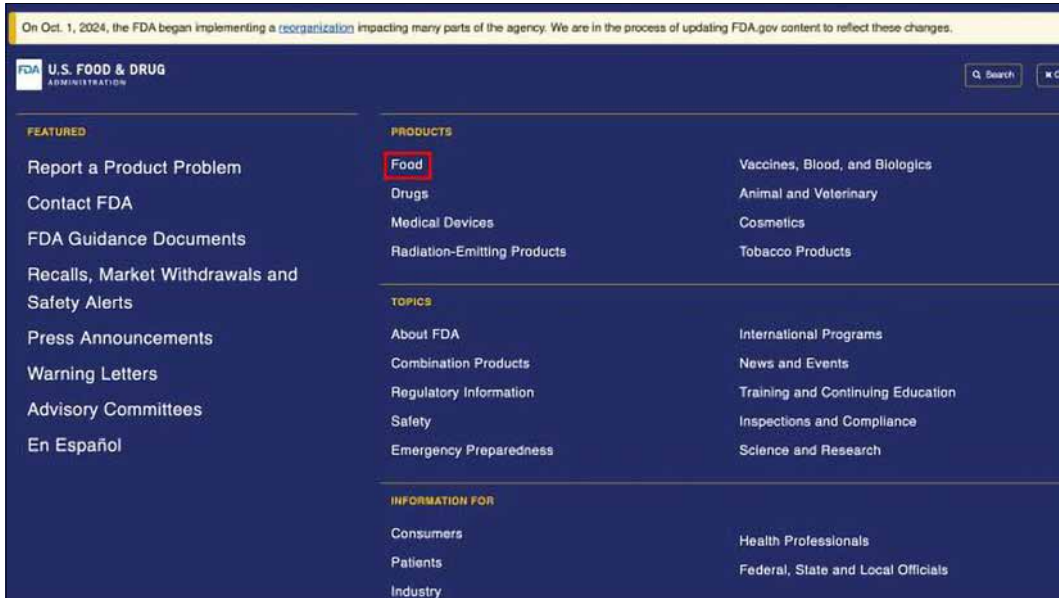
DB명	GRAS 신고(GRAS NOTICE)
관리기관	미국식품의약품청(FDA)
DB 내용	FDA 서신 형태의 GRAS 신고 정보
접속 주소	<a href="https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&amp;sort=GRN_No&amp;order=DESC&amp;startrow=51&amp;type=basic&amp;search=">https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&amp;sort=GRN_No&amp;order=DESC&amp;startrow=51&amp;type=basic&amp;search=</a>
정보 제공 건수	1,194건('24.11. 기준)

### ● DB 접속 방법

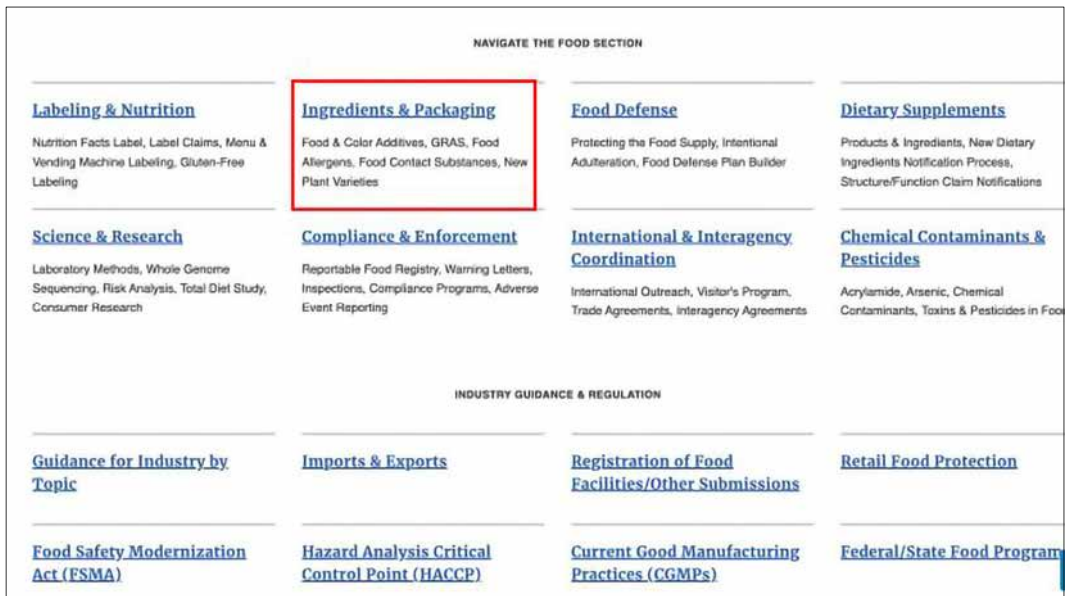
- 'FDA' 메인 홈페이지 접속 후 우측 상단의 '메뉴(Menu)' 클릭



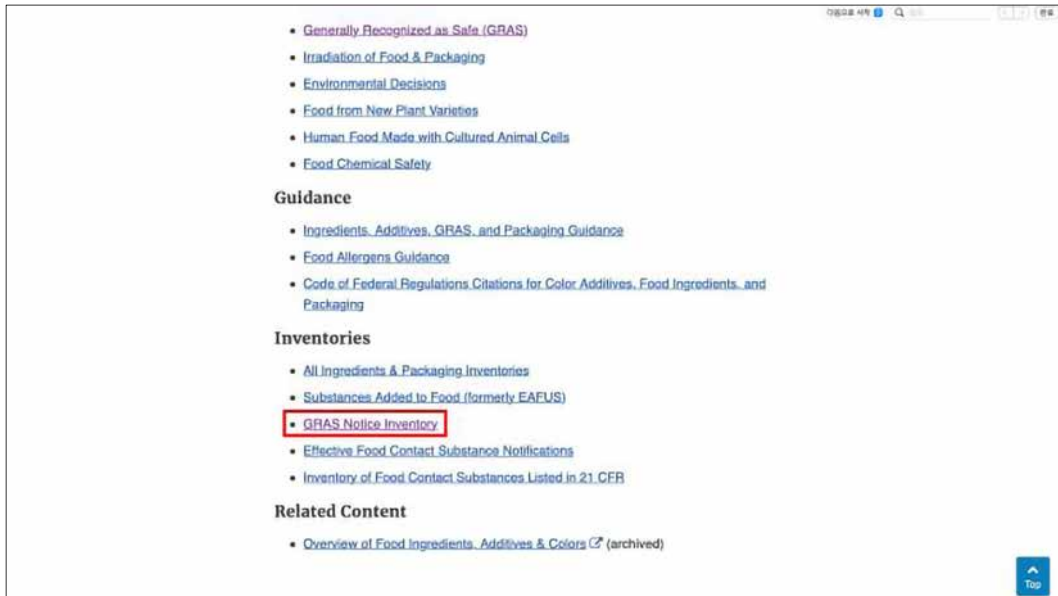
- ‘메뉴(Menu)’ 화면으로 이동 후 ‘Food’ 항목 클릭



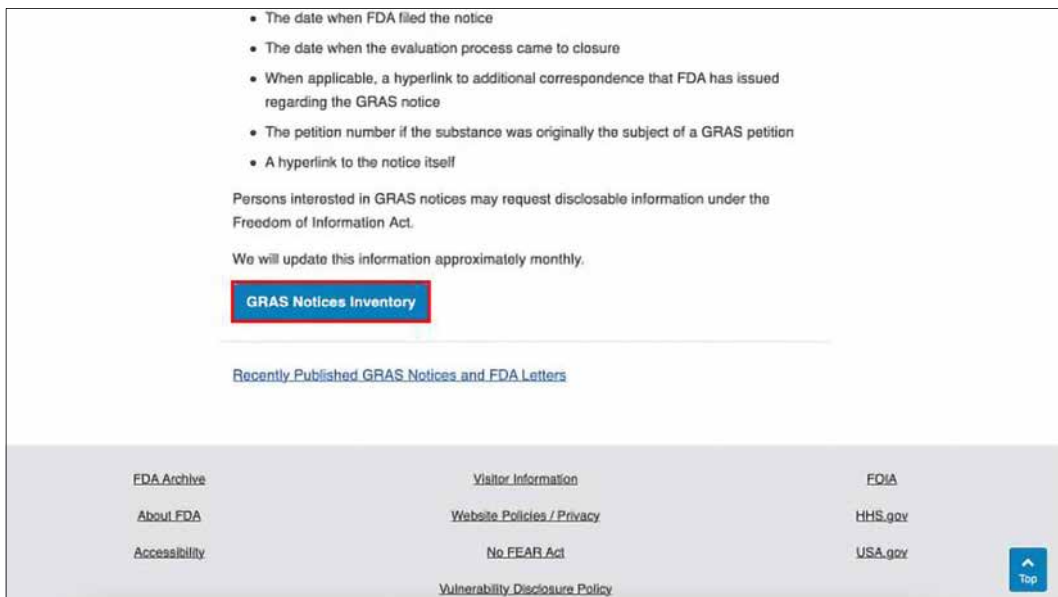
- ‘Food’ 화면에서 ‘성분&포장(Ingredients & Packaging)’ 항목 클릭



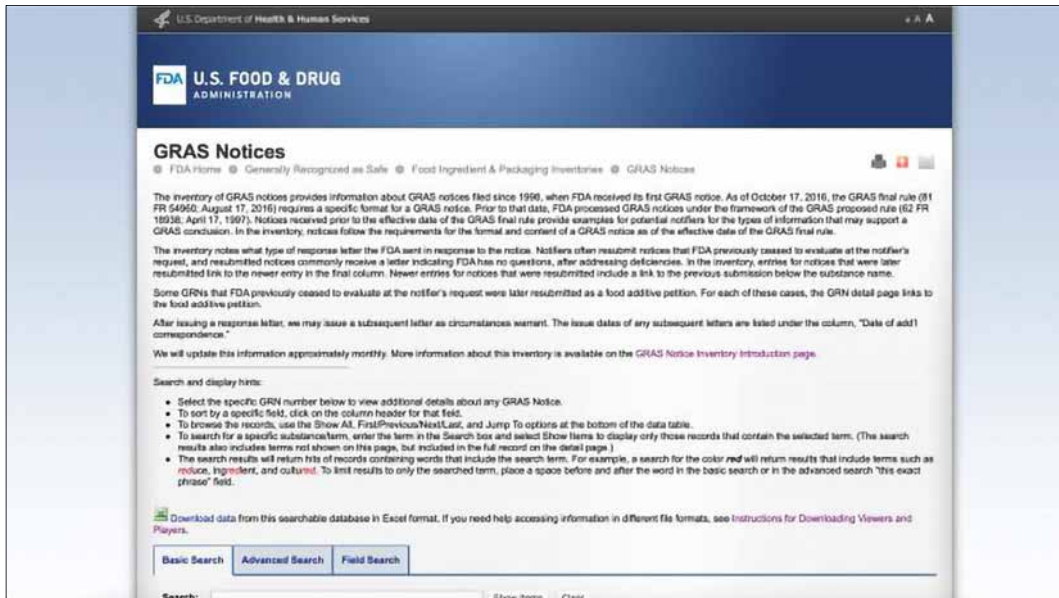
- ‘성분&포장(Ingredients & Packaging)’ 화면에서 ‘GRAS 신고 목록(GRAS Notices Inventory)’ 항목 클릭



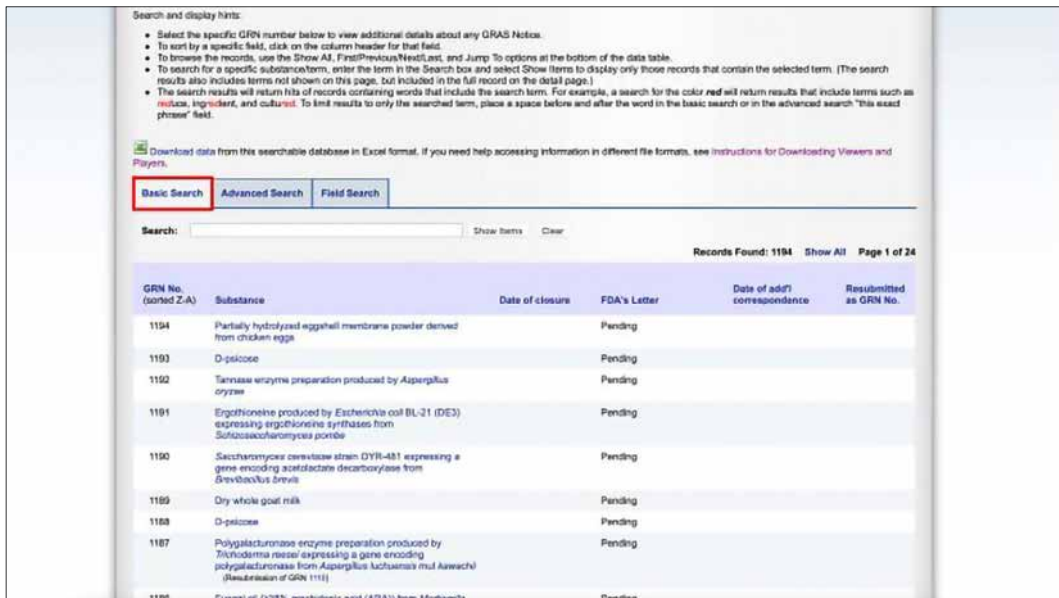
- ‘GRAS 신고 인벤토리(GRAS Notices Inventory)’ 화면에서 ‘GRAS 신고 인벤토리 (GRAS Notices Inventory)’ 항목 클릭



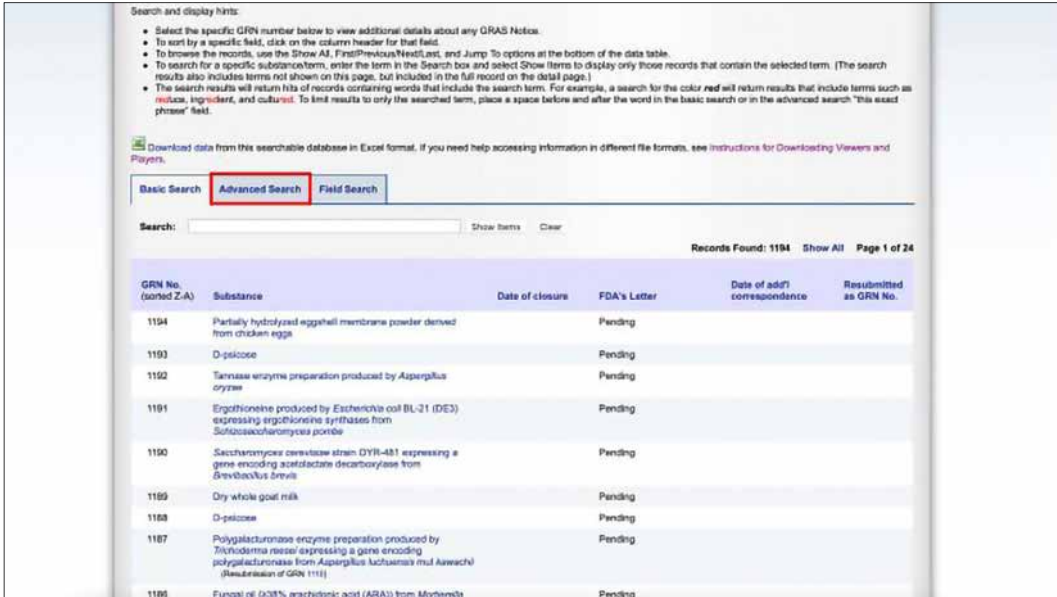
○ GRAS 신고 목록(Gras Notices) 접근 완료



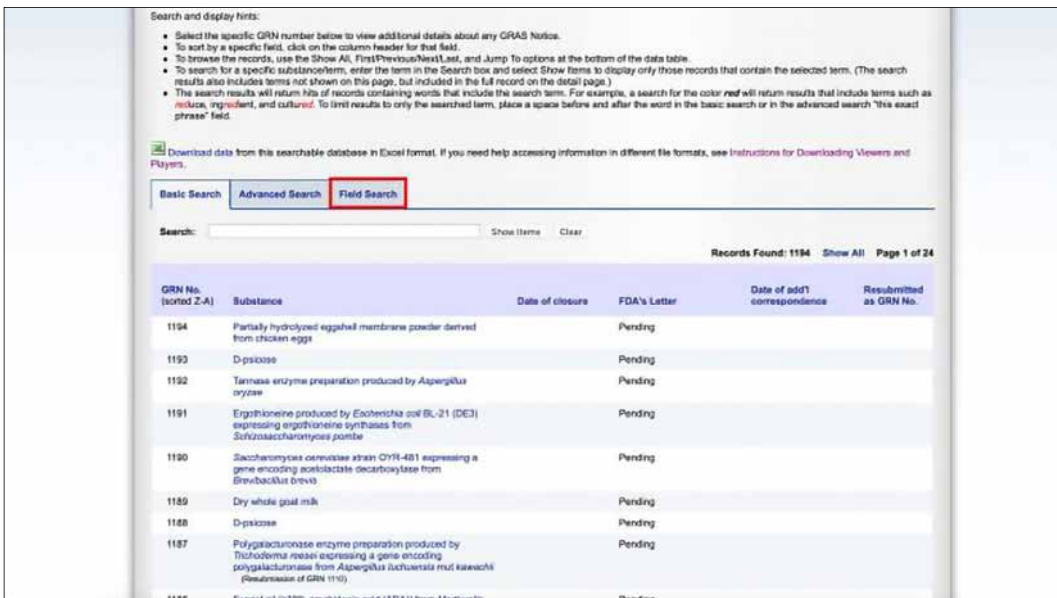
○ ‘기본검색(Basic Search)’, ‘고급검색(Advanced Search)’, ‘범주검색(Field Search)’ 기능 제공



- ‘고급검색(Advanced Search)’에서는 완전 일치어구(This Exact Phrase), 모든 단어 포함(All of these words), 하나라도 포함(Any of these words), 포함 시 제외(None of these words) 등의 기능 사용 가능



- ‘범주검색(Field Search)’에서는 제공범위 범주를 선택해 검색 가능



- ‘검색(Search)’에 검색하고자 하는 원료의 영문 명칭 입력 후 ‘결과보기(Show Items)’ 버튼 클릭

Search and display hints:

- Select the specific GRN number below to view additional details about any GRAS Notice.
- To sort by a specific field, click on the column header for that field.
- To browse the records, use the Show All, First/Previous/Next/Last, and Jump To options at the bottom of the data table.
- To search for a specific substance/term, enter the term in the Search box and select Show Items to display only those records that contain the selected term. (The search results also includes terms not shown on this page, but included in the full record on the detail page.)
- The search results will return hits of records containing words that include the search term. For example, a search for the color red will return results that include terms such as **red**uce, **ingre**dient, and **cultu**red. To limit results to only the searched term, place a space before and after the word in the basic search or in the advanced search "this exact phrase" field.

Download data from this searchable database in Excel format. If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Basic Search | **Advanced Search** | Field Search

Search: Vitamin C   Search within these results

Records Found: 2 Page 1 of 1

GRN No. (sorted Z-A)	Substance	Date of closure	FDA's Letter	Date of add'l correspondence	Resubmitted as GRN No.
769	Vitamin C (fruit and vegetable derived)	Oct 23, 2018	FDA has no questions (in PDF) (72 KB)		
451	Calcium ascorbate with added threonate	Aug 5, 2013	FDA has no questions		

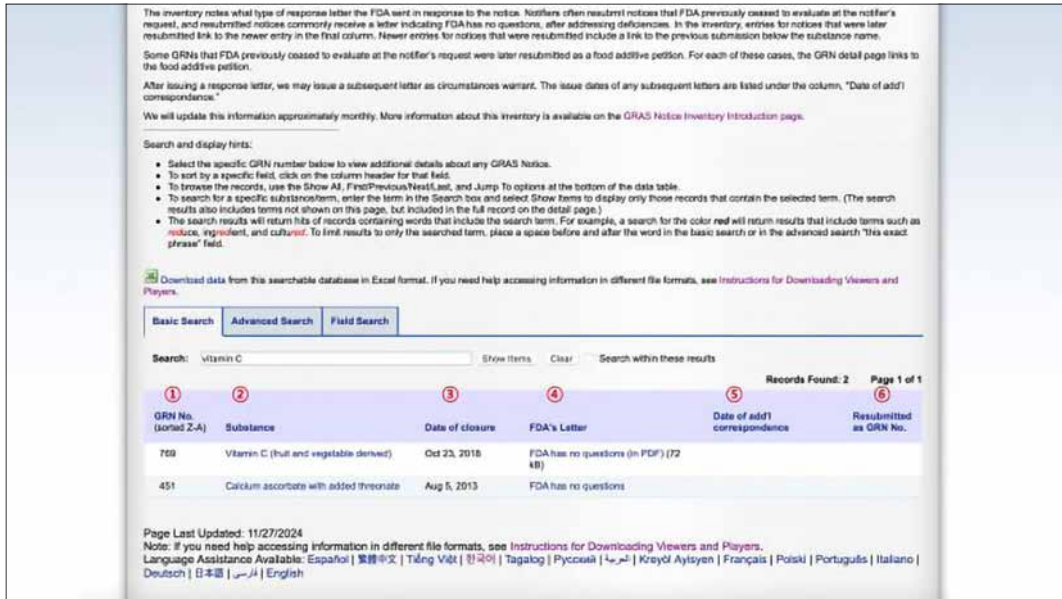
Page Last Updated: 11/27/2024  
 Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).  
 Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | العربية | English

FDA Accessibility | Contact FDA | Vulnerability Disclosure Policy | Careers | FDA Basics | FOIA | No FEAR Act | Nondiscrimination | Website Policies

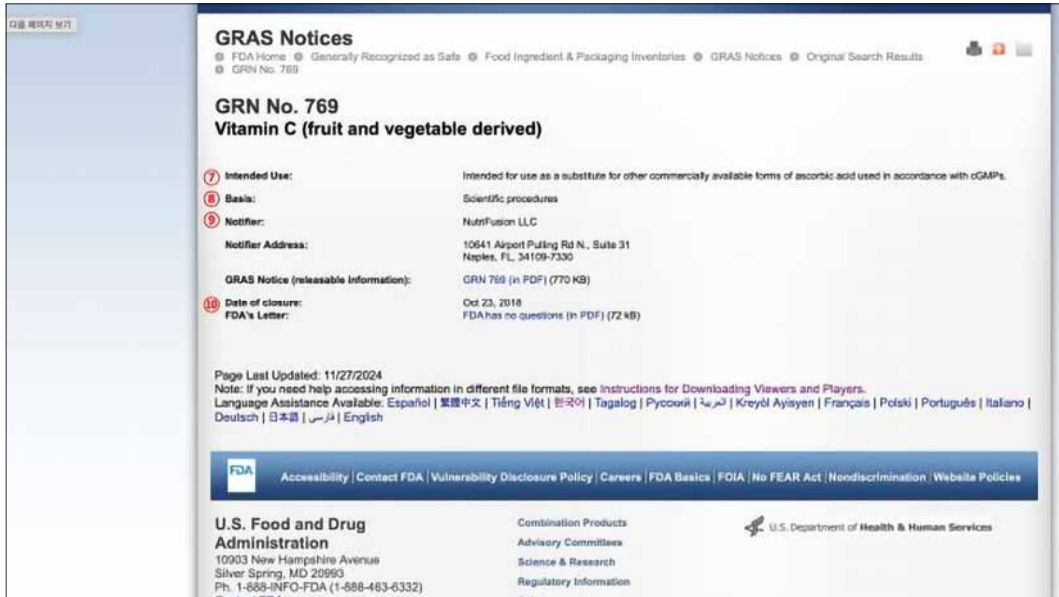
● 정보 제공 범위

- GRN 번호(FDA가 GRAS 통지에 지정한 고유번호), 물질명, 평가종결일자, FDA 회신서, 추가 서신일자, 재제출 GRN 번호 등의 정보 제공

**예시** | 원료명: Vitamin C



- ① GRN 번호: 769
- ② 물질명: Vitamin C(fruit and vegetable derived)
- ③ 평가종결일자: 2018년 10월 23일
- ④ FDA 회신서: '질문 없음(No Questions)' (FDA가 제출된 데이터를 검토한 결과, 안전성에 대해 추가적인 질문이 없으며 GRAS 상태를 인정한다는 의미)
- ⑤ 추가서신일자: -
- ⑥ 재제출GRN 번호: -



- ⑦ 사용용도: 통상 상업용으로 사용되는 아스코르빈산(비타민 C) 형태의 대체제로 사용하려는 의도
- ⑧ 근거: 과학적 근거
- ⑨ 제출자: NutriFusionLLC & 주소지
- ⑩ FDA 회신서: 편지형태의 회신서로 열람 가능

## [ 메디라인플러스 ]

### ● 개요

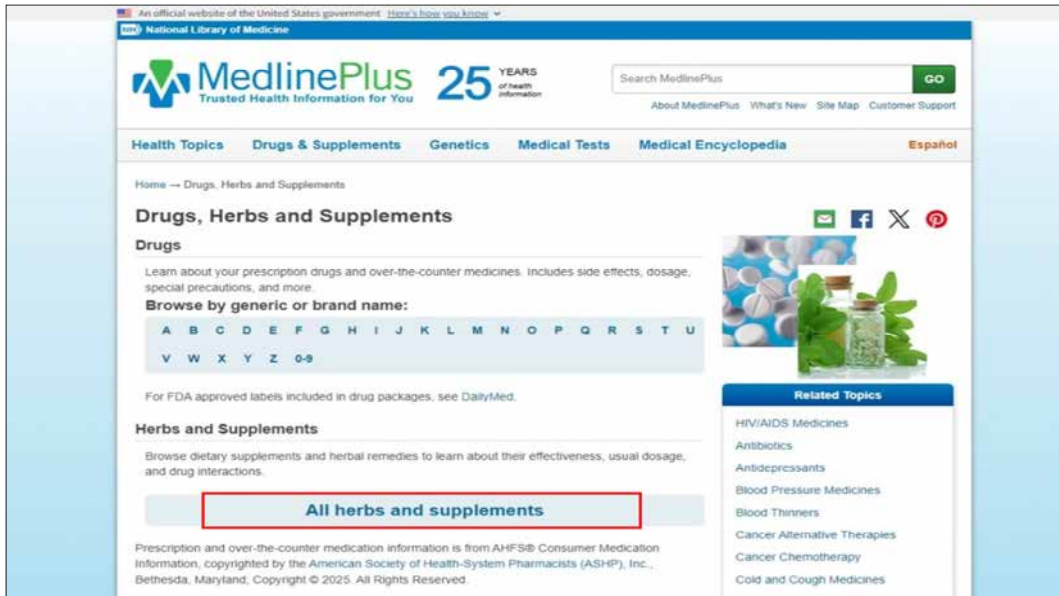
DB명	메디라인플러스(MedlinePlus)
관리기관	미국 국립보건원(NIH)
DB 내용	허브 및 식이보충제 효능, 사용량, 의약품 상호작용 정보 제공 데이터 베이스로 미국 국립의학도서관(National Library of Medicine)과 미국 국립보건원(National Institutes of Health) 혼합자료로 구성, 내용구성에 차이
접속 주소	https://medlineplus.gov/
정보 제공 건수	183건('24.11. 기준)

### ● DB 접속 방법

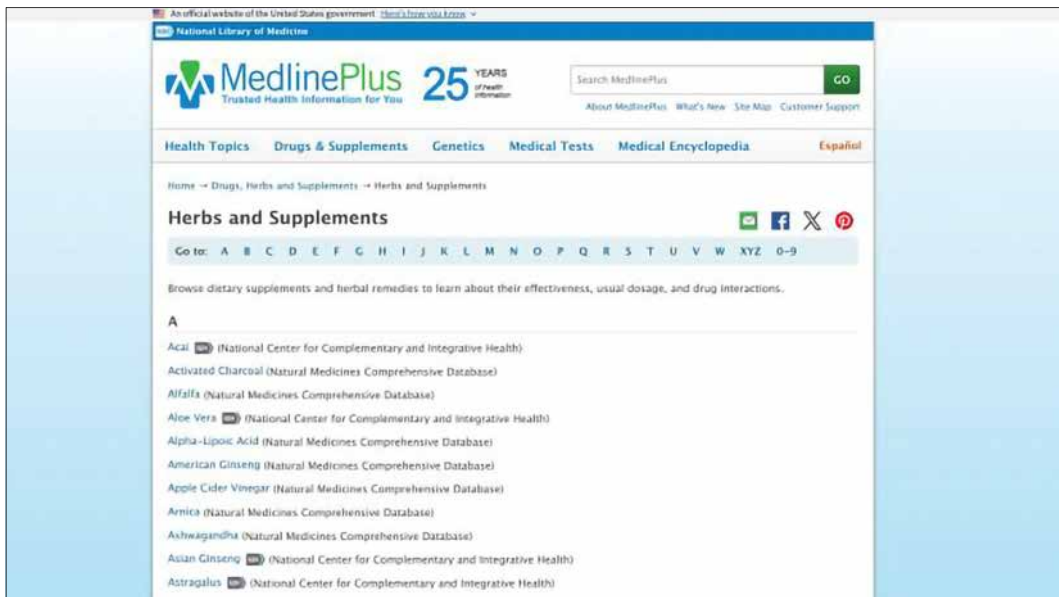
- 메디라인플러스(MedlinePlus) 홈페이지 화면에서 ‘의약품&보충제(Drug & Supplements)’ 항목 클릭



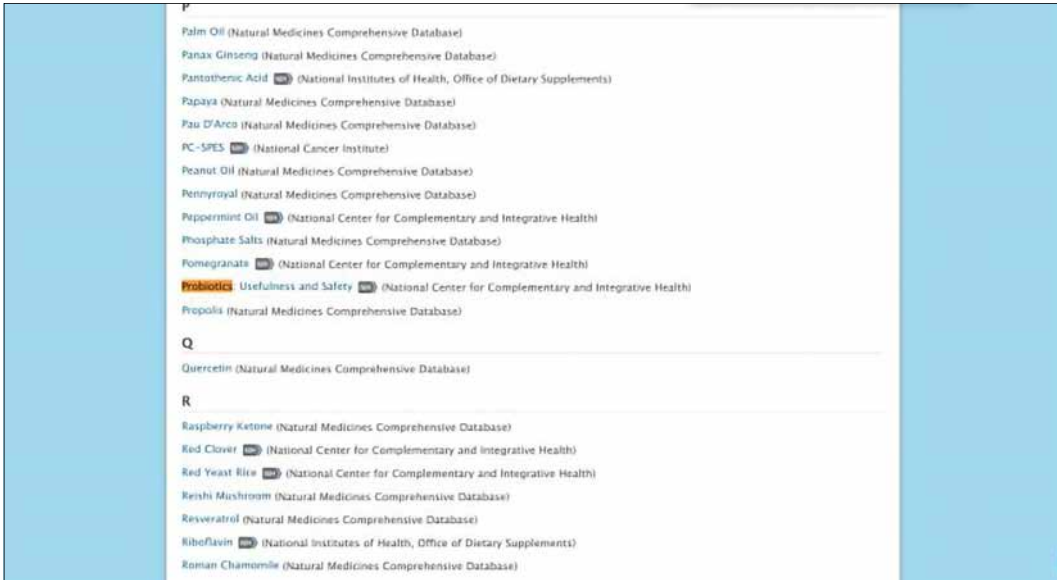
- ‘의약품, 허브 및 보충제(Drugs, Herbs and Supplements)’ 화면에서 ‘모든 허브, 보충제(All herbs and supplements)’ 항목 클릭



- 메디라인플러스(MedlinePlus) 데이터베이스 접근 완료



- 정렬순서는 알파벳순으로 되어있으며 '찾기기능(Ctrl+F)'을 이용해 탐색 가능



## ● 정보 제공 범위

- 개요, 성분의 특징, 작용원리, 규제현황 등 유용성과 안전성에 관한 정보열람 가능

## 예시 | 원료명: Probiotics

Home > Health Information > Probiotics: Usefulness and Safety

### Probiotics: Usefulness and Safety

Share

**1 What are probiotics?**  
 Probiotics are live microorganisms that are intended to have health benefits when consumed or applied to the body. They can be found in yogurt and other fermented foods, dietary supplements, and beauty products. Cases of severe or fatal infections have been reported in premature infants who were given probiotics, and the U.S. Food and Drug Administration (FDA) has warned health care providers about this risk.

Although people often think of bacteria and other microorganisms as harmful "germs," many are actually helpful. Some bacteria help digest food, destroy disease-causing cells, or produce vitamins. Many of the microorganisms in probiotic products are the same as or similar to microorganisms that naturally live in our bodies.

**2 What types of bacteria are in probiotics?**  
 Probiotics may contain a variety of microorganisms. The most common are bacteria that belong to groups called Lactobacillus and Bifidobacterium. Other bacteria may also be used as probiotics, and so may yeasts such as Saccharomyces boulardii.

Different types of probiotics may have different effects. For example, if a specific kind of Lactobacillus helps prevent an illness, that doesn't necessarily mean that another kind of Lactobacillus or any of the Bifidobacterium probiotics would do the same thing.

**3 Are probiotics the same as prebiotics?**  
 No, probiotics aren't the same as prebiotics. Prebiotics are nondigestible food components that selectively stimulate the growth or activity of desirable microorganisms.

**4 What are synbiotics?**  
 Synbiotics are products that combine probiotics and prebiotics.

**For Consumers**  
 5 Things To Know About Probiotics

**For Health Care Providers**  
 Risk of Invasive Disease in Preterm Infants Given Probiotics Formulated To Contain Live Bacteria or Yeast  
 Irritable Bowel Syndrome and Complementary Health Approaches

Probiotics - Systematic Reviews/Reviews/Meta-  
[Back to top](#)

## ■ 캐나다

### [ 안전성 평가 완료된 신소재 식품(유전자 변형 식품 포함) 목록 ]

#### ● 개요

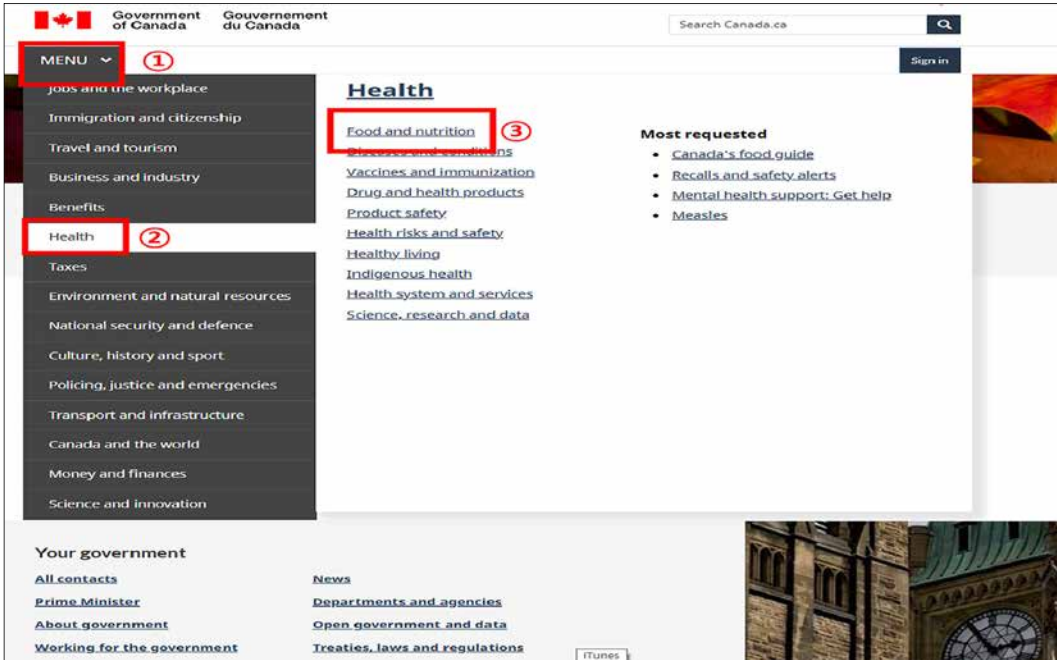
DB명	안전성 평가 완료된 신소재 식품(유전자 변형 식품 포함) 목록
관리기관	캐나다 보건부(HC)
DB 내용	사람이 섭취하기에 안전하다고 평가 완료된 신소재 식품 목록
접속 주소	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html">https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html</a>
정보 제공 건수	260건('24.11. 기준)

#### ● DB 접속 방법

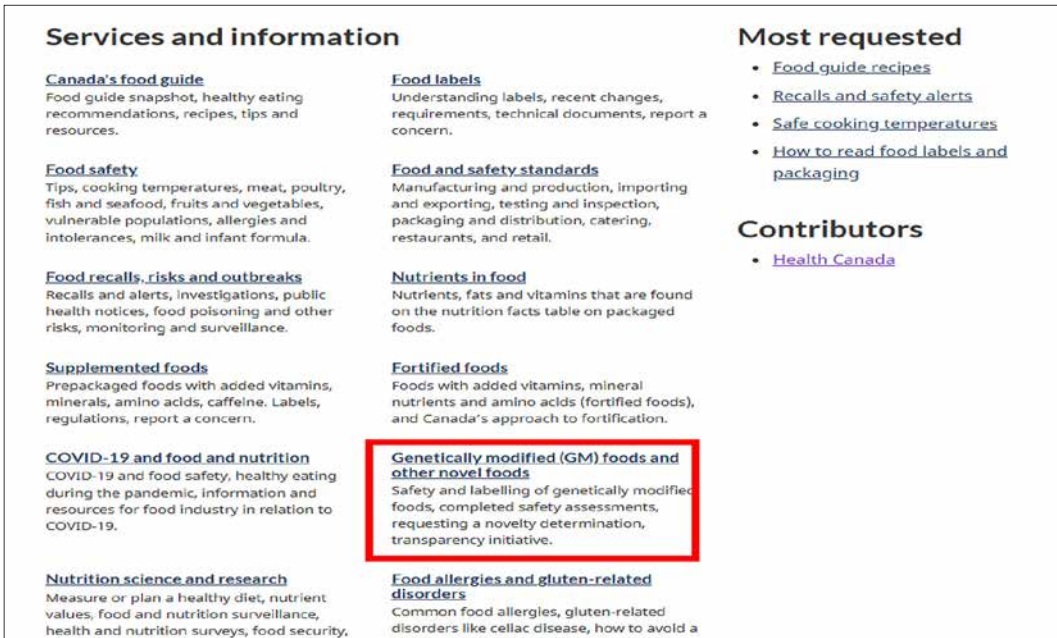
##### ○ 캐나다 보건부 'Health Canada' 접속

The screenshot shows the official website of the Government of Canada. At the top, there are logos for the Government of Canada and the Government of Canada in French, along with a search bar and a 'Français' language selector. Below the header is a 'MENU' dropdown and a 'Sign In' button. The main content area features a large banner with the text 'Canada.ca The official website of the Government of Canada'. Below the banner, there is a 'Most requested' section with links for 'Sign in to an account', 'Find a job', 'Employment Insurance and leave', 'Visit Canada', 'Public pensions (CPP and OAS)', 'Get a work permit', and 'Get a passport'. The bottom section is organized into a grid of service categories: 'Jobs', 'Business and industry', 'Health', 'Immigration and citizenship', 'Benefits', 'Environment and natural resources', 'Travel and tourism', 'Taxes', and 'Money and finances', each with a brief description of the services provided.

- ‘Menu’의 ‘Health’에서 ‘Food and nutrition’ 클릭



- 화면 하단의 ‘Genetically Modified(GM) foods and other novel foods’ 클릭



○ ‘Completed safety assessment’ 클릭

### Novel foods: Overview

Overview

Safety of genetically modified foods

Labelling genetically modified foods

**Completed safety assessments**

Requesting a novelty determination

Transparency initiative

#### On this page

- [Novel food](#)
- [Genetically modified \(GM\) food](#)
- [Health Canada's role in bringing novel foods to market](#)
- [Working together](#)
- [Guidelines and policies](#)

#### Novel food

Simply put, novel foods are food products that are new or changed compared to existing foods. We review novel foods for their safety before they can be sold in Canada.

A novel food is:

- a substance, including a microorganism (a living thing so small you need a microscope to see it), that does not yet have a history of safe use as a food
- a food that has been manufactured, prepared, preserved or packaged by a process that:
  - has not been previously used for that food, and
  - causes the food to undergo a major change
- a food that comes from a plant, animal or microorganism that has been genetically modified so that the plant, animal or microorganism:
  - shows characteristics that it didn't before

○ 신소재 식품 목록 확인

Table of completed novel food safety assessments		
Decision date (yyyy/mm/dd) ↑↓	Product ↑↓	Proponent ↑↓
2024/10/02	<a href="#">Insect resistant soybean – MON 94637</a>	Bayer CropScience Inc.
2024/09/04	<a href="#">Insect resistant and herbicide tolerant maize – DAS-Ø1131-3</a>	Pioneer Hi-Bred Canada Company
2024/08/14	<a href="#">Insect resistant maize – MON 95275</a>	Bayer CropScience Inc.
2024/07/18	<a href="#">Sourvisiae®</a>	Mascoma LLC (a Lallemand company)
2024/07/18	<a href="#">Insect Resistant and Herbicide Tolerant Maize – DP-51291-2</a>	Pioneer Hi-Bred Canada Company
2024/06/19	<a href="#">Insect-resistant and herbicide-tolerant DP910521 maize</a>	Pioneer Hi-Bred Canada Company
2024/06/10	<a href="#">Maize event EH913</a>	Helix Sementes e Mudas
2024/02/20	<a href="#">Short Stature Maize MON 94804</a>	Bayer CropScience Inc.
2024/01/31	<a href="#">β-Lactoglobulin protein from yeast strain Komagataella phaffii yRMK-66</a>	Remilk
2024/01/16	<a href="#">Arctic® apple event PG451</a>	Okanagan Specialty Fruits Inc.

● 정보 제공 범위

- 상기 목록에서는 결정일, 신소재 식품, 제안자 등에 관한 정보를 제공하고 있으며 보다 상세한 내용은 신소재 식품을 클릭하면 확인할 수 있음

## ■ 유럽연합

### [ 식품, 사료 정보 포털 데이터베이스(신소재 식품) ]

#### ● 개요

DB명	식품, 사료 정보 포털 데이터베이스
관리기관	유럽위원회(EC)/유럽식품안전청(EFSA)
DB 내용	신소재 식품 목록
접속 주소	https://eur-lex.europa.eu/eli/reg_impl/2017/2470/oj
정보 제공 건수	-

#### ● DB 접속 방법

##### ○ 유럽위원회의 ‘Food and Feed Information Portal Database’ 접속

The screenshot shows the homepage of the Food and Feed Information Portal Database. At the top, there is the European Commission logo and a search bar. Below the header, the page is divided into several columns, each representing a different category of substances or materials. Each category has a title, a short description, and a list of links for more information.

- Decontamination Substances:** The Commission has established a European Union data base of substances, other than potable water, authorized to remove surface contamination from products of animal origin in accordance with Article 3(2) of Regulation (EC) No 853/2004.
  - [Search for Decontamination Substances](#)
- Feed Additives:** The Commission has established the European Union Register of Feed Additives, which is regularly updated, and it makes reference/links to the relevant authorisation Regulations. Those Regulations include the specific requirements for placing the additives on the EU and EEA market.
  - [Search Feed Additives](#)
  - [Search Feed Additives authorisations](#)
  - [Download Register in Excel format](#)
  - [Latest updates to the Register](#)
  - [Archived expired authorisations \(PDF\)](#)
  - [APIs](#)
  - [Disclaimer](#)
- Food Additives:** This database is a searchable tool informing about the food additives approved for use in food in the EU and their conditions of use. It is based on the Union list of approved food additives laid down in Annex II to Regulation (EC) No 1333/2008.
  - [Search for Additives](#)
  - [Browse by categories](#)
  - [European Legislation on Food Additives](#)
  - [Information documents](#)
  - [APIs](#)
  - [Disclaimer](#)
- Food Allergens:** This database is a searchable tool informing on substances or products causing allergies or intolerances as listed in Annex II to Regulation
- Food Contact Materials:** This database is a searchable tool informing about Food Contact Materials Union Register of recycling installations, facilities, companies,
- Food Flavouring:** This database is a searchable tool informing about the flavouring substances approved for use in food in the EU and their conditions of

○ 화면 하단의 ‘Novel Food’의 ‘Union List of authorised novel foods’ 클릭

<p>(EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers.</p> <ul style="list-style-type: none"> <li>• Search for Allergens</li> </ul>	<p>schemes, authorisations and novel recycling technologies as described in Reg 2022/1616 under Art 24. Search the EU register of:</p> <ul style="list-style-type: none"> <li>• Recycling Companies</li> <li>• Recycling Facilities</li> <li>• Recycling Installations</li> <li>• Disclaimer</li> </ul>	<p>use. It is based on the Union list of approved flavourings and source materials laid down in Annex I to Regulation (EC) No 1334/2008.</p> <ul style="list-style-type: none"> <li>• Search for food flavouring</li> <li>• Browse by categories</li> <li>• European Legislation on Food flavourings</li> <li>• APIs</li> <li>• Disclaimer</li> </ul>
<p><b>Genetically Modified Organisms</b></p> <p>These search engines cover the Community register of GM food and feed (Regulation (EC) 1829/2003), the pending, withdrawn and expired GM products (Regulation (EU) 619/2011) and GMOs authorised under Directive 2001/18/EC.</p> <ul style="list-style-type: none"> <li>• Search genetically modified Food and Feed</li> <li>• Search Genetically Modified Organisms - Part B notifications (experimental releases)</li> <li>• Search Part C notifications (placing on the market)</li> </ul>	<p><b>Health Claims</b></p> <p>The search tool only allows searches for health claims, and not nutrition claims.</p> <ul style="list-style-type: none"> <li>• EU Register of Health Claims</li> <li>• Some health claims subject to the individual authorisation procedure</li> <li>• Download Register in Excel format</li> <li>• APIs</li> </ul>	<p><b>Infant Formulae &amp; Follow-on Formulae manufactured from protein hydrolysates</b></p> <p>The search tool allows for searches for both infant formulae and follow-on formulae.</p> <ul style="list-style-type: none"> <li>• Search for Infant Formulae and Follow-on Formulae</li> </ul>
<p><b>Novel Food</b></p> <p>The Implementing Regulation establishing the list of novel foods compiles all the authorised novel foods in the European Union to date. It includes their conditions of use, labelling requirements, and their specifications.</p> <ul style="list-style-type: none"> <li>• <b>Union List of authorised novel foods</b></li> <li>• Novel Food status Catalogue</li> <li>• Latest updates to the Novel Food status Catalogue</li> <li>• APIs</li> </ul>	<p><b>Nutrients</b></p> <p>This database is a searchable tool informing about the nutritional substances such as vitamins, minerals and others that are approved for use in the EU.</p> <ul style="list-style-type: none"> <li>• Search for Nutrients</li> <li>• Disclaimer</li> </ul>	<p><b>Smoke flavourings</b></p> <p>This database is a searchable tool informing about the smoke flavouring products approved for use in the EU and their conditions of use. It is based on the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavouring laid down in Annex to Regulation (EC) No 1321/2013.</p> <ul style="list-style-type: none"> <li>• Search for Smoke flavourings</li> <li>• Browse by categories</li> <li>• European Legislation on Smoke flavourings</li> <li>• APIs</li> <li>• Disclaimer</li> </ul>

○ Ctrl+f를 실행하여 검색하고자 하는 원료명 입력 후 신소재 식품의 상세 정보 확인

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
Argan oil from <i>Argania spinosa</i>	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Argan oil' and if used as seasoning 'Vegetable oil only for seasoning' shall be mentioned on the label	
	As seasonings	Not specified		
	Food Supplements as defined in Directive 2002/46/EC	In line with normal food use of vegetable oils		

● 정보 제공 범위

- 목록은 표1과 표2로 구분되어 있으며, 표1은 ▲ 승인된 신소재 식품, ▲ 신소재 식품의 사용조건(식품분류 및 최대허용수준), ▲ 표시 요건, ▲ 기타 요건을 명시하고 있으며 표2는 승인된 신소재 식품의 규격을 설명함

**예시** | 원료명: *Argania spinosa*에서 추출한 아르간 오일

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
Argan oil from <i>Argania spinosa</i>	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Argan oil' and if used as seasoning 'Vegetable oil only for seasoning' shall be mentioned on the label	
	As seasonings	Not specified		
	Food Supplements as defined in Directive 2002/46/EC	In line with normal food use of vegetable oils		

승인 신소재 식품	신소재 식품 사용 조건		추가적 표시요건	기타요건
Argania spinosa에서 추출한 아르간 오일	식품분류	최대허용수준	해당 식품에 포함된 신소재 식품의 명칭은 'Argan oil'로 표시되어야 하며, 조미용일 경우, '조미 전용 식물성 오일'이라고 명시해야 함	-
	조미료	지정되지 않음		
	2002/46/EC 지침에 정의된 식품보충제	일반 식물성 오일의 통상적인 사용과 동일		

Argan oil from <i>Argania spinosa</i>	<p><b>Description/Definition:</b> Argan oil is the oil obtained by cold pressing of the almond like kernels of the fruits of <i>Argania spinosa</i> (L.) Skeels. Kernels may be roasted prior to pressing, but with no direct contact with a flame.</p> <p><b>Composition:</b> Palmitic acid (C16:0): 12-15 % Stearic acid (C18:0): 5-7 % Oleic acid (C18:1): 43-50 % Linoleic acid (C18:2): 29-36 % Unsaponifiable matter: 0,3-2 % Total sterols: 100-500 mg/100 g Total tocopherols: 16-90 mg/100 g Oleic acidity: 0,2-1,5 % Peroxide value: &lt; 10 meq O<sub>2</sub>/kg</p>
---------------------------------------	---

Argania  
spinosa에서 추출한  
아르간 오일

**설명/정의:**

- 아르간 오일은 Argania spinosa (L.) Skeels의 열매 속 아몬드 모양의 씨앗을 냉압착하여 얻어지는 오일이다. 씨앗은 압착 전에 볶아질 수 있으나, 불꽃과 직접 접촉하지 않는다.

**구성성분:**

- 팔미트산(C16:0): 12-15%
- 스테아르산(C18:0): 5-7%
- 올레산(C18:1): 43-50%
- 리놀레산(C18:2): 29-36%
- 비검화물질: 0.3-2%
- 총 스테롤: 100-500 mg/100 g
- 총 토코페롤: 16-90 mg/100 g
- 올레산 산도: 0.2-1.5%
- 과산화물 값: < 10 meq O<sub>2</sub>/kg

## ■ 호주

### [ 호주뉴질랜드 식품기준 코드 - 별표 25 - 허용된 신규식품 목록 ]

#### ● 개요

DB명	호주뉴질랜드 식품기준 코드 - 별표 25 - 허용된 신규식품 목록 (Australia New Zealand Food Standards Code - Schedule 25- Permitted novel foods)
관리기관	호주뉴질랜드 식품기준청(FSANZ)
DB내용	허용된 신소재 식품 및 사용 조건
접속 주소	<a href="https://www.legislation.gov.au/F2015L00440/latest/text">https://www.legislation.gov.au/F2015L00440/latest/text</a>
정보 제공 건수	14건('24.11. 기준)

#### ● DB 접속 방법

##### ○ Federal Register of Legislation 접속

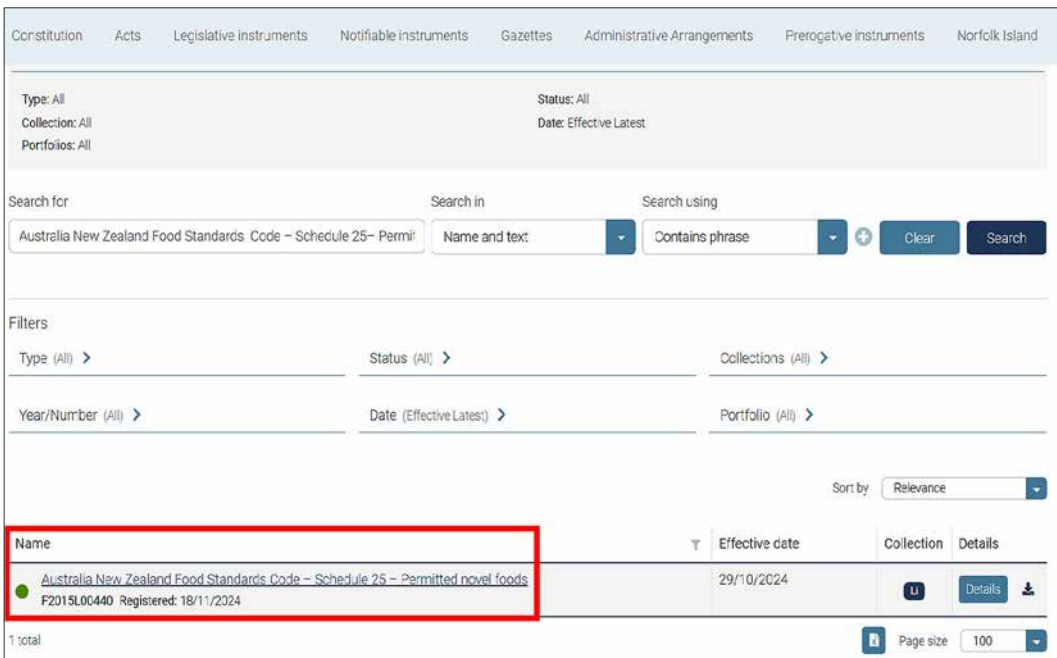


The screenshot shows the search interface of the Federal Register of Legislation. At the top, there are links for 'Help and resources', 'Register for My Account', and 'Sign in to My Account'. The main header includes the 'Australia Government' logo and the title 'Federal Register of Legislation'. Below the header, there is a navigation menu with categories: 'Constitution', 'Acts', 'Legislative instruments', 'Notifiable instruments', 'Gazettes', 'Administrative Arrangements', 'Prerogative instruments', and 'Norfolk island'. The main content area is titled 'Explore the Federal Register of Legislation' and features a search bar with 'Search' and 'Browse' tabs. The search bar includes a dropdown menu for 'All', 'In force', and 'No longer in force'. Below the search bar, there are input fields for 'Search for' (with an example 'example: Legislation Act 2003'), 'Search in' (with a dropdown menu for 'Name and text'), and 'Search using' (with a dropdown menu for 'Contains phrase'). There are also checkboxes for 'Filter by collection' with options for 'Act', 'Gazette', 'Legislative instrument', and 'Notifiable instrument'. A 'Search' button and a link to 'Advanced search' are located at the bottom of the search area.

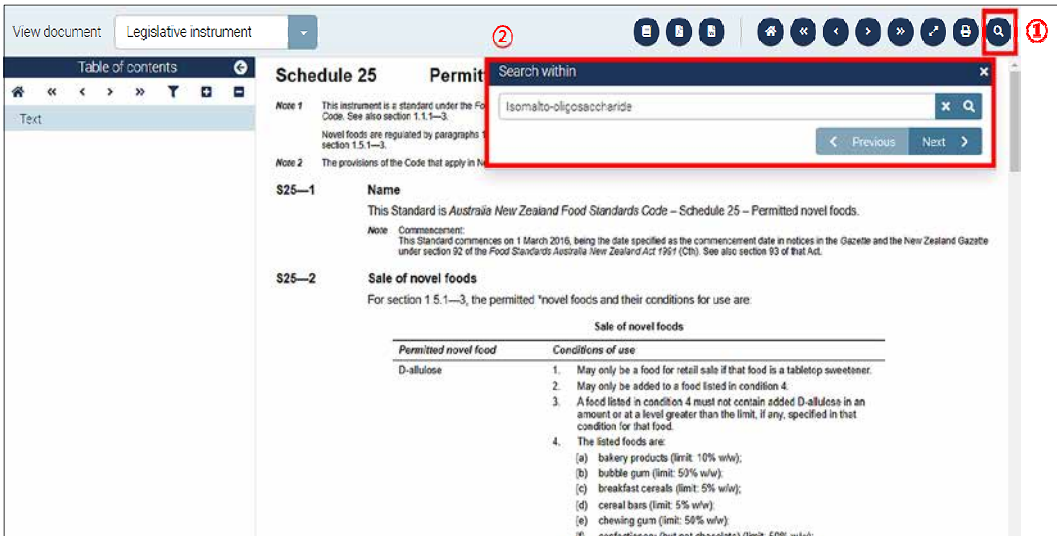
- ‘검색란(Search for)’에 ‘Australia New Zealand Food Standards Code – Schedule 25 – Permitted novel foods’ 입력 후 ‘Search’ 클릭



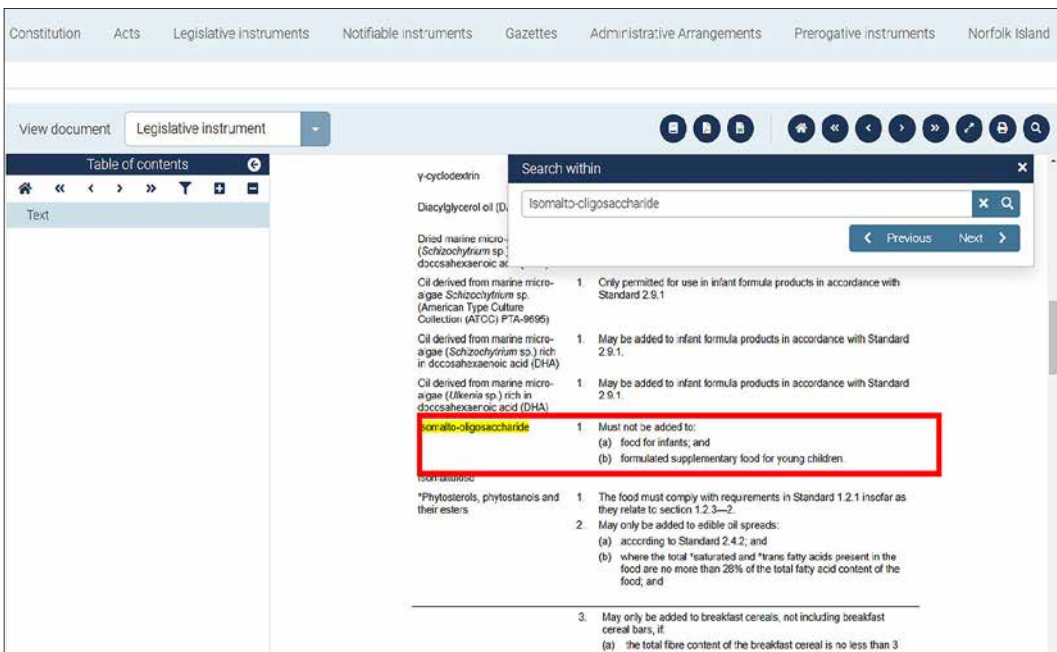
- 화면 아래쪽으로 이동하여 해당 문서 클릭



- ‘돋보기’ 아이콘 클릭 후 검색하고자 하는 식품명을 입력하거나 화면 스크롤을 내리면서 식품 검색




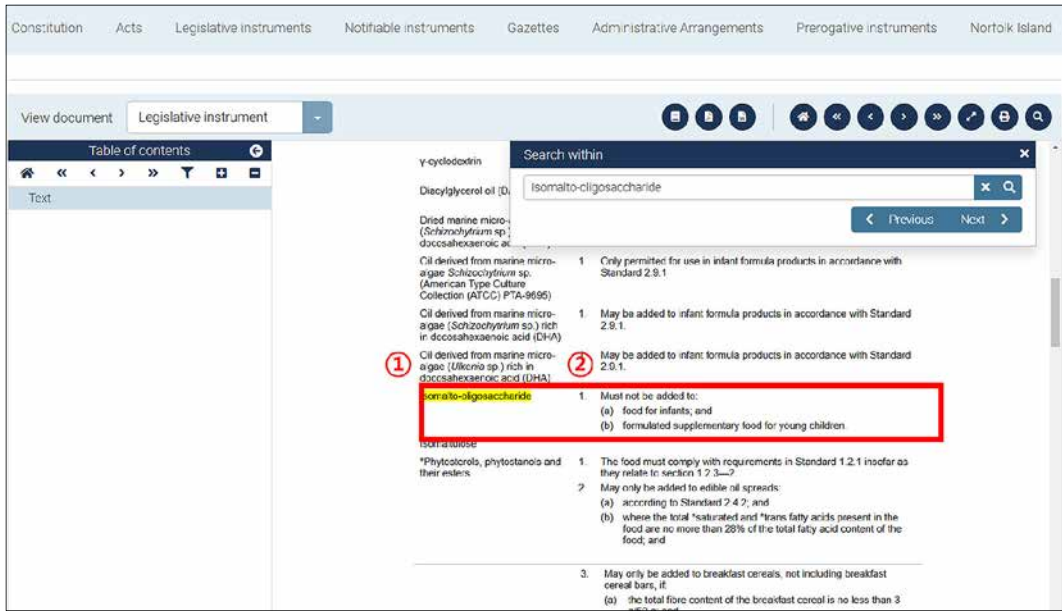
- 해당 식품 정보 확인



● 정보 제공 범위

- 허용된 신소재식품, 사용조건 정보를 제공하고 있으며 PDF, Word 형식으로 다운로드 가능

 예시 | 원료명: 아이소말토올리고당(Isomalto-oligosaccharide)



① 허용된 신소재식품: 아이소말토올리고당

② 사용조건: 1. 영유아용 식품 및 2. 유아용 조제 보충식품에 첨가 금지

## 인도

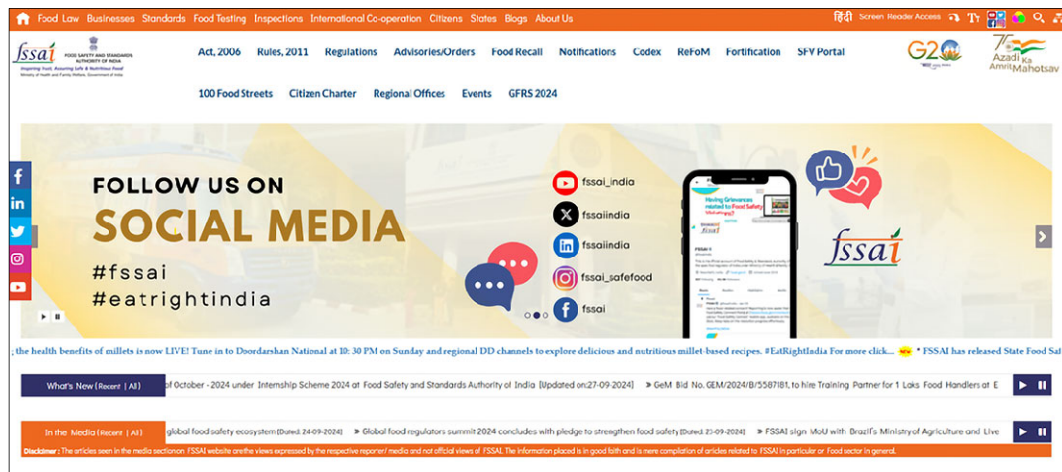
### [ 비정의 식품 ]

#### ● 개요

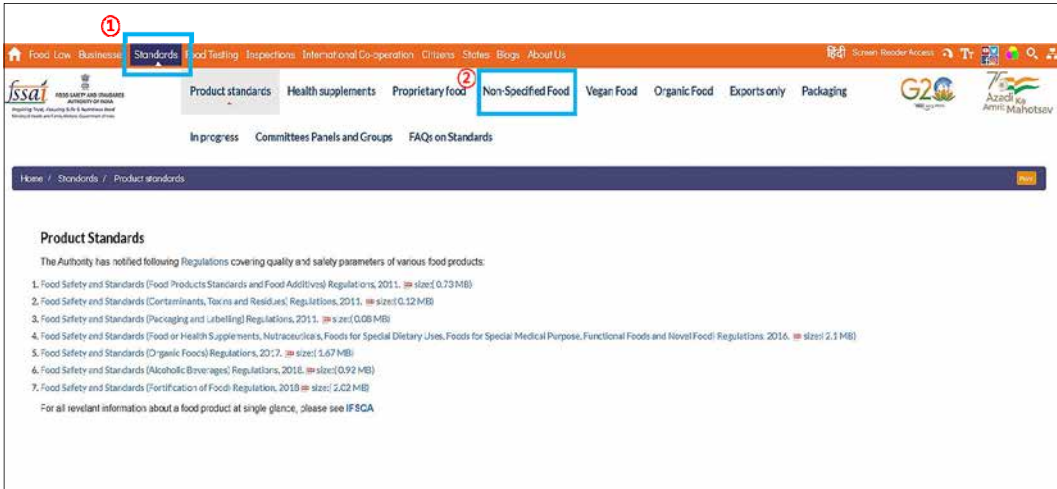
DB명	비정의 식품
관리기관	식품안전기준청(FSSAI)
DB 내용	비정의 식품 사용 승인·거절·중지·검토 중인 원료 목록 제공
접속 주소	<a href="https://fssai.gov.in/cms/non-specified-food.php">https://fssai.gov.in/cms/non-specified-food.php</a>
정보 제공 건수	570건('24.11. 기준) - 사용승인된(approved) 원료 232건, 사용거절된(rejected) 원료 147건, 사용중지/ 철회(closed/withdrawn)된 원료 132건, 사용 검토 중(under process)인 원료 59건

#### ● DB 접속 방법

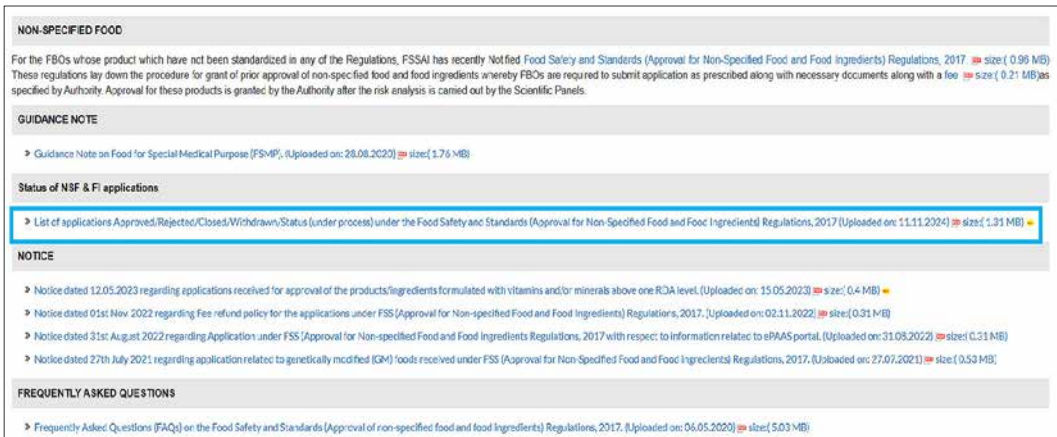
#### ○ Food Safety and Standards Authority of India 접속



○ 상단의 'Standards' 클릭 후 'Non-specified Food' 클릭



○ 화면 중간의 'List of applications Approved/Rejected/Closed/Withdrawn/Status...' 클릭



○ 해당 승인/거절/종료/철회 원료 목록 확인

List of product(s)/ingredient(s) applications "Approved" under Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017 as on 6 <sup>th</sup> November, 2024				
S. No.	Product / Ingredient Name	File Number & Date of Approval	FBO to Whom Approval is Granted	Product Category* (please see the link at lastpage for category details)
1	PreNAN- Human Milk Fortifier	01/Std/PA/FSSAI/2017 & 24.04.2018	M/s Nestle India Limited, Gurgaon-122002, Haryana.	99.5
2	Super Olein / Super Olein 630	03/Std/PA/FSSAI/2017 & 21.12.2017	M/s 3F Industries Limited, Nellore Dist. Andhra Pradesh-524323.	2.1.2
3	Lactogen 1 (with <i>L. reuteri</i> )	04/Std/PA/FSSAI/2017 & 03.08.2018	M/s Nestle India Limited, Gurgaon, Haryana- 122002.	13.1.1
4	Monk Fruit Juice / Monk Fruit Juice Concentrate	13/Std/PA/FSSAI/2017 & 27.02.2019	M/s Gujarat Enterprise Ahmedabad, Gujarat - 380009.	2.3.13
5	Dichloromethane (Methylene dichloride)	14/Std/PA/FSSAI/2017 & 22.06.2018	M/s Ishaana Nutraceuticals Pvt. Ltd., Dehradun, Uttarakhand- 248001.	99.1
6	Isopropyl alcohol (Propan-2-ol)	15/Std/PA/FSSAI/2017 & 22.06.2018	M/s Ishaana Nutraceuticals Pvt. Ltd., Dehradun, Uttarakhand- 248001.	99.1
7	Complex of <i>Cucumis melo</i> L. fruit extract (melon fruit extract), Gliadin (wheat extract) and Maltodextrin	19/Std/PA/FSSAI/2017 & 23.04.2018	M/s Sun Pharmaceutical Industries Ltd., Goregaon Mumbai-400063.	99.7
8	Dichloromethane(Methylene chloride)	22/Std/PA/FSSAI/2017 & 22.02.2018	M/s Zydus Healthcare Limited, Ahmedabad, Gujarat – 380015.	99.1
9	Isopropyl alcohol	23/Std/PA/FSSAI/2017 & 22.02.2018	M/s Zydus Healthcare Limited, Ahmedabad, Gujarat – 380015.	99.1
10	Blend of mucopolysaccharides and collagen type I	25/Std/PA/FSSAI/2017 & 23.04.2018	M/s SunDyota Numandis Probioceuticals Pvt. Ltd. Ahmedabad, Gujarat– 380015.	99.7
11	Blended Starch Balls	03/Std/PA/FSSAI/2018 & 25.09.2018	M/s Kulavilakku Amman Sago Factory, Taluk Namakkal District, Tamil Nadu-637401.	6.2.2

● 정보 제공 범위

- 원료명, 파일번호 & 승인/거절/중지/검토일자, 사용승인·거절·중지·검토 받은 업체 등에 관한 정보 제공



예시 | 사용 승인 원료 목록

List of product(s)/ingredient(s) applications "Approved" under Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017 as on 6 <sup>th</sup> November, 2024				
S. No.	Product / Ingredient Name	File Number & Date of Approval	FBO to Whom Approval is Granted	Product Category <sup>a</sup> (please see the link at lastpage for category details)
1	PreNAN- Human Milk Fortifier	01/Std/PA/FSSAI/2017 & 24.04.2018	M/s Nestle India Limited, Gurgaon-122002. Haryana.	99.5
2	Super Olein / Super Olein 630	03/Std/PA/FSSAI/2017 & 21.12.2017	M/s 3F Industries Limited, Nellore Dist. Andhra Pradesh-524323.	2.1.2
3	Lactogen 1 (with <i>L. reuteri</i> )	04/Std/PA/FSSAI/2017 & 03.08.2018	M/s Nestle India Limited, Gurgaon, Haryana- 122002.	13.1.1
4	Monk Fruit Juice / Monk Fruit Juice Concentrate	13/Std/PA/FSSAI/2017 & 27.02.2019	M/s Gujarat Enterprise Ahmedabad, Gujarat - 380009.	2.3.13
5	Dichloromethane (Methylene dichloride)	14/Std/PA/FSSAI/2017 & 22.06.2018	M/s Ishaana Nutraceuticals Pvt. Ltd., Dehradun, Uttarakhand- 248001.	99.1
6	Isopropyl alcohol (Propan-2-ol)	15/Std/PA/FSSAI/2017 & 22.06.2018	M/s Ishaana Nutraceuticals Pvt. Ltd., Dehradun, Uttarakhand- 248001.	99.1
7	Complex of <i>Cucumis melo</i> L. fruit extract (melon fruit extract), Gliadin (wheat extract) and Maltodextrin	19/Std/PA/FSSAI/2017 & 23.04.2018	M/s Sun Pharmaceutical Industries Ltd., Goregaon (E), Mumbai-400063.	99.7
8	Dichloromethane(Methylene chloride)	22/Std/PA/FSSAI/2017 & 22.02.2018	M/s Zydus Healthcare Limited, Ahmedabad, Gujarat – 380015.	99.1
9	Isopropyl alcohol	23/Std/PA/FSSAI/2017 & 22.02.2018	M/s Zydus Healthcare Limited, Ahmedabad, Gujarat – 380015.	99.1
10	Blend of mucopolysaccharides and collagen type I	25/Std/PA/FSSAI/2017 & 23.04.2018	M/s SunDyota Numandis Probioceticals Pvt. Ltd. Ahmedabad, Gujarat– 380015.	99.7
11	Blended Starch Balls	03/Std/PA/FSSAI/2018 & 25.09.2018	M/s Kulavilakku Amman Sago Factory, Taluk Namakkal District, Tamil Nadu-637401.	6.2.2

번호	제품명/원료명	파일 번호 및 승인 날짜	승인 받은 식품사업자
1	PreNAN - 모유 강화제	01/Std/PA/FSSAI/2017 24.04.2018	M/s Nestle India Limited, Gurgaon - 122002, Haryana
2	슈퍼 올레인 슈퍼 올레인 630	03/Std/PA/FSSAI/2017 21.12.2017	M/s 3F Industries Limited, Nellore Dist., Andhra Pradesh - 524323
3	락토젠 1 (로이테리 유산균 포함)	04/Std/PA/FSSAI/2017 03.08.2018	M/s Nestle India Limited, Gurgaon - 122002, Haryana
4	몽크프루트 주스 몽크프루트 주스 농축액	13/Std/PA/FSSAI/2017 27.02.2019	M/s Gujarat Enterprise, Ahmedabad, Gujarat - 380009
5	디클로로메탄 (메틸렌 디클로라이드)	14/Std/PA/FSSAI/2017 22.06.2018	M/s Ishaana Nutraceuticals Pvt. Ltd., Dehradun, Uttarakhand - 248001
6	이소프로필 알코올 (프로판-2-올)	15/Std/PA/FSSAI/2017 22.06.2018	M/s Ishaana Nutraceuticals Pvt. Ltd., Dehradun, Uttarakhand - 248001

## [ 식품 안전 및 기준(식품 또는 건강보조식품, 뉴트라슈티컬, 특수식이 목적식품, 특수의료목적식품, 기능성 식품, 신소재식품) 규정 ]

### ● 개요

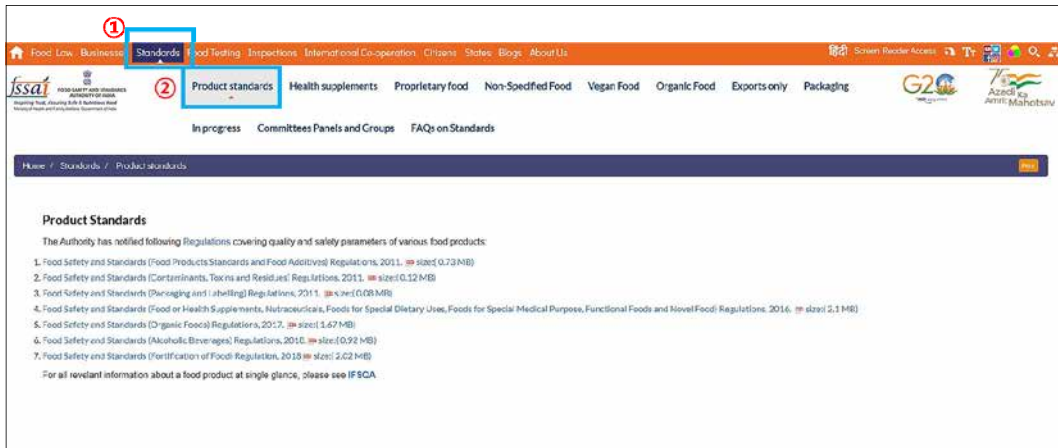
<b>DB명</b>	건강보조식품, 뉴트라슈티컬, 특수식이목적식품, 특수의료목적식품, 기능성 식품 및 신소재 식품 규정
<b>관리기관</b>	식품안전기준청(FSSAI)
<b>DB 내용</b>	품목별 식품첨가물 목록 제공
<b>접속 주소</b>	<a href="https://fssai.gov.in/cms/product-standards.php">https://fssai.gov.in/cms/product-standards.php</a>
<b>정보 제공 건수</b>	-

### ● DB 접속 방법

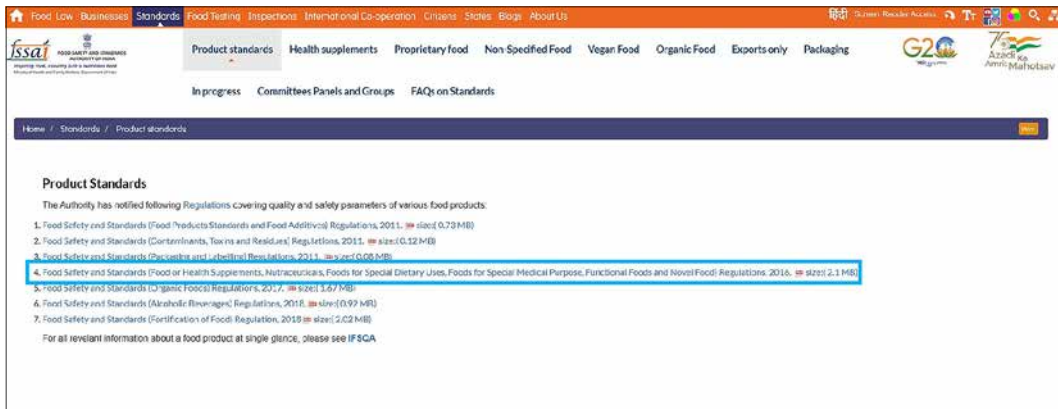
#### ○ Food Safety and Standards Authority of India 접속



○ 상단의 ‘Standards’ 클릭 후 ‘Product standards’ 클릭




○ 목록 중 ‘Food Safety and Standards(Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods and Novel Food), Regulations, 2016’ 클릭



○ 해당 규정 확인(웹사이트 오류가 빈번하여 해당 파일 다운로드 권장)

रजिस्ट्री सं० डी० एल०-33004/99 REGD. NO. D. L.-33004/99



# भारत का राजपत्र

## The Gazette of India

असाधारण  
EXTRAORDINARY  
भाग III—खण्ड 4  
PART III—Section 4  
प्रधिकार से प्रकाशित  
PUBLISHED BY AUTHORITY

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सं. 465] नई दिल्ली, सोमवार, दिसम्बर 26, 2016/पौष 5, 1938  
No. 465] NEW DELHI, MONDAY, DECEMBER 26, 2016/ PAUSA 5, 1938

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**स्वास्थ्य और परिवार कल्याण मंत्रालय**  
**(भारतीय खाद्य सुरक्षा और मानक प्राधिकरण)**  
**अधिसूचना**  
नई दिल्ली, 23 दिसम्बर, 2016

सं. 1-4/न्यूट्रास्यूटिकल/एफएसएसएआई-2013-खाद्य सुरक्षा और मानक (खाद्य या स्वास्थ्य अनुपूरक, न्यूट्रास्यूटिकल्स, विशेष आहार विषयक उपयोग के लिए खाद्य, विशेष चिकित्सीय प्रयोजन के लिए खाद्य, कृत्वकारी खाद्य और नूतन खाद्य) विनियमावली, 2015 का प्रारूप खाद्य सुरक्षा और मानक अधिनियम, 2006 (2006 का 34) की धारा 92 की उप-धारा (1) की अपेक्षानुसार, भारतीय खाद्य सुरक्षा और मानक प्राधिकरण की अधिसूचना सं. 1-4/न्यूट्रास्यूटिकल/एफएसएसएआई-2013 दिनांक 30 जुलाई, 2015 को भारत के राजपत्र, असाधारण, भाग-III, खंड 4 में प्रकाशित किया गया था, जिसमें उन व्यक्तियों से जिनके उससे प्रभावित होने कि संभावना थी, उस तारीख से जिसकी उक्त अधिसूचना में अंतर्निष्ठ राजपत्र कि प्रतियाँ जनता को उपलब्ध करा दी गयी थी साठ दिन की अवधि की समाप्ति से पहले आक्षेप और सुझाव मांगे गए थे;

और उक्त राजपत्र की प्रतियाँ जनता को 11 सितंबर, 2015 को उपलब्ध करा दी गई थी;

और जनता से उक्त प्रारूप विनियमों के संबंध में विनिर्दिष्ट अवधि के भीतर प्राप्त आपत्तियाँ और सुझावों पर भारतीय खाद्य सुरक्षा और मानक प्राधिकरण द्वारा विचार किया गया;

अतः, अब, भारतीय खाद्य सुरक्षा और मानक प्राधिकरण, भारतीय खाद्य सुरक्षा और मानक अधिनियम, 2006 (2006 की 34) की धारा 22 की उप-धारा (1) के साथ पठित धारा 92 की उप-धारा (2) के खंड (फ) द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, निम्नलिखित विनियम बनाता है, अर्थात : -

विनियम

1. संक्षिप्त नाम और प्रारंभ - (1) इन विनियमों का संक्षिप्त नाम खाद्य सुरक्षा और मानक (खाद्य या स्वास्थ्य अनुपूरक, न्यूट्रास्यूटिकल्स, विशेष आहार विषयक उपयोग के लिए खाद्य, विशेष चिकित्सीय प्रयोजन के लिए खाद्य, कृत्वकारी खाद्य और नूतन खाद्य) विनियमावली, 2016 है।
- (2) ये राजपत्र में इनके प्रकाशन की तारीख को प्रकृत होंगे तथा खाद्य कारोबार प्रचालकों को 1 जनवरी, 2018 से इन नियमों के सभी प्रावधानों का अनुपालन करना होगा।

5925 G/2016 (1)

○ Ctrl+f를 실행하여 원료 상세 정보 확인

S.No.	Vitamins and Minerals	Components
<b>A. Vitamins-</b>		
1.	Vitamin A	(i) Retinol - all trans retinol (ii) Retinyl acetate (iii) Retinyl palmitate
2.	Provitamin A	(i) Beta-Carotene
3.	Vitamin B <sub>1</sub>	(i) Thiamine chloride hydrochloride (ii) Thiamine mononitrate
4.	Vitamin B <sub>2</sub>	(i) Riboflavin (ii) Riboflavin 5'-phosphate, sodium
5.	Vitamin B <sub>6</sub>	(i) Pyridoxine hydrochloride (ii) Pyridoxal 5'-phosphate
6.	Vitamin B <sub>12</sub>	(i) Cyanocobalamin
7.	Vitamin C	(i) L-ascorbic acid (ii) Sodium-L-ascorbate (iii) Calcium-L-ascorbate (iv) Potassium-L-ascorbate (v) <i>o</i> -palmityl-L-ascorbic acid (vi) Ascorbyl-2-phosphate
8.	Vitamin D	(i) Vitamin D <sub>2</sub> (cholecalciferol) - Animal source (ii) Vitamin D <sub>3</sub> (ergocalciferol) - Plant source
9.	Vitamin E	(i) D.alpha-tocopherol (ii) DL.alpha-tocopherol (iii) D.alpha-tocopheryl acetate (iv) DL.alpha-tocopheryl acetate (v) D.alpha-tocopheryl acid succinate (vi) DL.alpha-tocopheryl acid succinate (vii) DL.alpha-tocopheryl polyethylene glycol succinate
10.	Vitamin K <sub>1</sub>	(i) Phylloquinone (ii) Phytoneadione (2-methyl 3-phytyl-1) (iii) 1,4-naphthoquinone (iv) Phytanadione
11.	Vitamin K <sub>2</sub> (MK-7)	(i) Menaquinone
12.	Vitamin K <sub>2</sub> (MK-4)	(i) Menaquinone
13.	Biotin	(i) D-biotin
14.	Folic Acid	(i) <i>n</i> -pteroyl-L-glutamic acid
15.	Niacin	(i) Nicotinic acid (ii) Nicotinamide (iii) Nicotinic acid amide
16.	Pantoic acid	(i) D-pantothenate, calcium

vitamin C

## ● 정보 제공 범위

부 록	내 용	제공 건수
부록 I	비타민 및 미네랄, 각 구성성분 목록	31건
부록 II	아미노산 및 기타 영양성분 목록	-
부록 III	영유아용 조제 식품을 제외한 특수 식이목적 식품 및 특수 의료목적 식품에 사용이 허용되는 비타민, 미네랄 및 미량 원소의 기준값	-
부록 IV	식물 또는 식물성 원료 목록	400건
부록 VA	건강보조식품, 기능성 식품 및 프로바이오틱스와 프리바이오틱스가 첨가된 식품에 사용되는 식품 첨가물 목록	39건
부록 VB	특수 식이목적 식품 및 프로바이오틱스와 프리바이오틱스가 첨가된 식품에 사용되는 식품 첨가물 목록	24건
부록 VC	영유아용 식품을 제외한 특수 의료목적 식품 및 프로바이오틱스와 프리바이오틱스가 첨가된 식품에 사용 가능한 식품 첨가물 목록	25건
부록 VD	영유아용 식품을 제외한 특수 의료목적 식품, 체중 감소 및 슬리밍용 조제식, 그리고 프로바이오틱스 및 프리바이오틱스가 첨가된 식품에 사용 가능한 식품 첨가물 목록	26건
부록 VE	다음에 사용 가능한 식품첨가물 목록(GMP 수준에서 사용) (I) 기능성 식품 (II) 영유아용 식품을 제외한 특수 식이목적 식품 (III) 특수 의료목적 식품 (IV) 프로바이오틱 성분 및 프리바이오틱 성분이 첨가된 식품 (V) 식물 또는 식물성 원료를 함유한 특수 식품 (VI) 건강보조식품	189건
부록 VF	다음 형태로 사용 가능한 식품 첨가물 목록(정제, 캡슐, 시럽) (I) 기능성 식품 (II) 영유아용 식품을 제외한 특수 식이목적 식품 (III) 특수 의료목적 식품 (IV) 프로바이오틱 성분 및 프리바이오틱 성분이 첨가된 식품 (V) 식물 또는 식물성 원료를 함유한 특수 식품 (VI) 건강보조식품	77건
부록 VI	뉴트라수티컬 식품 원료 목록	Part A(24건) Part B(187건)
부록 VII	프로바이오틱스(생균) 균주 목록	28건
부록 VIII	프리바이오틱 화합물 목록	13건
총 합계		1,063건



예시 | 원료명: 인삼(Korean Ginseng)

PART A				
①	②	③	④	⑤
S. No.	Nutraceutical ingredients	Common name	Purity Criteria	Permitted Range
			A, B, C needs to be tested qualitatively.	
10.	<i>Glucosamine hydrochloride</i>	Glucosamine	Glucosamine content	1,500-3,000 mg/day, Max
11.	<i>Glucosamine sulphate</i>	Glucosamine	Glucosamine content	2,500-5,000 mg/day, Max
12.	<i>Gymnema sylvestre</i> extract powder	Gudmar extract	Gymnemic acid content	500-1,500mg / day, Max
13.	Lactase ( $\beta$ -galactosidase)*	-	Enzyme activity	3,000 – 9,000 IU (or FCC units) / day, Max
14.	<i>Panax ginseng</i> (Syn;Korean Ginseng) extract - (obtained from 0.6 to 2.0 gm of Ginseng root, ( <i>Panaxginseng</i> ,C A. Meyer, Araliaceae)	Ginseng extract	Ginsenoside content ranging from 0.7 to 3%.	90 - 400 mg /day, Max

① 번호: 14

② 뉴트라슈티컬 영양성분

인삼(동의어 한국인삼) 추출물(0.6~2.0 g)의 인삼 뿌리에서 추출  
(*Panax ginseng* C.A. Meyer, 두릅나무과)

③ 일반명칭: 인삼 추출물

④ 순도기준: 진세노사이드 함량 0.7~3% 범위

⑤ 허용범위: 최대 90~400 mg/일

## ■ 일본

### [「건강식품」의 안전성·유효성 정보]

#### ● 개요

DB명	「건강식품」의 안전성·유효성 정보
관리기관	국립건강영양연구소
DB 내용	건강식품의 소재 정보에 대한 데이터베이스 및 유효성 정보
접속 주소	https://hfnet.nibiohn.go.jp/
정보 제공 건수	-

#### ● DB 접속 방법

- 홈페이지 접속 후 상단의 '소재 정보 데이터베이스(素材情報データベース)' 클릭

The screenshot shows the homepage of the National Institute of Health and Nutrition (NIHN) website. The main title is 「健康食品」の安全性・有効性情報. The navigation bar includes links for '新着情報' (New Information), '素材情報データベース' (Ingredient Information Database), '基礎知識' (Basic Knowledge), '被害関連情報' (Information on Adverse Effects), '特定保健用食品' (Specified Health Foods), 'コラム' (Column), 'ビタミン' (Vitamin), 'ミネラル' (Mineral), 'パンフレット' (Pamphlet), and '関連リンク' (Related Links). The '素材情報データベース' link is highlighted with a red box. Below the navigation bar is a banner image showing various vegetables and pills. At the bottom, there are two main sections: '一般向け' (General) and '専門家向け' (For Experts). Below these are three columns: '新着情報' (New Information), '被害関連情報' (Information on Adverse Effects), and 'お知らせ' (Notice). The '新着情報' section shows two recent updates: one from 2024/11/26 about functional food labeling, and another from 2024/11/26 about a warning from the US FDA regarding cyclophosphamide in certain products.

○ 연결된 페이지에서 하단으로 스크롤



○ '소재리스트(素材リスト)'에서 히라가나 순으로 열람 가능



○ 원료 선택 후 클릭시 PDF 파일로 연결됨



● 정보 제공 범위

- 명칭, 개요, 규제, 성분 특징, 분석 및 참고 자료

**예시** | 원료명: 프로바이오틱스

<p>1 <b>명칭</b> 프로바이오틱스 [英]Probiotics, Probiot</p> <p>2 <b>개요</b> 프로바이오틱스는 「適切な量を摂取したならば生きて腸生物」であり、乳酸菌、ビフィス菌を食の食品(発酵乳製品や植物性発酵食品)と呼ばれる。ただし、加熱処理により不活性化している。ここでは、これら腸生物を複数組み合わせたもの。乳酸菌、ビフィス菌、ザッカロバクテリウム、個別のページも参照のこと。</p> <p>3 <b>法規・制度</b> ■ 食薬区分 「専ら医薬品として使用される成分本質(原料)としない限り医薬品と認めない成分本質(原料)」</p> <p>4 <b>成分の特性・品質</b></p>	<p>5 <b>主な成分・性質</b> 「適切な量を摂取したとき、主に主成分として記載されている」(PMID:249123961)</p> <p><b>分析法</b> 有効性</p> <p><b>トピックス</b> メタ分析 ・ 2010年10月までを対象に4つのデータについて検討したメタ分析において、プロバイオティクス(11種)の摂取と腸内細菌叢(12種)、YG(10種)との相関は認められなかった。 RCTと海外 ・ 健康な成人男性38名(平均42歳、フィバー難消化性ラクトゼ試験においてPharmacia LactogenとPropionibacterium 2-101(10)の両方を)に、4週間摂取させた。YGに影響は認められなかった。空腹・消化量の中間値156名(オーストラリア)において、プロバイオティクス(Bifidobacterium animalis subsp. lactisを含む)を17名(37歳、平均68±9歳)、対(40名、平均68±8歳)の高齢者患者に摂取は認められなかった。(PMID:2454700)</p> <p><b>メタ分析</b> ・ 2020年12月までを対象にした4つのデータ(検索条件: n=18歳)について検討したメタ分析は、呼吸器感染症の重症化(2歳)との関連はなかった。 ・ 2020年9月までを対象にした5つのデータ(検索条件: n=18歳)について検討したメタ分析の結果は、上気道感染のリスク(3歳)、TNF-α(3歳)の低下と関連がなかった。症状発症回数(4歳)、発熱発症回数(4歳)、IgA(4歳)との関連は認められなかった。 ・ 2016年4月までを対象にした4つのデータの試験2つについて検討したメタ分析においては、2歳前感染症の発症回数(4歳)、発症の重症化は認められたが、発症率、学校の平均出席日数(9歳)に関連は認められなかった。 ・ 2014年7月までを対象にした3つのデータについて検討したメタ分析において、プロ</p>	<p>6 <b>参考文献</b> [PMID:10843700] Cochrane Database Syst Rev. 2008 Oct 16;(4):CD006061. [PMID:19928186] J Am Soil Water. 2008 Aug;7(2):44-7. [PMID:19133351] Allergy Clin Immunol. 2009 Feb;123(2):335-41. [PMID:20545680] Br J Dermatol. 2010 Sep;163(3):616-23. [PMID:19140301] Clin Exp Allergy. 2009 Apr;39(4):371-8. [PMID:19193866] Nutr Metab Cardiovasc Dis. 2011 Nov;21(11):845-50. [PMID:22941656] Food Cosmet Toxicol. 2012 Sep;50(9):102-14. [PMID:22290793] Infection Allergy Otolaryngol. 2012 Feb;11(1):3-14. [PMID:20315633] Nutr J. 2012 Oct;11:181. [PMID:22983794] Pediatrics. 2013 Sep;132(3):e66-78. [PMID:22527276] Pediatric Int. 2012 Oct;56(5):682-7. [PMID:20423500] Br J Nutr. 2013 Oct;110(7):1188-94. [PMID:24366721] BMJ. 2013 Dec;347:f6473. [PMID:23412488] Gastroenterol Hepatol. 2013 Jun;7(7):1141-7. [PMID:23425503] Pediatric Infect Dis J. 2012 Aug;31(8):819-8. [PMID:22924460] World J Gastroenterol. 2013 Aug 7;19(31):4718-23. [PMID:25117893] Nutr Metab Cardiovasc Dis. 2012 Jan;22(1):45-51. [PMID:25947283] Arch Dis Child. 2016 Nov;90(11):1032-9. [PMID:24595353] Eur J Clin Nutr. 2016 Apr;66(4):487-92. [PMID:25744041] Clin Med Sci. 2016 Sep;25(2):144-7. [PMID:24845610] Am J Clin Nutr. 2014 Jun;99(3):432-8. [3] 「医薬品の製造に関する基準」(第2版、一部改正について) [PMID:27159972] Genome Med. 2016 May;10(11):132. [PMID:26048833] Allergy Clin Immunol. 2015 Dec;116(4):852-61. [PMID:23303763] Br J Nutr. 2017 Mar;117(3):608-13. [PMID:18974113] Pediatrics. 2017 Aug;140(2):e201-203. [PMID:19388865] Medicina (Baltimore). 2018 Feb;97(2):e2679. [PMID:27324213] Emerg Infect Dis. 2016 Sep;22(9):1664-6. [PMID:27188552] Pediatric Gastroenterol Nutr. 2015 Nov;40(3):534-563. [PMID:30103531] Neurosci. 2018 Aug;12(10):1078. [PMID:25922096] Cochrane Database Syst Rev. 2015 Feb 3;(2):CD004605. [PMID:27915104] Medicina (Baltimore). 2016 Aug;95(4):e4509. [PMID:21517812] Medicines (Baltimore). 2015 Sep;38(7):e169161. [PMID:24818152] Ann Oncol. 2014 Oct;25(10):1999-200. [10] 医薬品の情報提供と法規 CMC出版 [PMID:26912385] Nutr Rev Gastroenterol Hepatol. 2014 Jun;11(6):505-14. [PMID:23412488] J Paediatr Child Health. 2012 Mar;52(3):211-20. [PMID:23832743] BMC Open. 2021 Mar;2(1):23:e042301. [PMID:33656611] Bioproc Res. 2021 Mar;26:41(3):85820253638. [PMID:23412488] J Paediatr Child Health. 2021 Mar;57(1):431-437. [PMID:33307941] Int J Food Sci Nutr. 2020 Dec;121:1-19. [PMID:33295643] Cochrane Database Syst Rev. 2020 Dec; 8;(12):CD013048. [PMID:31033065] Pediatric Infect Dis J. 2019 Sep;38(9):e224-e230. [PMID:24246672] Clin Nutr. 2016 Aug;35(4):881-7. [PMID:31856921] Br J Nutr. 2022 Apr;126(4):670-680. [PMID:20156320] World Microbiol. 2018 Dec;7(6):843-853. [2021114683] 日本製薬工業会 2020.3(11):2127. [PMID:30646641] Allergy. 2020 Sep;75(9):2137-2142.</p>
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- ① 명칭: 프로바이오틱스(프로바이오틱스 [英]Probiotics, Probiotic, Probiotic)
- ② 개요: 프로바이오틱스는 ‘적절한 양을 섭취했을 때 숙주에게 건강상 유익한 작용을 하는 살아있는 미생물’로 유산균, 비피더스균 등이 해당되는데, 이들 생균을 함유한 식품(발효유제품이나 식물성 발효식품 등) 포함해서 프로바이오틱스라고 불린다. (이하 생략)
- ③ 규제: ‘오직 의약품으로 사용되는 원재료’, ‘의약품적 효능효과를 나타내지 않는 한 의약품으로 판단하지 않는 원재료’ 모두 해당하지 않는다.
- ④ 성분의 특성: 적절한 양을 섭취했을 때 숙주에게 건강상 유익한 작용을 가져오는 살아있는 미생물
- ⑤ 분석: 사람에게의 영향(순환기, 호흡기 등)
- ⑥ 참고자료

## [ 식품 위험 허브 정보 - 수돗물·청량음료 내 화학물질 목록 ]

### ● 개요

<b>DB명</b>	식품 위험 허브 정보 - 수돗물·청량음료 내 화학물질 목록
<b>관리기관</b>	식품안전위원회
<b>DB 내용</b>	수도법, 식품위생법으로 기준치 등이 설정되어 있는 화학물질 목록 * 제공하는 DB 중 식품건강영향평가서, 법령근거기준에 식품안전위원회에서 제작한 내용뿐만 아니라 후생노동성, 환경성 등에서 제공하는 프로파일이 존재함. 기관에서 다루는 관점 등의 내용의 차이로 인한 고시로 보임
<b>접속 주소</b>	<a href="https://www.fsc.go.jp/foodsafetyinfo_map/foodhazinfohub/foodhazinfohub_drink.html">https://www.fsc.go.jp/foodsafetyinfo_map/foodhazinfohub/foodhazinfohub_drink.html</a>
<b>정보 제공 건수</b>	63건('24.11. 기준)

● DB 접속 방법

- 홈페이지 접속 후 ‘식품 위험정보 허브(食品ハザード情報ハブ)’ 탭 클릭



- 아래로 스크롤 후 ‘2) 수돗물·청량음료의 페이지는 이쪽(2.「水道水・清涼飲料水」のページはこちら)’ 링크 클릭




○ 수돗물과 청량음료에 대한 상세 정보 및 관련 연구 확인

【水道水・清涼飲料水において基準値等が設定されている化学物質等 (50音順で掲載)】

ハザード	ハザードの説明	食品健康影響評価書	法令に基づく基準等		関連情報
			水道水質基準 水質管理目標 【水道法】	清涼飲料水規格基準 【食品衛生法】	
1,1,1-トリクロロエタン	*	▶ 1,1,1-トリクロロエタン (清涼飲料水の規格基準の改正) ※	▶ 水質管理目標設定 項目と目標値 (環境省) ②		▶ 水道汚染に係る人の健康の保護に関する規制基準 (環境省) ② ▶ 土壤汚染基準別表 (環境省) ②
1,1-ジクロロエチレン	*	▶ 1,1-ジクロロエチレン (清涼飲料水の規格基準の改正) ※ ▶ 1,1-ジクロロエチレン (水道による供給される水の水道基準の廃止) ※	▶ 水質管理目標設定 項目と目標値 (環境省) ②		▶ 水道汚染に係る人の健康の保護に関する規制基準 (環境省) ② ▶ 土壤汚染基準別表 (環境省) ②
1,2-ジクロロエタン	*	▶ 1,2-ジクロロエタン (清涼飲料水の規格基準の改正) ※	▶ 水質管理目標設定 項目と目標値 (環境省) ②	▶ 清涼飲料水の規格基準※ 【PDF-312KB】 (厚生労働省) *	▶ 水道汚染に係る人の健康の保護に関する規制基準 (環境省) ② ▶ 土壤汚染基準別表 (環境省) ②
		▶ 1,4-ジオキサン	▶ 水道水質基準と質	▶ 清涼飲料水の規格基準※	▶ 水道汚染に係る人の健康の保護に関する規制基準 (環境省) ②

● 정보 제공 범위

- 위험설명, 식품건강영향평가서, 법령 근거 기준, 관련 정보

 예시 | 물질명: 알루미늄을 함유하는 첨가물(アルミニウムを含有する添加物)

亜硝酸態(性)窒素	-	酸性窒素(清涼飲料水の規格基準の改正)  > 亜硝酸態窒素(水道により供給される水の水道基準の設定) 	> 水道水質基準と基準値(環境省) 	> 清涼飲料水の規格基準※ [PDF:312KB] (厚生労働省) 	-
① アルミニウム及びその化合物	> リスクプロファイル  (厚生労働省) 	② <食品に係る評価書> > アルミニウム 	③ > 水道水質基準と基準値(環境省)  > 水質管理目標設定項目と目標値(環境省) 	-	④ > アルミニウムに関する情報(厚生労働省) 
アンチモン及びその化合物	-	> アンチモン(清涼飲料水の規格基準の改正) 	> 水質管理目標設定項目と目標値(環境省) 	> 清涼飲料水の規格基準※ [PDF:312KB] (厚生労働省) 	-
陰イオン界面活性剤	-	-	> 水道水質基準と基準値(環境省) 	-	-
ウラン及びその化合物	-	> ウラン(清涼飲料水の規格基準の改正) 	> 水質管理目標設定項目と目標値(環境省) 	-	-
揮発性イオン	-	-	> 水道水質基準と基準値(環境省) 	-	-

- ① 위험설명: 첨부된 리스크 프로파일 통해 상세 정보 확인 가능
- ② 식품건강영향평가서: 웹사이트 링크 통해 확인 가능
- ③ 법령 근거 기준
- ④ 관련 정보

## [식품 위험 허브 정보-영양성분 및 식품 구성성분 목록]

### ● 개요

DB명	식품 위험 허브 정보-영양성분 및 식품 구성성분 목록
관리기관	식품안전위원회
DB 내용	식품의 영양성분이나 그 외의 구성성분이 되고 있는 화학물질 등의 목록 * 제공하는 DB 중 식품건강영향평가서에 식품안전위원회에서 제작한 내용뿐만 아니라 후생노동성, 농림수산성 등에서 제공하는 프로파일이 존재함. 기관에서 다루는 관점 등의 내용의 차이로 인한 고시로 보임
접속 주소	<a href="https://www.fsc.go.jp/foodsafetyinfo_map/foodhazinfohub/foodhazinfohub_others.html">https://www.fsc.go.jp/foodsafetyinfo_map/foodhazinfohub/foodhazinfohub_others.html</a>
정보 제공 건수	5건('24.11. 기준)

### ● DB 접속 방법

- 홈페이지 접속 후 '식품 위험정보 허브(食品ハザード情報ハブ)' 탭 클릭



- 아래로 스크롤 후 '4. 「식품의 구성성분이 되는 화학 물질 등」의 페이지는 이쪽(4. 「食品の構成成分となる化学物質等」のページはこちら)' 링크 클릭

食品ハザード情報ハブには、1.微生物、2.水道水・清涼飲料水に含まれる化学物質、3.汚染物質、4.食品の構成成分となる化学物質等のページがあります。

**掲載情報**

- ▶ 1. 「微生物等」のページはこちら  
ウイルス、細菌、寄生虫、プリオン等について
- ▶ 2. 「水道水・清涼飲料水」のページはこちら  
水道法、食品衛生法で基準値等が設定されている化学物質等について
- ▶ 3. 「汚染物質」のページはこちら  
一次産品に含まれるハザード、食品の製造過程で生じるハザード、かび毒・自然毒等について
- ▶ 4. 「食品の構成成分となる化学物質等」のページはこちら  
食品の栄養成分やその他の構成成分となっている化学物質等について

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graph TD
    A[〇〇省 食品ハザード情報] --> D[食品安全委員会ウェブサイト 食品ハザード情報ハブ]
    B[〇〇庁 食品ハザード情報] --> D
    C[食品安全委員会 食品ハザード情報] --> D
  
```

- 식품의 구성성분이 되는 화학물질에 대한 상세 정보 및 관련 연구 확인

**ハザード情報**

	ハザードの説明	食品健康影響評価書	関連情報
キノコ・菌等植物	▶ リスクプロファイル(厚生労働省) ①	-	▶ 有毒植物による食中毒に注意し、まじょう(厚生労働省) ② ▶ 菌まじょうによる食中毒に注意し、まじょう(厚生労働省) ③ ▶ 食品安全：特異性植物(きのこ、たけのこ、山菜など)(農林水産省) ④ ▶ 菌まじょうによる食中毒に注意ください(食品安全委員会)
カフェイン	▶ ファクトシート [PDF:640KB] (食品安全委員会) ⑤	-	▶ 食品に含まれるカフェインの過剰摂取について「消費者庁」 ⑥ ▶ カフェインの過剰摂取について「農林水産省」 ⑦
興奮剤カリウム	▶ ファクトシート [PDF:115KB] (食品安全委員会) ⑧	-	-
大豆イソフラボン	-	▶ イソフラボン⑨	▶ 大豆及び大豆イソフラボンに関するQ&Aについて(厚生労働省) ⑩ ▶ 大豆及び大豆イソフラボンに関するQ&A(農林水産省) ⑪ ▶ 食品中の放射性物質に関する情報(食品安全委員会) ▶ 大豆イソフラボンを含む特定保健用食品の安全性評価の基本的な考え方 [PDF:101KB] (食品安全委員会) ⑫

● 정보 제공 범위

- 위험설명, 식품건강영향평가서, 관련 정보



예시 | 물질명: 카페인(カフェイン)

	ハザードの説明	食品健康影響評価書	関連情報
キノコ・高等植物	<p>&gt; <a href="#">リスクプロファイル</a> (厚生労働省) </p>	-	<p>&gt; <a href="#">有毒植物による食中毒に注意しましょう</a> (厚生労働省) </p> <p>&gt; <a href="#">毒キノコによる食中毒に注意しましょう</a> (厚生労働省) </p> <p>&gt; <a href="#">食品安全：特用林産物</a> (きのこ、たけのこ、山菜など) (農林水産省) </p> <p>&gt; <a href="#">毒キノコによる食中毒にご注意ください</a> (食品安全委員会)</p>
カフェイン	<p>① &gt; <a href="#">ファクトシート</a> [PDF:400KB] (食品安全委員会) </p>	② -	③ <p>&gt; <a href="#">食品に含まれるカフェインの濃縮剤について</a> (消費者庁) </p> <p>&gt; <a href="#">カフェインの濃縮剤について</a> (農林水産省) </p>
臭素酸カリウム	<p>&gt; <a href="#">ファクトシート</a> [PDF:115KB] (食品安全委員会) </p>	-	-
大豆イソフラボン	-	> <a href="#">イソフラボン</a>	<p>&gt; <a href="#">大豆及び大豆イソフラボンに関するQ&amp;Aについて</a> (厚生労働省) </p> <p>&gt; <a href="#">大豆及び大豆イソフラボンに関するQ&amp;A</a> (農林水産省) </p> <p>&gt; <a href="#">食品中の放射性物質に関する情報</a> (食品安全委員会)</p> <p>&gt; <a href="#">大豆イソフラボンを含む特定保健用食品の安全性評価の基本的な考え方</a> [PDF:101KB] (食品安全委員会) </p>

- ① 위험설명: PDF 상세 파일 확인 가능
- ② 식품건강영향평가서: -
- ③ 관련 정보: 소비자청, 농림수산성 고시 정보 확인 가능

## 베트남

### [건강보호식품 생산, 영업 간 사용이 금지된 물질 목록 규정]

#### ● 개요

DB명	건강보호식품 생산, 영업 간 사용이 금지된 물질 목록 규정 (No.10/2021/TT-BYT)
관리기관	보건부 식품안전국(VFA)
DB 내용	건강보호식품 생산, 영업 간 사용이 금지된 물질 목록 정보를 제공함
접속 주소	<a href="https://vfa.gov.vn/van-ban.html">https://vfa.gov.vn/van-ban.html</a>
정보 제공 건수	80건

#### ● DB 접속 방법

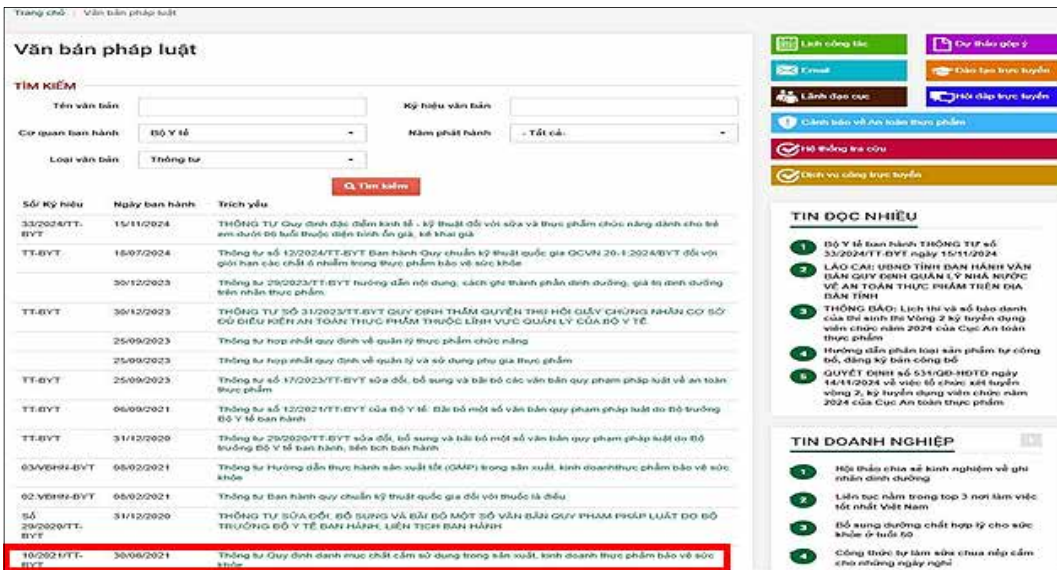
- ‘식품안전국 누리집’ 접속 후 ‘문서 서비스(Văn bản)’ 클릭

The screenshot shows the official website of the Vietnam Food Administration (VFA). The header includes the VFA logo, the text 'SỞ Y TẾ CỤC AN TOÀN THỰC PHẨM', and navigation links. The main menu contains 'Giới thiệu', 'Tin tức', 'Văn bản', 'Thủ tục hành chính', 'Truyền thông', 'Thanh, Kiểm tra', 'Ngộ độc thực phẩm', 'Hoạt động chi cục', 'Media', 'Dự án - Đầu thầu', and 'Khoa học công nghệ'. The 'Văn bản' menu item is highlighted with a red box. Below the menu, there are news items and a sidebar with various service icons like 'Lịch công tác', 'Dự thảo góp ý', 'Email', 'Đào tạo trực tuyến', 'Lãnh đạo cục', 'Hỗ trợ trực tuyến', 'Cảnh báo về An toàn thực phẩm', 'Hệ thống tra cứu', and 'Dịch vụ công trực tuyến'.

- ‘법률문서(Văn bản pháp luật)’ 화면으로 이동 후 카테고리 설정: 발행기관(cơ quan ban hành)-보건부(Bộ Y tế), 문서종류(Loại văn bản)-시행규칙(Thông tư), ‘찾기(Tìm kiếm)’ 클릭



- 시행규칙 목록 중 ‘건강보호식품 생산, 영업 간 사용이 금지된 물질 목록 규정 (No.10/2021/TT-BYT)’ 클릭 ⇒ 접속 후 PDF 파일 다운로드



● 정보 제공 범위

- 금지물질 영문 물질명, 학명 등의 정보 제공

**BỘ Y TẾ**                      **CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM**  
**Độc lập - Tự do - Hạnh phúc**

**① PHỤ LỤC**  
**DANH MỤC CÁC CHẤT**

(Ban hành kèm theo Thông tư số 10/2021/TT-BYT ngày 30 tháng 6 năm 2021)

STT	② Tên chất	③ Tên khoa học
1	1-3-dimethylamylamine	4-methylhexan-2-amine
2	Aildenafil	5-[5-[(3S,5R)-3,5-dimethylpiperazin-1-yl]sulfonyl-2-ethoxyphenyl]-1-methyl-3-propyl-6H-pyrazolo[4,3-d]pyrimidin-7-one
3	Aminotadalafil	(2R,8R)-6-amino-2-(1,3-benzodioxol-5-yl)-3,6,17-triazatetracyclo[8.7.0.03,8.011,16]heptadeca-1(10),11,13,15-tetraene-4,7-dione
4	Aromatase inhibitor	Aminoglutethimide
		Formestane
		3-(4-aminophenyl)-3-ethylpiperidine-2,6-dione
		(8R,9S,10R,13S,14S)-4-hydroxy-10,13-dimethyl-2,6,7,8,9,11,12,14,15,16-decahydro-1H-cyclopenta[a]phenanthrene-3,17-dione

+84-28-3980 3279 • www.ThuVienPhapLuat.VN

① 부록: 물질 목록

② 물질명

③ 과학명

## 1-2. 섭취근거

### ■ 미국

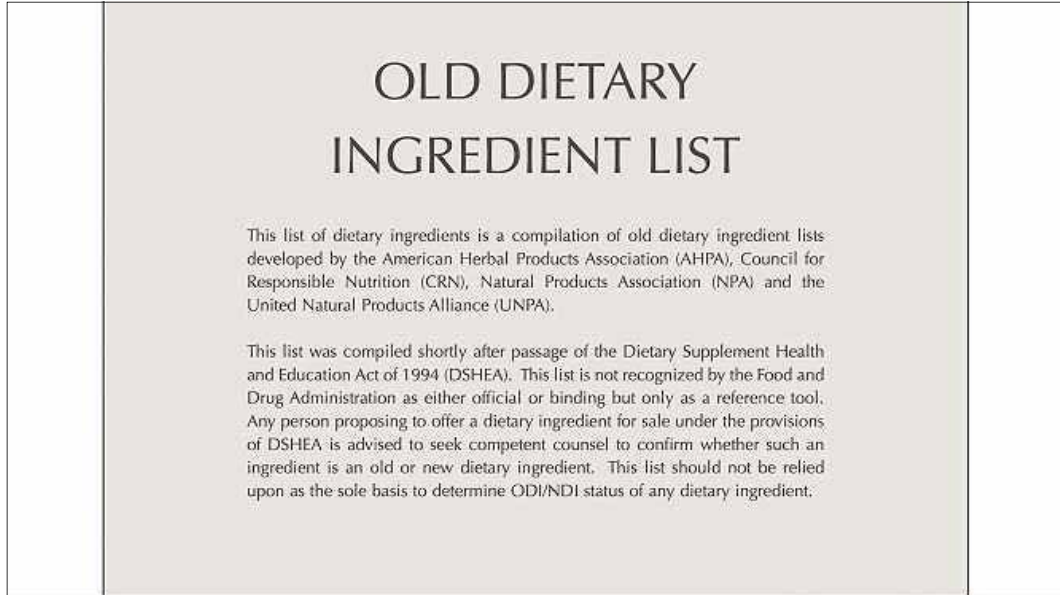
#### [ 기존 식이 성분 목록 ]

##### ● 개요

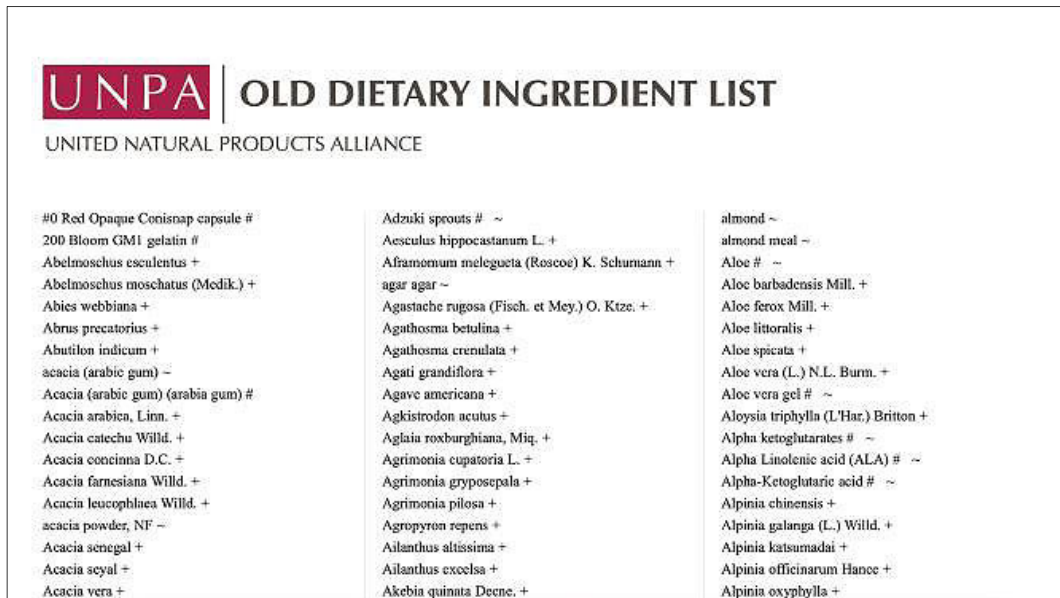
DB명	기존 식이 성분 목록(Old Dietary Ingredient List)
관리기관	United Natural Products Alliance(UNPA)
DB 내용	물질목록리스트(원료명) 1994년 Dietary Supplement Health and Education Act 제정 직후에 사설 단체인(AHPA, CRN, NPA, UNPA)가 수집한 비공식적 목록으로 FDA는 이를 공식적으로 인정하지 않음
접속 주소	<a href="https://blog.priceplow.com/wp-content/uploads/unpa-old_dietary_ingredients_list-1999.pdf">https://blog.priceplow.com/wp-content/uploads/unpa-old_dietary_ingredients_list-1999.pdf</a>
정보 제공 건수	2,995건('24.11. 기준)

● DB 접속 방법

- 기존 식이 성분 목록(Old Dietary Ingredient List)은 PDF 형식의 파일로 제공



- 알파벳 순서로 나열되어 있으며 원료 옆 기호는 각각 +-AHPA, ~-CRN, #-NPA, \* -UNPA를 의미하며 ‘찾기기능(Ctrl+F)’을 사용해 원료명 검색 가능



- 정보 제공 범위
- 원료명만 제공



예시 | 원료명: Vitamin C

UNPA | OLD DIETARY INGREDIENT LIST  
UNITED NATURAL PRODUCTS ALLIANCE

ground limestone ~	Hordeum vulgare L. +	Inula japonica Thunb. +
Guniacum officinale +	horehound extract ~	Inula racemosa Hook. +
guaiifenesin -	Horseradish # -	Inulin # -
Guar gum # ~	Horsetail rush #	iodine ~
Guarana # ~	Horsetail/Shave grass(Arvense equiset.) # ~	Iodine (kelp) #
guava powder, spray dried ~	Houttuynia cordata +	Ipomoea digitata, Linn. +
gugulipid -	Humulus lupulus L. +	Ipomoea hederaceae +
gum arabic ~	Hydnocarpus kurzii +	Ipomoea paniculata +
gum ghatti ~	Hydrangea # ~	Ipomoea paniculata R. Br. +
Gum guggul, guggulipid # -	Hydrangea arborescens L. +	Ipomoea sepiaria +
gum karaya -	Hydrastine # -	Ipomoea turpethum, Br. +
gum preblend w/ Vitamin C ~	Hydrastis canadensis L. + ~	Iris germanica L. 'Florentina' +
Gymnema sylvestre +	hydrocotyle asiatica -	Iris pallida Lam. 'Dalmatica' +
Halloysitum rubrum +	Hydrocotyle asiatica, Linn. Umbelliferae +	Iris versicolor L. +
Hamamelis virginiana L. +	hydrogenated cotton oil ~	Iris virginica L. +
Harpagophytum procumbens DC. ex Meisn. +	hydrogenated soy oil ~	Irish Moss # -
Hawthorn berries # -	hydrogenated vegetable fat ~	iron -
Heart # ~	hydrogenated vegetable oil ~	Iron (bisglycinate) #
Hedeoma pulegioides (L.) Pers. +	hydroxyapatite ~	Iron (citrate) #
	Hydroxyapatite ~	

## ■ 캐나다

### [ 천연건강제품 원료 데이터베이스 ]

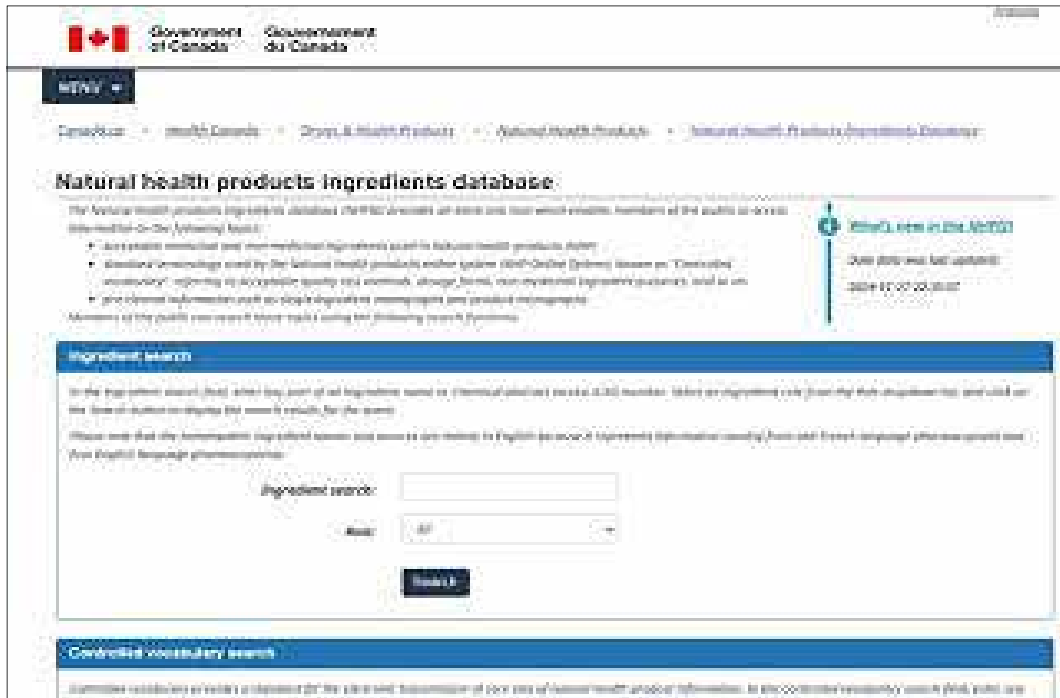
#### ● 개요

DB명	천연건강제품 원료 데이터베이스(NHPID)
관리기관	캐나다 보건부(HC)
DB 내용	천연건강제품 승인 약용 및 비약용 원료, 시스템 표준용어집, 사전승인 정보(단일 원료 모노그래프, 제품 모노그래프)
접속 주소	<a href="https://webprod.hc-sc.gc.ca/nhpid-bdipsn/">https://webprod.hc-sc.gc.ca/nhpid-bdipsn/</a>
정보 제공 건수	-

● DB 접속 방법

① 승인 약용 및 비약용 원료 검색

● 캐나다 보건부의 'Natural health products ingredients database' 접속



● 'Ingredient search'에서 검색하고자 하는 원료명 입력 후 'Search' 클릭



○ 해당 원료 클릭

Search results		
Filter items <input type="text"/>	Showing 1 to 6 of 6 entries   Show <input type="text" value="10"/> entries	
List of returned ingredients		
Ingredient <input type="text"/>	Proper name(s) <input type="text"/>	Common name(s) <input type="text"/>
<a href="#">Folium ginseng</a> (Defined Organism Substance)	<a href="#">Panax ginseng</a>	<ul style="list-style-type: none"> <li>Folium ginseng</li> <li>Ren shen ye</li> </ul>
<a href="#">Panax ginseng</a> (Organism) Pre-Cleared information: <ul style="list-style-type: none"> <li><a href="#">Ginseng, Panax</a></li> <li><a href="#">Workout Supplements</a></li> <li><a href="#">Cognitive function products</a></li> </ul>	<a href="#">Panax ginseng</a>	<ul style="list-style-type: none"> <li>Asian ginseng</li> <li>Chinese ginseng</li> <li>Hong shen</li> <li>Korean ginseng</li> <li>Korean red ginseng</li> <li>Oriental ginseng</li> <li>Panax ginseng</li> <li>Red ginseng</li> <li>Ren shen</li> </ul>
<a href="#">Panax Ginseng Root Extract</a> (Defined Organism Substance)	<a href="#">Panax ginseng</a>	<ul style="list-style-type: none"> <li>Ginseng (Panax Ginseng) Extract</li> <li>Ginseng Extract</li> <li>Oriental Ginseng Extract</li> <li>Panax Ginseng Root Extract</li> </ul>
<a href="#">Panax ginseng root infusion</a> (Defined Organism Substance)	<a href="#">Panax ginseng</a>	<a href="#">Panax ginseng root infusion</a>
<a href="#">Radix et Rhizoma Ginseng</a> (Defined Organism Substance) Pre-Cleared information: <a href="#">Traditional Chinese Medicine Ingredients</a>	<a href="#">Panax ginseng</a>	<ul style="list-style-type: none"> <li>Radix et Rhizoma Ginseng</li> <li>Ren shen</li> </ul>
<a href="#">Radix et Rhizoma Ginseng Rubra</a> (Defined Organism Substance)	<a href="#">Panax ginseng</a>	<ul style="list-style-type: none"> <li>Hong shen</li> <li>Radix et Rhizoma Ginseng Rubra</li> <li>Red Ginseng</li> </ul>

○ 해당 원료의 상세 정보 확인

Organism - Panax ginseng
<p><b>NHPID name:</b> <a href="#">Panax ginseng</a></p> <p><b>Reference:</b> <a href="#">GRIN</a></p> <p><b>Proper name(s):</b> <a href="#">Panax ginseng</a></p> <p><b>Common name(s):</b></p> <ul style="list-style-type: none"> <li><a href="#">Asian ginseng</a></li> <li><a href="#">Chinese ginseng</a></li> <li><a href="#">Hong shen</a></li> <li><a href="#">Korean ginseng</a></li> <li><a href="#">Korean red ginseng</a></li> <li><a href="#">Oriental ginseng</a></li> <li><a href="#">Panax ginseng</a></li> <li><a href="#">Red ginseng</a></li> <li><a href="#">Ren shen</a></li> <li><a href="#">No English equivalent to synonym "Ginseng de Corée"</a></li> </ul> <p><b>Category:</b> Approved Herbal Name</p> <p><b>Monographs:</b> <a href="#">Cognitive function products</a>, <a href="#">Ginseng, Panax</a>, <a href="#">Workout Supplements</a></p> <p><b>Schedule 1:</b> <a href="#">Plant and plant material</a></p> <p><b>Source material(s):</b> <a href="#">Panax ginseng</a> ( Parts: <a href="#">Whole plant</a> )</p> <p><b>Preparations:</b> <a href="#">Dry</a>, <a href="#">Fresh</a></p>
<p><b>Roles</b></p>
<p><b>Medicinal</b></p> <p><b>Rationale:</b> Classified as an NHP under Schedule 1, item 1 (a plant or a plant material) of the Natural Health Products Regulations. Please note that either this organism, or one of its parts, or the organism or part from which this ingredient is derived, is considered at risk. Details are available from the following reference(s): <a href="http://laws-lois.justice.gc.ca/eng/regulations/SOR-96-263/page-4.html#h-17">http://laws-lois.justice.gc.ca/eng/regulations/SOR-96-263/page-4.html#h-17</a>.</p> <p><b>Reference:</b> <a href="#">NNHPD</a></p>

● 정보 제공 범위

- NHPID 명칭, 참조, 정식명칭, 일반명칭, 분류, 모노그래프, 부록1, 공급원, 제제, 역할 등에 관한 정보 제공



예시 | 원료명: 인삼(Korean ginseng)

**Organism - Panax ginseng**

① NHPID name: *Panax ginseng*

② Reference: *GRIN*

③ Proper name(s): *Panax ginseng*

④ Common name(s):

- *Asian ginseng*
- *Chinese ginseng*
- *Hong shen*
- *Korean ginseng*
- *Korean red ginseng*
- *Oriental ginseng*
- *Panax ginseng*
- *Red ginseng*
- *Ren shen*
- *No English equivalent to synonym "Ginseng de Corée"*

⑤ Category: *Approved Herbal Name*

⑥ Monograph(s): *Cognitive function products, Ginseng, Panax, Workout Supplements*

⑦ Schedule 1: *Plant and plant material*

⑧ Source material(s): *Panax ginseng ( Parts: Whole plant )*

⑨ Preparations: *Dry, Fresh*

---

⑩ **Roles**

**Medicinal**

*Rationale: Classified as an NHP under Schedule 1, item 1 (a plant or a plant material) of the Natural Health Products Regulations. Please note that either this organism, or one of its parts, or the organism or part from which this ingredient is derived, is considered at risk. Details are available from the following reference(s): <http://laws-lois.justice.gc.ca/eng/regulations/SOR-96-263/page-4.html#h-17>.*

- ① NHPID 명칭: Panax ginseng
- ② 참조: GRIN
- ③ 정식명칭: Panax ginseng
- ④ 일반명칭: 아시아 인삼, 중국 인삼, 홍삼, 한국 인삼, 한국 홍삼, 동양 인삼, Panax ginseng, 홍삼, 런션, 'Ginseng deCoree'에 해당하는 영어 동의어 없음
- ⑤ 분류: 승인된 약초명
- ⑥ 모노그래프: 인지 기능 제품, Ginseng, Panax, 운동 보충제
- ⑦ 부록 1: 식물 및 식물 재료
- ⑧ 공급원료: Panax ginseng(부분: 전체 식물)
- ⑨ 제제: 건조, 신선
- ⑩ 역할: 의약적

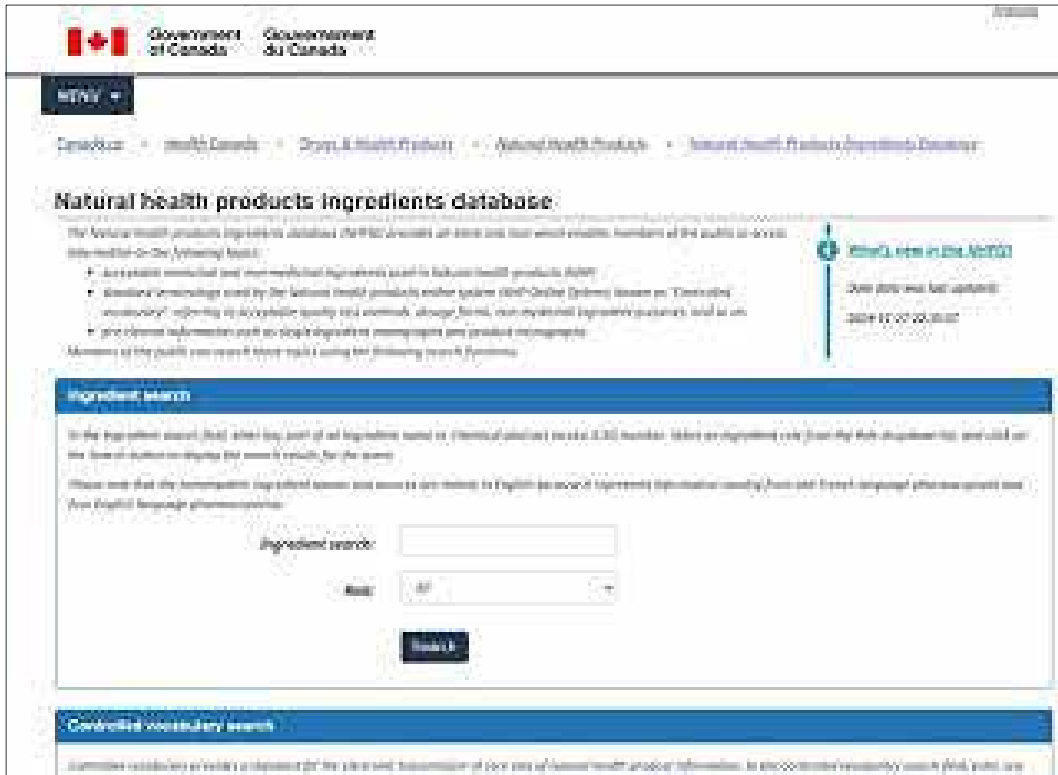
근거: 천연건강제품규정의 부록 1, 항목 1에 따라 건강제품으로 분류.

참고로 이 유기체 또는 그 일부, 혹은 해당 성분이 유래된 유기체나 그 일부는 위험이 있는 것으로 간주. 자세한 내용은 아래 링크를 참조바람:

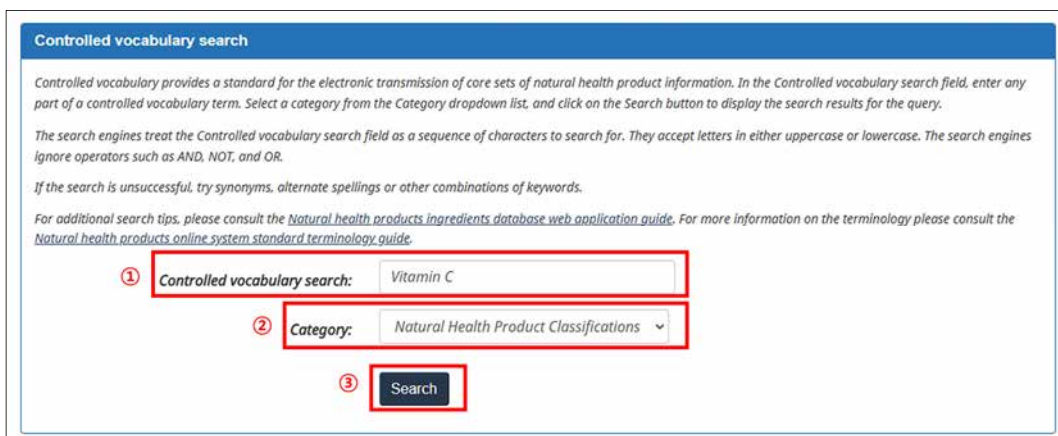
<http://laws-lois.justice.gc.ca/eng/regulations/SOR-96-263/page-4.html#h-17>

## ② 시스템 표준 용어집

### ● 캐나다 보건부의 'Natural health products ingredients database' 접속



### ● 화면 중간의 'Controlled vocabulary search'에서 검색하고자 하는 원료 입력 후 해당 분류를 선택하여 'Search' 클릭



○ 해당 원료의 상세 정보 확인

**Search results**

Filter items  Showing 1 to 1 of 1 entries | Show  entries

List of returned controlled vocabulary terms

Name	Description
Vitamin	Vitamins are naturally occurring organic substances required by the body to maintain health. The following are vitamins: 1. Biotin, 2. Folate, 3. Niacin, 4. Pantothenic acid, 5. Riboflavin, 6. Thiamine, 7. Vitamin A, 8. Vitamin B6, 9. Vitamin B12, 10. Vitamin C, 11. Vitamin D, 12. Vitamin E, 13. Vitamin K1, 14. Vitamin K2.

● 정보 제공 범위

○ 원료명 및 설명 제공

**예시 | 원료명: 비타민 C(Vitamin C)**

**Search results**

Filter items  Showing 1 to 1 of 1 entries | Show  entries

List of returned controlled vocabulary terms

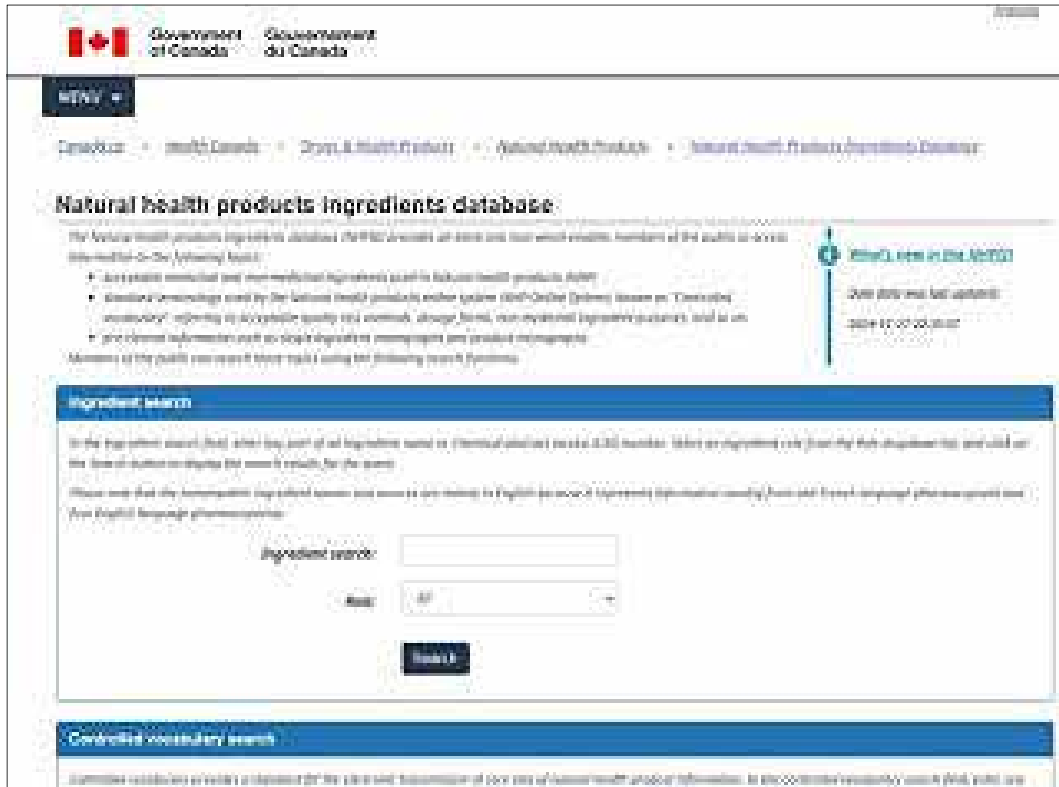
① Name	② Description
Vitamin	Vitamins are naturally occurring organic substances required by the body to maintain health. The following are vitamins: 1. Biotin, 2. Folate, 3. Niacin, 4. Pantothenic acid, 5. Riboflavin, 6. Thiamine, 7. Vitamin A, 8. Vitamin B6, 9. Vitamin B12, 10. Vitamin C, 11. Vitamin D, 12. Vitamin E, 13. Vitamin K1, 14. Vitamin K2.

① 명칭: 비타민

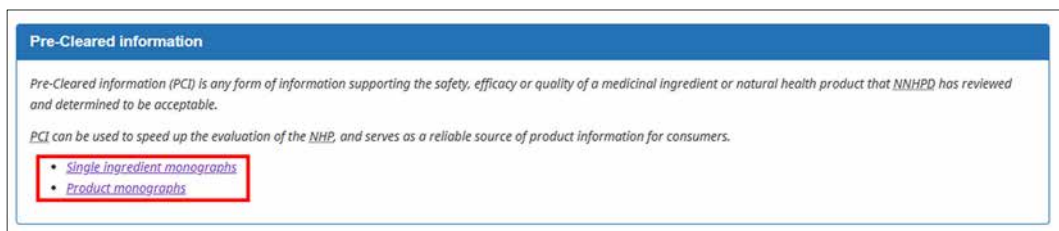
② 설명: 비타민은 건강을 유지하기 위해 신체가 필요로 하는 자연적으로 발생하는 유기물질로서 비타민의 목록은 다음과 같다: 1.비오틴, 2.엽산, 3.나이아신, 4.판토텐산, 5.리보플라빈, 6.티아민, 7.비타민 A, 8.비타민 B6, 9.비타민 B12, 10.비타민 C, 11.비타민 D, 12.비타민 E, 13.비타민 K1, 14.비타민 K2

### ③ 사전 승인 정보(단일 원료 모노그래프 또는 제품 모노그래프)

- 캐나다 보건부의 'Natural health products ingredients database' 접속



- 화면 아래의 'Pre-Cleared information'에서 단일 원료 모노그래프 및 제품 모노그래프 중 검색하고자하는 모노그래프를 클릭



- 검색하고자 하는 원료를 화면을 아래로 내리면서 검색하거나 원료의 첫 알파벳 글자를 클릭하여 검색

### Single ingredient monographs

A monograph is a written description of particular elements on an identified topic. Single ingredient monographs apply to formulations containing only one medicinal ingredient.

Monographs in the lists below which are followed by an asterisk (\*) have been uploaded directly onto the NHP Ingredients Database and are available to generate in the ePLA by pre-populating the required fields. Those monographs without an asterisk are currently referenced by the NHP Ingredients Database but do not yet have a generated monograph, which means that less information is pre-populated in the ePLA. When attesting to a monograph with an asterisk, which means attesting to a generated monograph, the 'Compendial from Generated Monographs' application type must be selected from the Compendial from Generated Monograph Electronic Product Licence Application Form. When attesting to a monograph without an asterisk, which means attesting to a monograph that is not generated, the 'Compendial' application type must be selected from the Electronic Product Licence Application Form.

[Electronic product licence application form](#)

. A B C D E F G H I J K L M N O P Q R S T U V W

T

- [T-3'-diindolylmethane \(DIM\)](#) (PDF version - 210 K)
- [5-HTP](#) (PDF version - 240 K)

Top of page ▲

A

- [Acai - Euterpe oleracea](#) (PDF version - 156 K)
- [African Wild Mango - Irvingia gabonensis](#) (PDF version - 161 K)
- [AHCC Extract - Granule](#) (PDF version - 254 K)
- [AHCC Extract - Powder](#) (PDF version - 252 K)

### Pre-Cleared information

Pre-Cleared information (PCI) is any form of information supporting the safety, efficacy or quality of a medicinal ingredient or natural health product that NNHPD has reviewed and determined to be acceptable. PCI can be used to speed up the evaluation of the NHP, and serves as a reliable source of product information for consumers.

- [Single ingredient monographs](#)
- [Product monographs](#)
- [All](#)

- 해당 원료의 상세 정보 확인

## CHITOSAN

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the [alternate format help](#) section.

(PDF Version - 50.2 KB)

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

**Notes**

- Text in parentheses is additional optional information which can be included on the label at the applicant's discretion.
- The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant on the label.

**Date**

November 29, 2024

**Proper name(s), Common name(s), Source information**


*Table 1. Proper name(s), Common name(s), Source information*

Proper name(s)	Common name(s)	Source information	
		Source material(s)	Part(s)
Poly-beta-(1,4)-2-amino-2-deoxy-d-glucose	<ul style="list-style-type: none"> <li>• Chitosan</li> <li>• Poliglusam</li> </ul>	<ul style="list-style-type: none"> <li>• Crab</li> <li>• Krill</li> <li>• Shrimp</li> </ul>	Exoskeleton
		<ul style="list-style-type: none"> <li>• Clam</li> <li>• Oyster</li> </ul>	Shell

*References: Proper name: Sweetman 2011; Common names: Sweetman 2011; Source information: Sweetman 2011; Dutta et al. 2004.*

● 정보 제공 범위

- ▲ 원료명, ▲ 일반명칭, ▲ 공급원정보, ▲ 복용방식, ▲ 복용형태, ▲ 사용목적, ▲ 복용법, ▲ 사용기간, ▲ 리스크 정보, ▲ 비의약품료, ▲ 보관방법, ▲ 사양, ▲ 제품정보에서 등에 관한 상세한 정보 제공
- PDF 다운로드 가능

 예시 | 원료명: 키토산(Chitosan)

**Proper name(s), Common name(s), Source information ①**

Table 1. Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information	
		Source material(s)	Part(s)
Poly-beta-(1,4)-2-amino-2-deoxy-d-glucose	<ul style="list-style-type: none"> <li>• Chitosan</li> <li>• Poliglusam</li> </ul>	<ul style="list-style-type: none"> <li>• Crab</li> <li>• Krill</li> <li>• Shrimp</li> </ul>	Exoskeleton
		<ul style="list-style-type: none"> <li>• Clam</li> <li>• Oyster</li> </ul>	Shell

References: Proper name: Sweetman 2011; Common names: Sweetman 2011; Source information: Sweetman 2011; Dutta et al. 2004.

**Route of administration ②**

Oral

**Dosage form(s) ③**

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

\* 일부만 발취

① 정식명칭, 일반명칭, 공급원정보

정식명칭	일반명칭	공급원 정보	
		공급원	부분
Poly-beta-(1,4)-2-amino-2-deoxy-d-glucose	키토산, 폴리글루삼	게, 크릴새우, 새우	껍질
		조개, 굴	껍데기

② 투여경로: 경구용

③ 복용형태: 이 모노그래프는 모노그래프 가이드 문서에 명시된 대로 식품 또는 식품과 유사한 복용 형태는 제외함. 경구 복용에 적합한 복용 형태는 개요(compendial) 신청용 웹 기반 제품 허가 신청서의 복용 형태 드롭다운 메뉴 목록에 명시되어 있음

## ■ 유럽연합

### [ 식품, 사료 정보 포털 데이터베이스(영양성분) ]

#### ● 개요

DB명	식품, 사료 정보 포털 데이터베이스
관리기관	유럽위원회(EC)/유럽식품안전청(EFSA)
DB 내용	유럽연합에서 사용 승인된 영양성분 정보 제공
접속 주소	<a href="https://ec.europa.eu/food/food-feed-portal/screen/nutrients/search">https://ec.europa.eu/food/food-feed-portal/screen/nutrients/search</a>
정보 제공 건수	52건('24.11. 기준) - 유럽연합 사용 승인 영양성분 목록

● DB 접속 방법

○ 유럽위원회의 ‘Food and Feed Information Portal Database’ 접속

European Commission | English | Search

## Food and Feed Information Portal Database

European Commission > Food > Food and Feed Information Portal

Search | Search all domains

### Decontamination Substances

The Commission has established a European Union data base of substances, other than potable water, authorized to remove surface contamination from products of animal origin in accordance with Article 3(2) of Regulation (EC) No 853/2004.

- Search for Decontamination Substances

### Feed Additives

The Commission has established the European Union Register of Feed Additives, which is regularly updated, and it makes reference/links to the relevant authorisation Regulations. Those Regulations include the specific requirements for placing the additives on the EU and EEA market.

- Search Feed Additives
- Search Feed Additives authorisations
- Download Register in Excel format
- Latest updates to the Register
- Archived expired authorisations (PDF)
- APIs
- Disclaimer

### Food Additives

This database is a searchable tool informing about the food additives approved for use in food in the EU and their conditions of use. It is based on the Union list of approved food additives laid down in Annex II to Regulation (EC) No 1333/2008.

- Search for Additives
- Browse by categories
- European Legislation on Food Additives
- Information documents
- APIs
- Disclaimer

### Food Allergens

This database is a searchable tool informing on substances or products causing allergies or intolerances as listed in Annex II to Regulation

### Food Contact Materials

This database is a searchable tool informing about Food Contact Materials Union Register of recycling installations, facilities, companies,

### Food Flavouring

This database is a searchable tool informing about the flavouring substances approved for use in food in the EU and their conditions of

○ 화면 하단의 ‘Nutrients’의 ‘Search for Nutrients’ 클릭

### Health Claims

The search tool only allows searches for health claims, and not nutrition claims.

- EU Register of Health Claims
- Some health claims subject to the individual authorisation procedure
- Download Register in Excel format
- APIs

### Infant Formulae & Follow-on Formulae manufactured from protein hydrolysates

The search tool allows for searches for both infant formulae and follow-on formulae.

- Search for Infant Formulae and Follow-on Formulae

### Novel Food

The Implementing Regulation establishing the list of novel foods compiles all the authorised novel foods in the European Union to date. It includes their conditions of use, labelling requirements, and their specifications.

- Union List of authorised novel foods
- Novel Food status Catalogue
- Latest updates to the Novel Food status Catalogue
- APIs

### Nutrients

This database is a searchable tool informing about the nutritional substances such as vitamins, minerals and others that are approved for use in the EU.

- Search for Nutrients**
- Disclaimer

### Smoke flavourings

This database is a searchable tool informing about the smoke flavouring products approved for use in the EU and their conditions of use. It is based on the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavouring laid down in Annex to Regulation (EC) No 1321/2013.

- Search for Smoke flavourings
- Browse by categories
- European Legislation on Smoke flavourings
- Disclaimer

- Recycling Facilities
- Recycling Installations
- Disclaimer

- Browse by categories
- European Legislation on Food flavourings
- Disclaimer

- 검색란에 검색하고자 하는 원료명 입력 후 검색(Search) 클릭

Food and Feed Information Portal Database

European Commission > Food > Food and Feed Information Portal > Nutrients > Search Nutrients

SEARCH OPTIONS

Nutrients (52 matching records)

Nutrients type: All

Nutrients name: All

Nutrients subtype: All

Search

Clear filters

vitamin c

Nutrient type	Nutrient name	Nutrient subtypes
Other	Aloe-Emodin	-/-
Other	Amino Acids	L-alanine L-arginine L-aspartic acid L-citrulline L-cysteine Cystine L-histidine L-glutamic acid L-glutamine glycine L-isoleucine L-leucine L-lysine L-lysine acetate L-methionine L-ornithine L-phenylalanine L-proline L-threonine L-tryptophan

- 해당 원료 클릭

Food and Feed Information Portal Database

European Commission > Food > Food and Feed Information Portal > Nutrients > Search Nutrients

SEARCH OPTIONS

Nutrients (1 matching records)

Nutrients type: All

Nutrients name: All

Nutrients subtype: All

Search

Clear filters

vitamin c

Nutrient type	Nutrient name	Nutrient subtypes
Vitamin	Vitamin C	L-ascorbic acid sodium-L-ascorbate calcium-L-ascorbate potassium-L-ascorbate L-ascorbyl 6-palmitate magnesium L-ascorbate zinc L-ascorbate

○ 해당 원료의 상세 정보 확인

## Characteristics

<b>Nutrient type</b>	Vitamin
<b>Nutrient name</b>	Vitamin C
<b>Nutrient subtype</b>	L-ascorbic acid sodium-L-ascorbate calcium-L-ascorbate potassium-L-ascorbate L-ascorbyl 6-palmitate magnesium L-ascorbate zinc L-ascorbate
<b>Specific usage disposition</b>	-/-
<b>Remark</b>	-/-

## Legislations

REGULATION (EC) No 1925/2006, applicable from 01/07/2007

REGULATION (EU) No 609/2013, applicable from 19/07/2013

DIRECTIVE 2002/46/EC

● 정보 제공 범위

- 해당 원료의 영양성분 유형, 명칭, 세부유형, 사용 요건 등 영양성분의 특성 및 관련 규정 정보 제공



예시 | 원료명: 비타민 C

Characteristics	
① Nutrient type	Vitamin
② Nutrient name	Vitamin C
③ Nutrient subtype	L-ascorbic acid sodium-L-ascorbate calcium-L-ascorbate potassium-L-ascorbate L-ascorbyl 6-palmitate magnesium L-ascorbate zinc L-ascorbate
④ Specific usage disposition	-/-
⑤ Remark	-/-
⑥ Legislations	
REGULATION (EC) No 1925/2006, applicable from 01/07/2007	
REGULATION (EU) No 609/2013, applicable from 19/07/2013	
DIRECTIVE 2002/46/EC	

- ① 영양성분 유형: 비타민
- ② 영양성분 명칭: 비타민 C
- ③ 영양성분 세부유형: L-아스코르브산, 소듐-L-아스코르브산, 칼슘-L-아스코르브산, 포타슘-L-아스코르브산, L-아스코르빌 6-팔미테이트, 마그네슘-L-아스코르브산, 아연-L-아스코르브산
- ④ 특정 사용 요건: 해당사항 없음
- ⑤ 비교: 해당사항 없음
- ⑥ 관련 규정: 2007년 7월 1일부터 적용 Regulation (EC) No 1925/2006  
2013년 7월 19일부터 적용 Regulation (EC) No 609/2013  
Directive 2002/46/EC

## 호주

### [ 의약품(허용 성분) 결정 ]

#### ● 개요

<b>DB명</b>	의약품(허용 성분) 결정[Therapeutic Goods(Permissible Ingredients) Determination (No.3)2024]* * 의약품(허용 성분 결정), <a href="https://www.legislation.gov.au/F2024L01196/asmade/text">https://www.legislation.gov.au/F2024L01196/asmade/text</a>
<b>관리기관</b>	연방의료제품청(TGA)
<b>DB내용</b>	등재의약품에 사용할 수 있는 원료 및 관련 요건 제공
<b>접속 주소</b>	<a href="https://www.legislation.gov.au/F2024L01196/asmade/text">https://www.legislation.gov.au/F2024L01196/asmade/text</a>
<b>정보 제공 건수</b>	5,273건('24.11. 기준)

#### ● DB 접속 방법

##### ○ Federal Register of Legislation 접속

The screenshot shows the Australian Government Federal Register of Legislation website. At the top, there are links for 'Help and resources', 'Register for My Account', and 'Sign in to My Account'. The main header includes the Australian Government logo and the title 'Federal Register of Legislation'. Below the header, there is a navigation menu with categories: Constitution, Acts, Legislative instruments, Notifiable instruments, Gazettes, Administrative Arrangements, Prerogative instruments, and Norfolk Island. The main content area is titled 'Explore the Federal Register of Legislation' and features a search interface. The search interface has tabs for 'Search' and 'Browse'. There are three buttons for filtering results: 'All' (selected), 'In force', and 'No longer in force'. Below these, there are input fields for 'Search for' (with an example 'example: Legislation Act 2003'), 'Search in' (with a dropdown menu set to 'Name and text'), and 'Search using' (with a dropdown menu set to 'Contains phrase'). There are also checkboxes for 'Filter by collection' with options for 'Act', 'Gazette', 'Legislative instrument', and 'Notifiable instrument'. At the bottom of the search interface, there are 'Search' and 'Advanced search' buttons.

- ‘검색란(Search for)’에 ‘Therapeutic Goods (Permissible Ingredients) Determination (No.3) 2024’ 입력 후 ‘Search’ 클릭

Australian Government Federal Register of Legislation

Explore the Federal Register of Legislation

Search for:

Search in: Name and text

Search using: Contains phrase

Filter by collection:  Act  Gazette  Legislative instrument  Notifiable instrument

**Search** Advanced search

- 화면 아래쪽으로 이동하여 해당 문서 클릭

Constitution Acts Legislative instruments Notifiable instruments Gazettes Administrative Arrangements Prerogative instruments Norfolk Island

Type: All Status: All  
Collection: All Date: Effective Latest  
Portfolios: All

Search for: Therapeutic Goods (Permissible Ingredients) Determination (No.3) 2024

Search in: Name and text

Search using: Contains phrase

Filters:

Name	Effective date	Collection	Details
Therapeutic Goods (Permissible Ingredients) Determination (No.3) 2024 F2024L01196 Registered: 23/09/2024	23/09/2024		<a href="#">Details</a>

1 total

Page size: 100

- ‘돋보기’ 아이콘 클릭 후 검색하고자 하는 원료의 영문 명칭 입력 후 클릭

The screenshot shows a web interface for a legislative instrument. At the top, there is a search bar with a magnifying glass icon (labeled 1) and a search input field containing 'korean ginseng'. A red box highlights the search bar area, and a circled '2' is placed above it. Below the search bar, a table titled 'Schedule 1—Specified ingredients when' is visible. The table has four columns: 'Item', 'Ingredient Name', 'Purpose', and 'Specific requirements'. The table lists three ingredients: KADSURA COCCINEA, KAEMPFERIA GALANGA, and KALMIA LATIFOLIA. The 'Specific requirements' column for KALMIA LATIFOLIA contains detailed text about beta-arbutin and hydroquinone concentrations.


- 해당 원료의 요건 확인

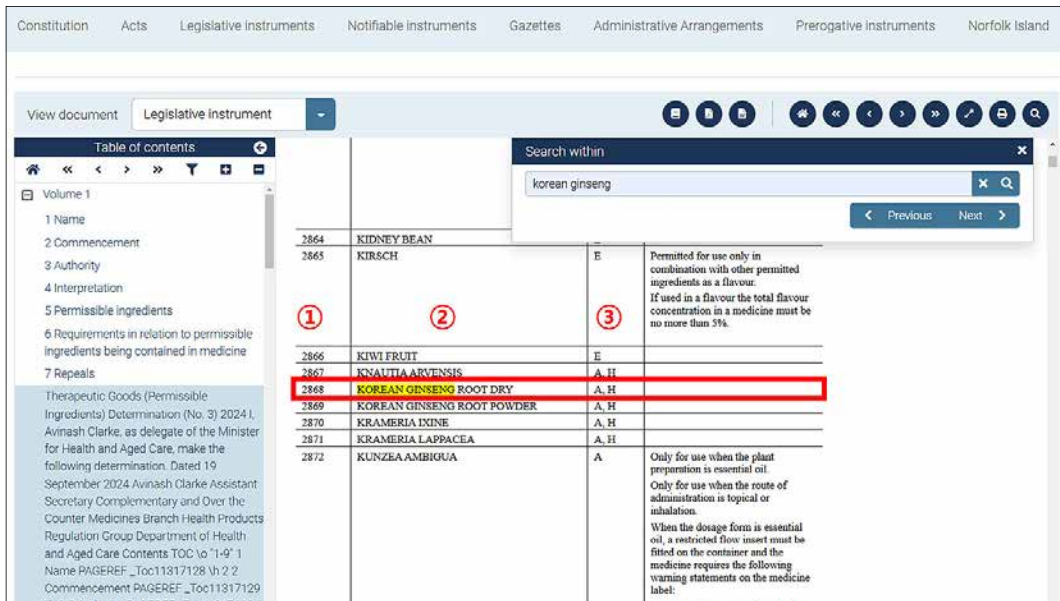
The screenshot shows the same web interface as above, but with the search results table expanded. The search bar still contains 'korean ginseng'. The table lists several ingredients, with 'KOREAN GINSENG ROOT DRY' highlighted in red. The 'Specific requirements' column for this ingredient contains detailed text about its use in combination with other permitted ingredients and its concentration in a medicine.

Item	Ingredient Name	Purpose	Specific requirements
2864	KIDNEY BEAN		
2865	KIRSCH	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2866	KIWI FRUIT	E	
2867	KNAUTIA ARVENSIS	A, H	
2868	KOREAN GINSENG ROOT DRY	A, H	
2869	KOREAN GINSENG ROOT POWDER	A, H	
2870	KRAMERIA IXINE	A, H	
2871	KRAMERIA LAPPAEA	A, H	
2872	KUNZEA AMBIGUA	A	Only for use when the plant preparation is essential oil. Only for use when the route of administration is topical or inhalation. When the dosage form is essential oil, a restricted flow insert must be fitted on the container and the medicine requires the following warning statements on the medicine label.

● 정보 제공 범위

- 품목(번호), 원료명, 용도, 요건 등의 정보 제공하고 있으며 PDF, Word 형식으로 다운로드 가능
- TGA eBusiness Services는 광범위한 원료 데이터베이스를 기반으로 상세한 정보를 제공하고 있는 것에 반해, 본 목록에서는 등재의약품에 한하여 원료 정보를 비교적 간단히 제공하고 있음

 예시 | 원료명: 인삼(Korean Ginseng)



Product Number	Ingredient Name	Purpose	Notes
2864	KIDNEY BEAN	E	Permitted for use only in combination with other permitted ingredients as a flavour. If used in a flavour the total flavour concentration in a medicine must be no more than 5%.
2865	KIRSCH	E	
2866	KIWI FRUIT	E	Only for use when the plant preparation is essential oil. Only for use when the route of administration is topical or inhalation. When the dosage form is essential oil, a restricted flow insert must be fitted on the container and the medicine requires the following warning statements on the medicine label:
2867	KNAUTIA ARVENSIS	A, H	
2868	KOREAN GINSENG ROOT DRY	A, H	
2869	KOREAN GINSENG ROOT POWDER	A, H	
2870	KRAMERIA IXINE	A, H	
2871	KRAMERIA LAPPACEA	A, H	
2872	KUNZEA AMBIGUA	A	

- ① 품목: 2868
- ② 원료명: Korean ginseng root dry
- ③ 용도(purpose): A, H

\* A(active ingredient): 활성원료  
 E(excipient): 부형제(맛, 향, 또는 색상을 제공하는 성분 포함)  
 H(homeopathic preparation ingredient): 동종요법 제제 원료

## [ 호주식품성분데이터베이스 ]

### ● 개요

DB명	호주식품성분데이터베이스
관리기관	호주뉴질랜드 식품기준청(FSANZ)
DB내용	식품 성분 관련 데이터베이스 제공
접속 주소	<a href="https://www.foodstandards.gov.au/science-data/monitoring-nutrients/afcd">https://www.foodstandards.gov.au/science-data/monitoring-nutrients/afcd</a>
정보 제공 건수	1,616건의 식품 및 256건의 영양성분 정보('24.11. 기준)

### ● DB 접속 방법

- 호주뉴질랜드 식품기준청의 'Australian Food Composition Database' 접속

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Home > Science and data > Australian Food Composition Database


## Australian Food Composition Database

The Australian Food Composition Database (AFCD) gives information on the nutrients in a wide range of foods available in Australia, from seafood to cereals.

- 화면 하단의 ‘Searchable database’ 클릭

## Australian Food Composition Database


The Australian Food Composition Database (AFCD) gives information on the nutrients in a wide range of foods available in Australia, from seafood to cereals.



### Searchable database


Welcome to the Australian Food Composition Database (AFCD, previously known as NUTTAB). Search the AFCD for information about a food or nutrient.

The AFCD contains nutrient data for 1,616 foods available in Australia and up to 256 nutrients per food.



### Downloadable files

Download files to load into databases, or to view in Microsoft Excel.



- 품목(Food), 알파벳 순(Alphabetical list), 식품군(Food group), 영양성분 (Nutrient) 중 검색 방법 선택

### Australian Food Composition Database - Release 2.0

Search by:

Food
Alphabetical list
Food group
Nutrient

Filter:

Show  foods

Public Food Key	Food Name
Alcoholic beverages: Beers	
F000994	Beer, full strength (alcohol 4-4.9% v/v)
F000995	Beer, full strength (alcohol 4-4.9% v/v), carbohydrate modified Tag: Low carb beer
F000996	Beer, high alcohol (5% v/v & above)
F001004	Beer, light (alcohol 1-2.9% v/v) Tag: Light beer
F001006	Beer, mid-strength (alcohol 3-3.9% v/v)
Alcoholic beverages: Cider and perry	
F002955	Cider, apple (alcohol approximately 4-5% v/v)
Alcoholic beverages: Spirits	
F000050	Alcoholic beverage, spirit, approximately 30% v/v, all (Brandy, Gin, Rum, Vodka and Whisky), cooked
F000051	Alcoholic beverage, spirit, approximately 40% v/v, all (Brandy, Gin, Rum, Vodka and Whisky)
Alcoholic beverages: Wines	
F009566	Wine, fortified, port
F009567	Wine, fortified, sherry, dry style (approximately 1% sugars)

- 예: 영양성분(Nutrient) 클릭 후 Filter란에 검색하고자 하는 영양성분 입력

Australian Food Composition Database - Release 2.0

Search by:

Food    Alphabetical list    Food group    **Nutrient**

Filter:     Show 50 nutrients

Nutrient	Definition
<b>Proximates</b>	
Proximates are nutrients that contribute energy to a food or beverage.	
<b>Energy, without dietary fibre</b>	Energy content has been calculated by adding the contribution to energy from each of protein, available carbohydrate, fat, alcohol, sugar alcohols and organic acids, according to the following equation: $\text{Energy (kJ)} = \text{protein (g)} \times 17 + \text{sugars (g)} \times 16 + \text{other available carbohydrate (starch + dextrin + maltodextrin + raffinose + stachyose + other undifferentiated oligosaccharides + glycogen) (g)} \times 17 + \text{fat (g)} \times 37 + \text{alcohol (g)} \times 29 + \text{sorbitol/mannitol/glycerol (g)} \times 15 + \text{citric/malic/quinic acids (g)} \times 10 + \text{lactic/acetic acids (g)} \times 15$ .  Note that the energy factors used in this equation are not consistent with those specified for the calculation of energy in Standard 1.2.8 – Nutrition Information Requirements of the Australia New Zealand Food Standards Code. Energy is expressed in kilojoules (kJ) where one kilocalorie is equal to approximately 4.2 kilojoules.
<b>Energy, including dietary fibre</b>	Energy content has been calculated by adding the contribution to energy from each of protein, available carbohydrate, fat, dietary fibre, alcohol, sugar alcohols and organic acids, according to the following equation: $\text{Energy (kJ)} = \text{protein (g)} \times 17 + \text{sugars (g)} \times 16 + \text{other available carbohydrate (starch + dextrin + maltodextrin + raffinose + stachyose + other undifferentiated oligosaccharides + glycogen) (g)} \times 17 + \text{fat (g)} \times 37 + \text{dietary fibre (g)} \times 8 + \text{alcohol (g)} \times 29 + \text{sorbitol/mannitol/glycerol (g)} \times 15 + \text{citric/malic/quinic acids (g)} \times 10 + \text{lactic/acetic acids (g)} \times 15$ .  Note that the energy factors used in this equation are not consistent with those specified for the calculation of energy in Standard 1.2.8 – Nutrition Information Requirements of the Australia New Zealand Food Standards Code. Energy is expressed in kilojoules (kJ) where one kilocalorie is equal to approximately 4.2 kilojoules.
<b>Moisture</b>	Moisture content has been determined by drying foods to achieve constant weight.
<b>Protein</b>	Protein content has been calculated by multiplying the measured nitrogen content of a food by the nitrogen-to-protein conversion factor, which differs depending on the food.
<b>Nitrogen</b>	The nitrogen content of a food is used to calculate the protein content of that same food, using established nitrogen-to-protein conversion factors (Greenfield & Southgate, 2003 and USDA, 2010). Nitrogen has generally been determined by the Kjeldhal nitrogen technique.

- 상세 정보 확인

Australian Food Composition Database - Release 2.0

Search by:

Food    Alphabetical list    Food group    **Nutrient**

Filter:     Show 50 nutrients

Nutrient	Definition
<b>Vitamins</b>	
Vitamins are organic compounds that are needed in the diet in small amounts.	
<b>Vitamin C</b>	Also called ascorbic acid. In this database, vitamin C refers to the two related compounds that have vitamin C activity: ascorbic acid and dehydroascorbic acid. In analyses from approximately 1990 onwards, vitamin C has been determined using HPLC, whereas in studies from the 1980s, a microfluorimetric method may have been used. Both types of techniques measure both L-Ascorbic acid and dehydroascorbic acid, both of which have vitamin C activity.

Showing 1 to 1 of 1 nutrients (filtered from 253 total nutrients)

Previous 1 Next

● 정보 제공 범위

- 품목, 식품군, 영양성분 등으로 구분하여 데이터베이스를 제공
- 1,616건의 식품과 253가지 영양성분 정보를 제공하고 있음

**예시 | 비타민 C**



① 영양성분: 비타민 C

② 정의: 비타민은 소량으로 식단에 필요한 유기 화합물이다.

비타민 C는 아스코르빈산(Ascorbic acid)이라고도 하며 이 데이터베이스에서 비타민 C는 비타민 C 활성을 가진 두 가지 관련 화합물인 아스코르빈산과 디하이드로아스코르빈산을 의미한다. 약 1990년부터의 분석에서는 HPLC(고성능 액체 크로마토그래피) 방법이 사용되었으며, 1980년대 연구에서는 미세형광 측정법이 사용되었을 수 있다. 두 가지 분석 기법 모두 비타민 C 활성을 가진 L-아스코르빈산과 디하이드로아스코르빈산을 측정한다.

## 중국

### [ 식품원료 검색데이터베이스 ]

#### ● 개요

DB명	식품원료 검색데이터베이스(食品原料查詢数据库)
관리기관	식품화반넷
DB 내용	보건식품 원료 목록, 보건식품 사용금지 물질 목록, 보건식품 보조원료 목록, 보건식품 영양소보충제 원료 목록, 일반식품 원료 목록, 신식품 원료 목록
접속 주소	<a href="http://dbxinshipin.foodmate.net/">http://dbxinshipin.foodmate.net/</a>
정보 제공 건수	878건('24.11. 기준)
기타	동 DB는 신규 승인 물질 추가에 따라 목록을 동태적으로 조정하고, 중문명과 라틴어 학명 검색 기능을 제공하나 라틴어 학명을 전수 제공하고 있지 않으므로 검색 시 중문명 사용을 권장함

● 식품원료 DB 접속 방법

- ‘식품원료 검색플랫폼(<http://dbxinshipin.foodmate.net/>)’ 접속

분류	중문명	라틴명	용도의食品名	批准日期	公告号	备注说明
新食品原料	红芯黄果		乳及乳制品(调制乳和风味发酵乳、乳粉及其制品)、饮料类、果冻	2024-10-10	2024年第3号	查看详情
新食品原料	拟水芹属油			2024-10-10	2024年第3号	查看详情
普通食品原料	蛋肉脂肪(在更名为蛋壳膜)					查看详情
普通食品原料	蛋壳膜粉(在更名为蛋壳膜膜蛋白)					查看详情
普通食品原料	玉米发酵粉					查看详情
普通食品原料	柠檬皮			2023-07-19		查看详情
药食同源	地黄(植物名:地黄)	Rehmannia glutinosa Libosch.		2024-06-26	2024年第4号	查看详情
药食同源	灵芝(植物名:灵芝)	Cytriosporon japonicus (L.) Kze-Gaut.		2024-06-26	2024年第4号	查看详情
药食同源	天冬(植物名:天冬)	Asparagus cochinchinensis (Lour.) Merr.		2024-06-26	2024年第4号	查看详情
药食同源	化橘红(植物名:化州橘)	Citrus grandis 'Tomentosa'		2024-06-26	2024年第4号	查看详情
药食同源	化橘红(植物名:柚)	Citrus grandis (L.) Osbeck		2024-06-26	2024年第4号	查看详情
普通食品原料	高果糖甜菊糖					查看详情
普通食品原料	罗汉果					查看详情
普通食品原料	红草果					查看详情
新食品原料	N-乙酰肌醇葡萄糖		乳及乳制品、饮料类、果冻、糖果、糕点	2024-06-05	2024年第3号	查看详情

- ‘①食品중문명(食品中文名)’에 물질 명칭[예: 영지(灵芝)] 입력 ②검색(搜索) 버튼 클릭

분류	중문명	라틴명	용도의食品名	批准日期	公告号	备注说明
新食品原料	红芯黄果		乳及乳制品(调制乳和风味发酵乳、乳粉及其制品)、饮料类、果冻	2024-10-10	2024年第3号	查看详情
新食品原料	拟水芹属油			2024-10-10	2024年第3号	查看详情
普通食品原料	蛋肉脂肪(在更名为蛋壳膜)					查看详情
普通食品原料	蛋壳膜粉(在更名为蛋壳膜膜蛋白)					查看详情
普通食品原料	玉米发酵粉					查看详情
普通食品原料	柠檬皮			2023-07-19		查看详情
药食同源	地黄(植物名:地黄)	Rehmannia glutinosa Libosch.		2024-06-26	2024年第4号	查看详情
药食同源	灵芝(植物名:灵芝)	Cytriosporon japonicus (L.) Kze-Gaut.		2024-06-26	2024年第4号	查看详情
药食同源	天冬(植物名:天冬)	Asparagus cochinchinensis (Lour.) Merr.		2024-06-26	2024年第4号	查看详情
药食同源	化橘红(植物名:化州橘)	Citrus grandis 'Tomentosa'		2024-06-26	2024年第4号	查看详情
药食同源	化橘红(植物名:柚)	Citrus grandis (L.) Osbeck		2024-06-26	2024年第4号	查看详情
普通食品原料	高果糖甜菊糖					查看详情
普通食品原料	罗汉果					查看详情
普通食品原料	红草果					查看详情
新食品原料	N-乙酰肌醇葡萄糖		乳及乳制品、饮料类、果冻、糖果、糕点	2024-06-05	2024年第3号	查看详情

○ 검색 결과에서 ③상세보기 클릭

分类	中文名称	拉丁名称	适用的食品类别	批准日期	公告号	查看详情
保健食品原料	灵芝		保健食品	2024-05-01	2023年第57号	③ 查看详情
保健食品原料	破壁灵芝孢子粉		保健食品	2021-03-01	特食司2020年54号公告	查看详情
药食同源	灵芝 (植物名: 灵芝)	Ganoderma sinense Zhao, Xu et Zhang		2023-11-17	2023年 第9号	查看详情
药食同源	灵芝 (植物名: 赤芝)	Ganoderma lucidum (Leys s. ex Fr.) Karst.		2023-11-17	2023年 第9号	查看详情
保健食品原料	灵芝	Ganoderma lucidum	可用于保健食品	2006-07-01	国家药监局[2005]2-05号	查看详情
保健食品原料	松杉灵芝	Ganoderma tsugae	可用于保健食品	2005-07-01	国家药监局[2005]2-02号	查看详情
保健食品原料	破壁灵芝孢子粉			2014-05-09	国卫办食品函[2014]390号	查看详情

○ 상세보기 제공 내용

分类名称	保健食品原料
中文名称	灵芝
数据来源	<a href="https://www.samr.gov.cn/zw/zfxgk/fdzdgnr/tssps/art/2023/art_3d6d45a948bb41aaa65ee9a453atc622.html">https://www.samr.gov.cn/zw/zfxgk/fdzdgnr/tssps/art/2023/art_3d6d45a948bb41aaa65ee9a453atc622.html</a>
基本信息	功效：有助于增强免疫力。
食用量	4-6 g
适用的食品类别	保健食品
不适宜人群	少年儿童、孕妇、乳母
其他需要说明的情况	适宜人群：免疫力低下者。灵芝：原料应符合现行版《中国药典》相同品种项下相关规定，对于有食品安全国家标准要求的原料，安全指标（包括农药残留及重金属等）还应符合现行标准规定。
批准日期	2024-05-01
公告号	2023年第57号

● 정보 제공 범위

- 원료별 상세 정보에서 해당 원료의 분류명칭, 중문 및 라틴어 명칭, 자료출처 등의 정보 제공



예시 | 원료명: 영지

分类名称	保健食品原料
中文名称	灵芝
数据来源	<a href="https://www.samr.gov.cn/zw/zfxxgk/fdzdgknr/tssps/art/2023/art_3d6d45a948bb41aaa65ee9a453a1c622.html">https://www.samr.gov.cn/zw/zfxxgk/fdzdgknr/tssps/art/2023/art_3d6d45a948bb41aaa65ee9a453a1c622.html</a>
基本信息	功效：有助于增强免疫力。
食用量	4-6 g
适用的食品类别	保健食品
不适宜人群	少年儿童、孕妇、乳母
其他需要说明的情况	适宜人群：免疫力低下者。灵芝：原料应符合现行版《中国药典》相同品种项下相关规定，对于有食品安全国家标准要求的原料，安全指标（包括农药残留及重金属等）还应符合现行标准规定。
批准日期	2024-05-01
公告号	2023年第57号

- ① 분류명칭: 보건식품 원료
- ② 중문명칭: 영지
- ③ 자료출처: [https://www.samr.gov.cn/zw/zfxxgk/fdzdgknr/tssps/art/2023/art\\_3d6d45a948bb41aaa65ee9a453a1c622.html](https://www.samr.gov.cn/zw/zfxxgk/fdzdgknr/tssps/art/2023/art_3d6d45a948bb41aaa65ee9a453a1c622.html)
- ④ 기본정보: 효능\_면역력 증가에 도움
- ⑤ 섭취량: 4-6 g
- ⑥ 적용 식품유형: 보건식품
- ⑦ 부적합 섭취군: 아동, 임산부, 수유부
- ⑧ 기타 설명이 필요한 사항  
적합 섭취군: 면역력 저하자  
영지: 원료는 현행 버전(중국약전) 동일 품목의 관련 규정을 준수해야 하고, 식품안전 국가표준 요구가 있는 원료의 경우 안전지표(잔류농약 및 중금속 등 포함) 또한 현행 표준 규정을 준수해야 함
- ⑨ 승인일자: 2024-05-01
- ⑩ 공고번호: 2023년 제57호

## [ 중국약전 ]

### ● 개요

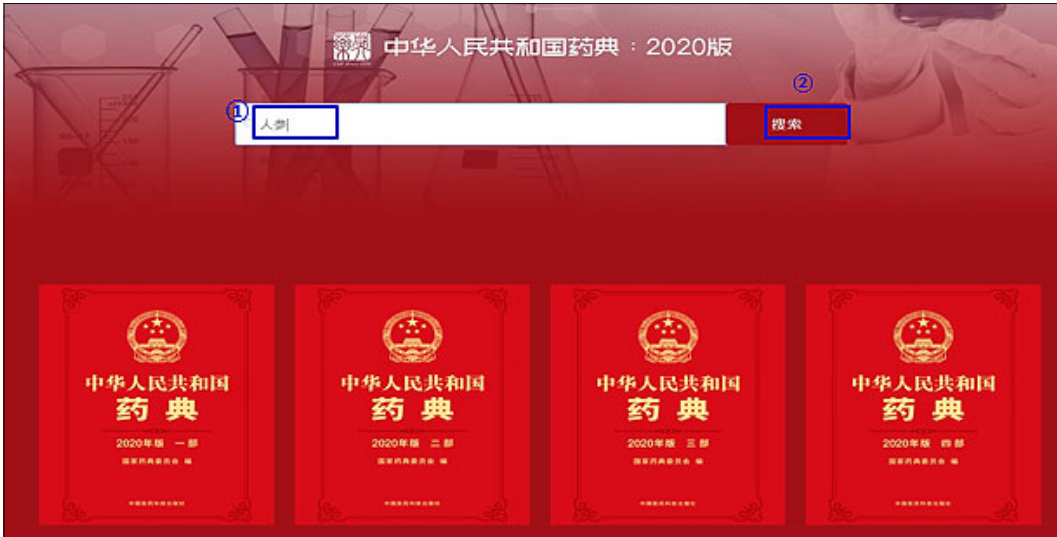
DB명	중화인민공화국약전: 2020판(中华人民共和国药典: 2020版)
관리기관	국가약전위원회
DB 내용	제11차 약전위원회 위원 명단, 약전 연혁, 약전 개정판의 신규 품목 목록, 약재 및 음편[饮片/한약(달인 약)], 식물유지와 추출물, 중국어 병음 색인, 학명 등
접속 주소	<a href="https://ydz.chp.org.cn/#/main">https://ydz.chp.org.cn/#/main</a>

### ● 중국약전 DB 접속 방법

- ‘중국어약전(2020판) 검색플랫폼(<https://ydz.chp.org.cn/#/main>)’ 접속



- ① 검색어[예: 인삼(人參)] 입력 후 ② 검색(搜索) 버튼 클릭



- ② 검색 결과에서 '인삼' 클릭



## 상세 내용

 **中华人民共和国药典：2020版**

Q / 数据库 / 词条详情

**中华人民共和国药典：2020年版，一部**  
在线阅读

目录

- 前言
- 第十一版药典委员会委员名单
- 委员会组成与编写工作人员
- 中国药典沿革
- 本版药典《一部》新增品种名单
- 本版药典《一部》未收载2015年版品种
- 凡例
- 品名目录
- 药材和饮片
- 植物油脂和提取物
- 成方制剂和单味制剂
- 索引
  - 中文索引
  - 汉语拼音索引
  - 拉丁名索引
  - 拉丁学名索引

### 人参

◎ 最后更新时间: 2023-10-07 15:58:45    77706

本品为五加科植物人参 *Panax ginseng* C.A.Mey. 的干燥根和茎基。多于秋季采挖，洗净后晒干或烘干。栽培的俗称“园参”；野生在山林野生状态下自然生长的称“林下山参”；习称“野山参”。

**【性状】**

类圆锥形或圆柱形，长3~15cm，直径1~2cm。表面灰黄色，上部或全体有疏状排列的细横纹及明显的纵纹，下部有支根2~3条，并常有多数须根的痕痕，须根上部有不明显的须根痕。根茎（芦头）长1~4cm，直径0.3~1.5cm，多作歪扭弯曲，具不定根（芦根）和稀疏的凹状纵纹（芦痕），质较硬，断面淡黄白色，显粉性，形成层呈环状棕色，上部有黄棕色的点状树脂道及放射状裂隙，香气特异，味微苦、甘。

或主根与根茎近等长或较短，呈圆柱形、圆锥形或人字形，长3~6cm，表面灰黄色，具纵皱纹，上部或中下部有须根，支根多为2~3条，须根少而细长，须根不乱，有较明显的须根痕。根茎细长，少数短粗，中上部具稀疏或密而深陷的横纹，不定根较短，垂下面。

**【鉴别】**

(1) 本品横切面：木栓部为数列细胞。栓内层窄。韧皮部外侧有裂隙，内侧薄壁细胞排列较疏松，有树脂道散在。内皮层细胞明显，形成层成环，木质部射线宽广，射线单个散在或数个相联，射线排列成放射状，射线旁偶有非木化的纤维；薄壁细胞含草酸钙簇晶。

粉末淡黄白色。射线细胞片可见，黄白色块状分泌腔。草酸钙簇晶直径20~60 $\mu$ m，棱角锐尖，并沿细胞表面呈类方形或多角形，壁薄呈状弯曲。射线细胞壁较厚，直径10~50 $\mu$ m，淀粉粒多数，单粒类球形，半透明或不透明多角形，直径4~20 $\mu$ m，脐点状或环状；复粒由2~6分粒组成。

(2) 取本品粉末1g，加浓氨试液40ml，加热回流1小时，取出浓氨试液，药渣晾干，加0.5ml浓硝酸，加水稀至2ml，超声处理30分钟，取上清液加3倍量氨试液，离心，取上清液，药渣晾干，残渣加甲醇1ml使溶解，作为供试品溶液。另取人参对照药材1g，同法制成对照药材溶液。再取人参皂苷Rb<sub>1</sub>对照品、人参皂苷Rg<sub>1</sub>对照品、人参皂苷R<sub>1</sub>对照品及人参皂苷F<sub>2</sub>对照品，加甲醇制成每1ml各含2mg的混合溶液，作为对照品溶液。照薄层色谱法（通则0502）试验，吸取上述三种溶液各1~2 $\mu$ l，分别点于同一硅胶G薄层板上，以三氯甲烷-乙酸乙酯-甲醇（15:40:22:10）10℃以下放置的预饱和液为展开剂，展开，取出，晾干，喷以10%硫酸乙醇溶液，在105℃加热至显黄色清晰，分别置日光和紫外灯（365nm）下检视。供试品色谱中，在与对照药材色谱和对照品色谱相应位置上，分别显相同颜色的斑点或荧光斑点。

- 정보 제공 범위
- 해당 원료의 성상, 감별, 검사, 함량측정, 효능, 사용량, 사용방법, 보관방법 및 주의사항 등

**예시 | 원료명: 인삼**

The image shows a detailed label for Ginseng (인삼) with 15 numbered callouts pointing to various sections:

- 1. 물질명 (Material Name)
- 2. 성상 (Appearance)
- 3. 감별 (Identification)
- 4. 검사 (Testing)
- 5. 함량측정 (Content Measurement)
- 6. 음편 (한약/달인 약) (Taste/Preparation)
- 7. 조제 (Preparation)
- 8. 함량측정 (Content Measurement)
- 9. 감별 (Identification)
- 10. 검사 (Testing)
- 11. 성미와 귀경 (Taste and Meridian)
- 12. 효능 및 주요치료 (Effects and Main Treatments)
- 13. 사용법 및 사용량 (Usage and Dosage)
- 14. 주의사항 (Precautions)
- 15. 보관방법 (Storage Method)

- ① 물질명: 인삼
- ② 성상: 주뿌리는 방추형 또는 원주형으로 길이는 3~15cm이고, 지름은 1~2cm 등
- ③ 감별: 본 품의 단면은 코르크 층 여러 개의 세포 등
- ④ 검사: 수분은 12.0%를 초과하지 않고, 총 회분 함량은 5.0% 미만 등
- ⑤ 함량측정: 고성능 액체 크로마토그래피(동축0512)에 따라 측정
- ⑥ 음편(饮片): 한약(달인 약)
- ⑦ 조제: 물에 담금, 얇은 절편, 건조 또는 사용 시 분쇄하거나 으깨서 사용
- ⑧ 함량측정: 동일 약재, 진세노사이드Rg<sub>1</sub>(C<sub>42</sub>H<sub>72</sub>O<sub>14</sub>)와 진세노사이드 Re(C<sub>48</sub>H<sub>82</sub>O<sub>18</sub>) 함유 총량은 0.27% 이상이어야 하고, 진세노사이드 Rb<sub>1</sub>(C<sub>54</sub>H<sub>92</sub>O<sub>23</sub>)은 0.18% 이상이어야 함
- ⑨ 감별: (단면 제외)
- ⑩ 검사: 동일 약재
- ⑪ 성미(性味)와 귀경(归经): 단맛, 약간 쓴맛, 미온; 비장, 폐, 심장 및 신장
- ⑫ 효능 및 주요치료: 원기보충, 심신 안정, 수족냉증 완화 등
- ⑬ 사용법 및 사용량: 3~9 g, 달이거나 분말로 갈아서 복용함. 2 g/회, 2회/일
- ⑭ 주의사항: 여로(藜芦), 오령지(五灵脂)와 함께 사용 불가
- ⑮ 보관방법: 서늘하고 건조한 곳에 밀봉하여 보관함

## 일본

### [ 특정 보건용 식품 일람 ]

#### ● 개요

DB명	특정 보건용 식품 일람
관리기관	소비자청
DB 내용	특정 보건용 식품에 대한 상품 정보 일람 및 성분
접속 주소	https://www.caa.go.jp/policies/policy/food_labeling/foods_for_specified_health_uses/
정보 제공 건수	1,042건('24.11. 기준)

#### ● DB 접속 방법

- '소비자청' 접속 후 '정책(製作)' 탭의 '식품표시(食品表紙)' 클릭



- ‘영양이나 보건 기능에 관한 표시 제도에 대해서’ 란의 ‘특정 보건용 식품(特定保険用食品)’ 탭 클릭

The screenshot shows a grid of menu items. The item '特定保健用食品' (Specific Health Food) is highlighted with a red rectangular box. Other menu items include '安全や衛生に関する表示の制度について', '品質等選択に役立つ表示の制度について', '製造所固有記号の届出をされる方へ', '栄養や保健機能に関する表示の制度について', '食品表示リコール情報及び違反情報サイト', and '公表資料'.

- ‘허가품목일람(許可品目一覧)’ 탭의 ‘특정 보건용 식품 허가(승인)품목 일람(特定保険用食品許可(承認)品目一覧)’ 클릭

The screenshot shows a webpage with a sidebar on the right containing navigation links like '特別用途食品', '品質等選択に役立つ表示の制度について', '食品表示リコール情報及び違反情報サイト', '公表資料', '会議・研究会', and 'その他'. The main content area has a button '特定保健用食品の許可申請を検討している事業者の方はこちら'. Below it is a section titled '許可品目一覧' (List of Permitted Products) containing a link: '特定保健用食品許可(承認)品目一覧[Excel::235KB](令和6年8月15日更新) NEW'. This link is highlighted with a red rectangular box. Below the link, there is text and several sub-links: '特定保健用食品の有効性及び安全性の科学的根拠については、下記のホームページをご参照ください。', '国立健康・栄養研究所(「健康食品」の安全性・有効性情報)', '特定保健用食品情報の検索方法', and '特定保健用食品の商品情報'. At the bottom, there is a section titled '検討会情報' (Review Meeting Information) with a link: '特定保健用食品制度(疾病リスク低減表示)に関する検討会'.

○ 허가된 보건용 식품의 허가 품목 상세 정보 확인 가능

번호	제품명	제조사	법인명	제품의 종류	허가 세부내역	제조업종	1일섭취량	허가일	허가종류	제조업종
1008	일본의방 블루트	株式会社ブルーベリー	010400000000	음식첨가제	블루베리 추출물	음식첨가제	100g	2018.02.28	1008	음식첨가제
1009	일본의방 블루-비트	株式会社ブルーベリー	010400000000	음식첨가제	블루베리 추출물	음식첨가제	100g	2018.02.28	1009	음식첨가제
1000	비즈리드	日新製菓株式会社	021000000000	제조업종	비즈리드	제조업종	100g	2018.02.28	1000	제조업종
1001	다다의방 코어비트	株式会社コアビート	010000000000	음식첨가제	코어비트	음식첨가제	100g	2018.02.28	1001	음식첨가제
1000	비즈리드	株式会社コアビート	021000000000	제조업종	비즈리드	제조업종	100g	2018.02.28	1000	제조업종
1000	비즈리드	株式会社コアビート	021000000000	제조업종	비즈리드	제조업종	100g	2018.02.28	1000	제조업종



## ■ 대만

### [ 식품원료 통합 조회 플랫폼 ]

#### ● 개요

DB명	식품원료 통합 조회 플랫폼(食品原料整合查詢平臺)
관리기관	위생복지부 식품약품관리서
DB 내용	식품원료에 대한 다년간의 섭취 안전성 평가 등의 정보를 종합하여 구축한 식품원료 통합 DB로 '식품에 사용 가능한 원료', '안전성 미확인으로 사용 불가한 원료' 정보 제공
접속 주소	<a href="https://consumer.fda.gov.tw/Food/Material.aspx?nodeID=160">https://consumer.fda.gov.tw/Food/Material.aspx?nodeID=160</a>
정보 제공 건수	1,699건('24.11. 기준) - 식품에 사용 가능한 원료: 1,165건 - 안전성 미확인으로 사용 불가한 원료: 534건
기타	해당 DB는 포지티브리스트가 아니며 모든 전통 식품원료가 등재되어 있지는 아니함. 등재된 품목 중 과학적 연구를 통해 섭취 안전에 대한 우려가 제기될 경우 해당 식품원료에 대한 섭취 안전성을 재평가하고 결과에 따라 해당 식품원료에 대한 사용제한 등의 규정을 제정함. DB 정보 내용은 수시로 업데이트될 수 있음

● DB 접속 방법

- ‘식품약물 소비자 카테고리’ 접속 후 ‘통합 조회 서비스(整合查詢服務)’ 클릭



- ‘통합 조회 서비스’ 화면으로 이동 후 ‘1.식품(1.食品)’ 클릭



- ‘식품(食品)’ 화면으로 이동 후 ‘2.식품원료 통합 조회 플랫폼(2.食品原料整合查詢平臺)’ 클릭



- ‘식품원료 통합 조회 플랫폼’ 접속 완료



- ‘키워드(關鍵字)’에 검색하고자 하는 원료의 중문 또는 영문 명칭(학명 포함) 입력 후 ‘검색(搜尋)’ 버튼 클릭

6.有關本平臺之「未確認安全性尚不得使用之原料」分類，除涉及毒品、藥品或經評估不適合供為食品原料者，其餘品項因無相關資料佐證其長期食用安全性，故尚不得供為食品原料使用，如仍有使用需求者，請至本署網站(<http://www.fda.gov.tw/TC/siteContent.aspx?sid=10811>)，依「非傳統性食品原料申請作業指引」辦理，俾供評估。

6.本平臺之資料內容，將不定期更新，惟仍請依最新之相關法規與函釋為準，各界自應本其個案之產品屬性、適用之管理規定，或食用安全性綜合判斷，如有具體個案涉訟或裁罰案件，當以司法確定判決或相關管理規定之判定為準，本平臺內容雖經數度校正，惟外誤疏漏之處，諒難避免，尚祈不吝指正。

大分類：  次分類：

關鍵字：

共有 1699 筆搜尋結果

項次	類別	中文名稱	外文名稱	學名	部位	附件
1	草、木本植物類(1)供茶包、膳食調理包或萃取後作為原料	羅母珠；相思子；紅珠木；羅母子	Rosary pea	Abrus precatorius L.	根	
2	草、木本植物類(1)供茶包、膳食調理包或萃取後作為原料	五加皮	Cortex Acanthopanax Radicis	Acanthopanax gracilistylus W. W. Smith	根皮	

- 검색 결과에서 해당 원료의 중문 명칭(하이퍼링크) 클릭

6.有關本平臺之資料內容，將不定期更新，惟仍請依最新之相關法規與函釋為準，各界自應本其個案之產品屬性、適用之管理規定，或食用安全性綜合判斷，如有具體個案涉訟或裁罰案件，當以司法確定判決或相關管理規定之判定為準，本平臺內容雖經數度校正，惟外誤疏漏之處，諒難避免，尚祈不吝指正。

大分類：  次分類：

關鍵字：

共有 1 筆搜尋結果

項次	類別	中文名稱	外文名稱	學名	部位	附件
1	微生物及其來源製取之原料	<a href="#">紅麴</a>	Anka	Monascus anka, Monascus barkeri, Monascus pilosus, Monascus purpureus, Monascus ruber	菌體	

○ 해당 원료의 상세 정보 확인

衛生福利部食品藥物管理署  
Food and Drug Administration  
FDA 食品藥物消費者專區

## 整合查詢服務

食品 ▾ 西藥 ▾ 檢驗方法查詢 食品藥物管理署官網業務專區 食品藥物管理署官網法規資訊

化粧品禁限用成分管理規定 人體器官保存庫 ▾

首頁 > 整合查詢服務 > 食品 > 食品原料整合查詢平臺

### 食品原料整合查詢平臺

次分類：微生物及其來源製取之原料 **紅麴**

[詳細資料](#)

大分類	可供食品使用之原料
次分類	微生物及其來源製取之原料
中文名稱	紅麴
外文名稱	Anka
學名	Monascus anka, Monascus barkeri, Monascus pilosus, Monascus purpureus, Monascus ruber
部位	菌體
備註	可供為食品原料或食品加工使用。
檔案下載	

- -1) 정보 제공 범위\_식품에 사용 가능한 원료
- 상세 정보에서 해당 원료의 분류, 중문 및 영문 명칭, 학명, 부위 등 정보 제공



예시 | 원료명: 홍국

食品原料整合查詢平臺	
次分類：微生物及其來源製取之原料 <b>紅麴</b>	
<b>詳細資料</b>	
① 大分類	可供食品使用之原料
② 次分類	微生物及其來源製取之原料
③ 中文名稱	紅麴
④ 外文名稱	Anka
⑤ 學名	Monascus anka, Monascus barkeri, Monascus pilosus, Monascus purpureus, Monascus ruber
⑥ 部位	菌體
⑦ 備註	可供為食品原料或食品加工使用。
⑧ 檔案下載	

- ① 대분류: 식품에 사용 가능한 원료
- ② 소분류: 미생물 및 그 출처로 만든 원료
- ③ 중문 명칭: 홍국(紅麴)
- ④ 외국어(영문) 명칭: Anka
- ⑤ 학명: Monascus anka, Monascus barkeri, Monascus pilosus, Monascus purpureus, Monascus ruber
- ⑥ 부위: 균체
- ⑦ 비고: 식품원료 또는 식품 가공에 사용 가능
- ⑧ 파일 다운로드: -

● -2) 정보 제공 범위\_안전성 미확인으로 사용 불가한 원료

- 상세 정보에서 해당 원료의 분류, 중문 및 영문 명칭, 학명, 부위 등 정보 제공



예시 | 원료명: 한국 당귀

食品原料整合查詢平臺	
次分類：未確認安全性尚不得使用之原料 韓國當歸；朝鮮當歸	
詳細資料	
① 大分類	未確認安全性尚不得使用之原料
② 次分類	未確認安全性尚不得使用之原料
③ 中文名稱	韓國當歸；朝鮮當歸
④ 外文名稱	
⑤ 學名	Angelica gigas
⑥ 部位	
⑦ 備註	未經確認其食用安全性前，不得供為食品原料使用。
⑧ 檔案下載	

- ① 대분류: 안전성 미확인으로 사용 불가한 원료
- ② 소분류: 안전성 미확인으로 사용 불가한 원료
- ③ 중문 명칭: 한국 당귀, 북한 당귀
- ④ 외국어(영문) 명칭: -
- ⑤ 학명: Angelica gigas
- ⑥ 부위: -
- ⑦ 비고: 섭취 안전성이 확인되기 전까지 식품원료로 사용 불가
- ⑧ 파일 다운로드: -

## 1-3. 기준·규격

### ■ 호주

#### [ 호주뉴질랜드 식품기준 코드-별표 23-금지된 식물 및 곰팡이 ]

##### ● 개요

<b>DB명</b>	호주뉴질랜드 식품기준 코드-별표 23-금지 식물 및 곰팡이 목록 (Australia New Zealand Food Standards Code - Schedule 23 - Prohibited plants and fungi)
<b>관리기관</b>	호주뉴질랜드 식품기준청(FSANZ)
<b>DB내용</b>	금지 식물 및 곰팡이 목록
<b>접속 주소</b>	<a href="https://www.legislation.gov.au/F2015L00435/latest/text">https://www.legislation.gov.au/F2015L00435/latest/text</a>
<b>정보 제공 건수</b>	-

##### ● DB 접속 방법

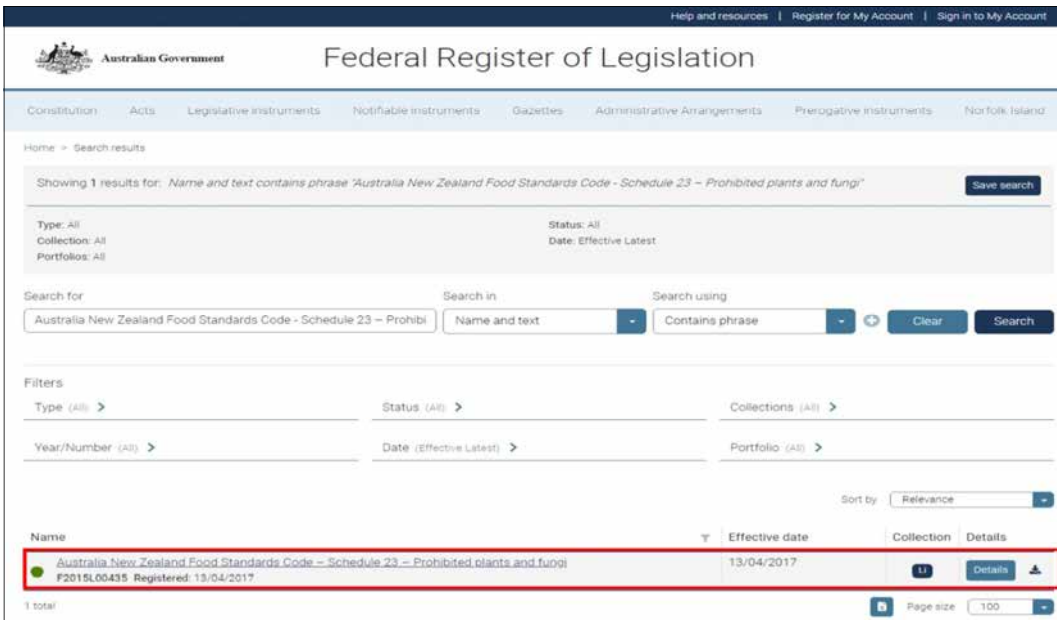
##### ○ Federal Register of Legislation 접속

The screenshot shows the search interface of the Federal Register of Legislation. At the top, there are navigation links for 'Help and resources', 'Register for My Account', and 'Sign in to My Account'. Below the header, there are tabs for 'Constitution', 'Acts', 'Legislative instruments', 'Notifiable instruments', 'Gazettes', 'Administrative Arrangements', 'Prerogative instruments', and 'Norfolk Island'. The main content area is titled 'Explore the Federal Register of Legislation' and features a search bar with a 'Search' button and a 'Browse' link. The search bar includes a dropdown menu for 'All' (selected), 'In force', and 'No longer in force'. Below the search bar, there are input fields for 'Search for' (with an example 'example: Legislation Act 2003'), 'Search in' (with a dropdown menu set to 'Name and text'), and 'Search using' (with a dropdown menu set to 'Contains phrase'). There are also checkboxes for 'Filter by collection' with options for 'Act', 'Gazette', 'Legislative instrument', and 'Notifiable instrument'. At the bottom, there are 'Search' and 'Advanced search' buttons.

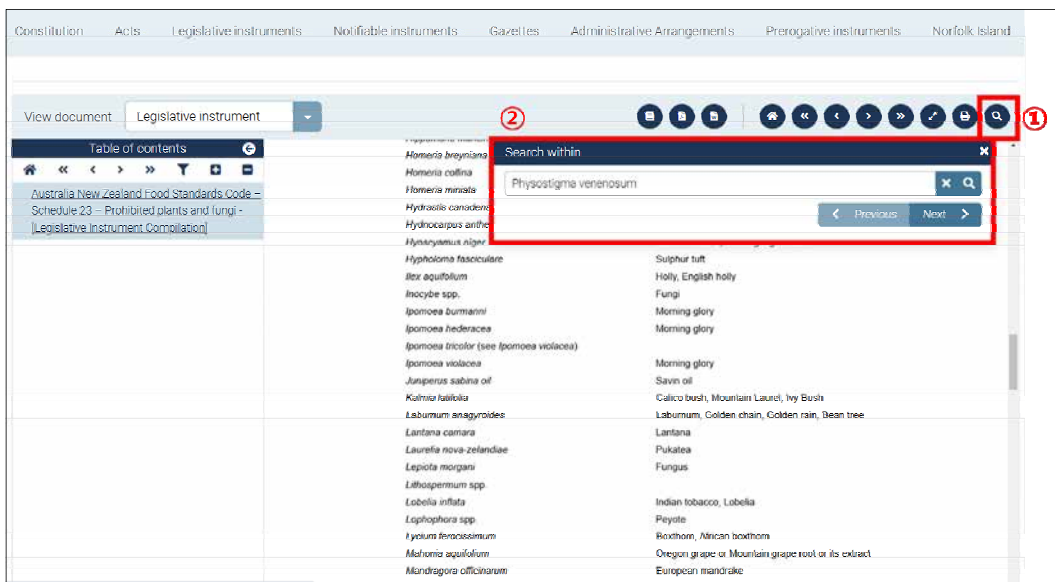
- 검색란(Search for)에 'Australia New Zealand Food Standards Code - Schedule 23 - Prohibited plants and fungi' 입력 후 Search 클릭



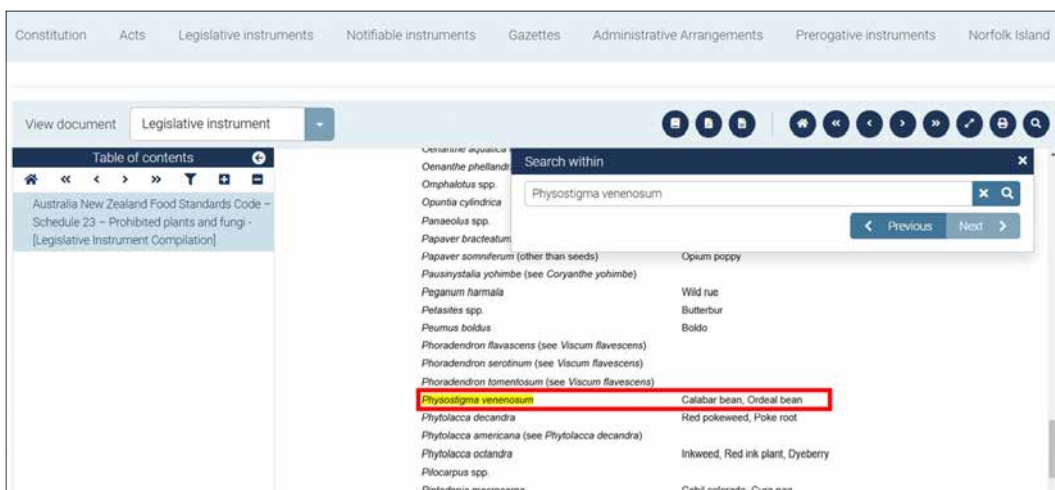
- 화면 아래쪽으로 이동하여 해당 문서 클릭



○ ‘돋보기’ 아이콘 클릭 후 검색하고자 하는 원료의 영문 명칭 입력 후 클릭



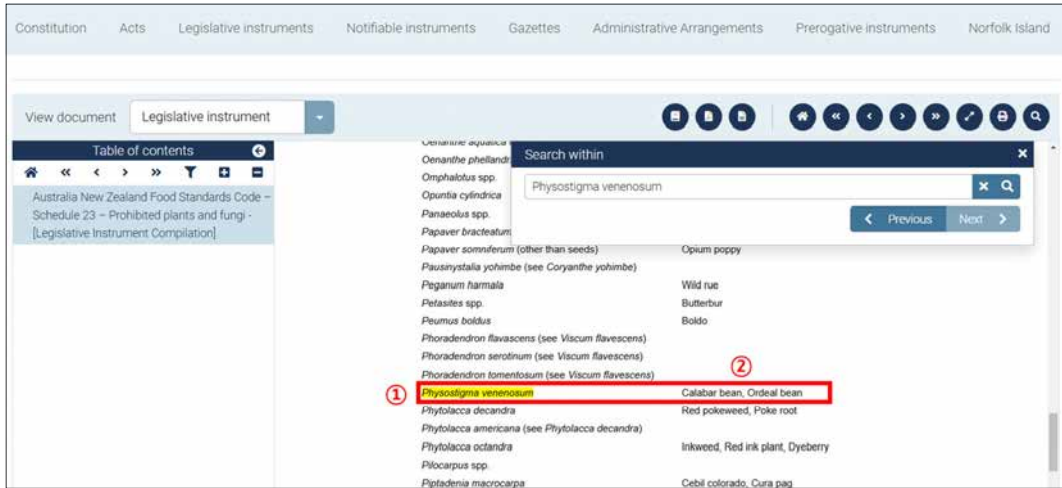
○ 해당 금지 식물 및 곰팡이 확인



● 정보 제공 범위

- 해당 원료에 대한 증명칭 및 일반명칭 정보를 제공하고 있으며 PDF, Word 형식으로 다운로드 가능

**예시** | 원료명: 피조스티그마(Physostigma venenosum)



- ① 증명칭: 피조스티그마(Physostigma venenosum)
- ② 일반명칭: 칼라바콩(Calabar bean), 심판약물(Ordeal bean)

## [ 호주뉴질랜드 식품기준 코드-별표 24-제한된 식물 및 곰팡이 ]

### ● 개요

<b>DB명</b>	호주뉴질랜드 식품기준 코드-별표 24-제한 식물 및 곰팡이 목록 (Australia New Zealand Food Standards Code – Schedule 24 – Restricted plants and fungi)
<b>관리기관</b>	호주뉴질랜드 식품기준청(FSANZ)
<b>DB내용</b>	제한 식물 및 곰팡이
<b>접속 주소</b>	<a href="https://www.legislation.gov.au/F2015L00438/latest/text">https://www.legislation.gov.au/F2015L00438/latest/text</a>
<b>정보 제공 건수</b>	18건(*24.11. 기준)

### ● DB 접속 방법

#### ○ Federal Register of Legislation 접속



- ‘검색란(Search for)’에 ‘Australia New Zealand Food Standards Code – Schedule 24 – Restricted plants and fungi’ 입력 후 ‘Search’ 클릭

Help and resources | Register for My Account | Sign in to My Account

Australian Government Federal Register of Legislation

Constitution Acts Legislative instruments Notifiable instruments Gazettes Administrative Arrangements Prerogative instruments Norfolk Island

Explore the Federal Register of Legislation

Search Browse

All In force No longer in force

Search for: Australia New Zealand Food Standards Code - Schedule 24 - Restricted plants and fungi

Search in: Name and text Search using: Contains phrase

Filter by collection: Act Gazette Legislative instrument Notifiable instrument

Search Advanced search

- 화면 아래쪽으로 이동하여 해당 문서 클릭

Constitution Acts Legislative instruments Notifiable instruments Gazettes Administrative Arrangements Prerogative instruments Norfolk Island

Australia New Zealand Food Standards Code - Schedule 24 - Rost Name and text Contains phrase Clear Search

Filters

Type (All) Status (All) Collections (All)

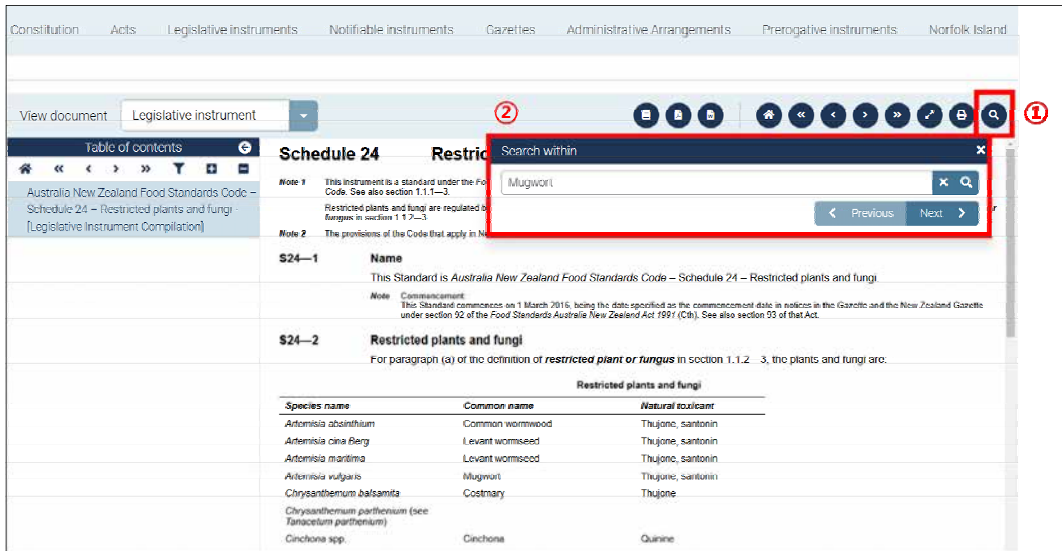
Year/Number (All) Date (Effective Latest) Portfolio (All)

Sort by: Relevance

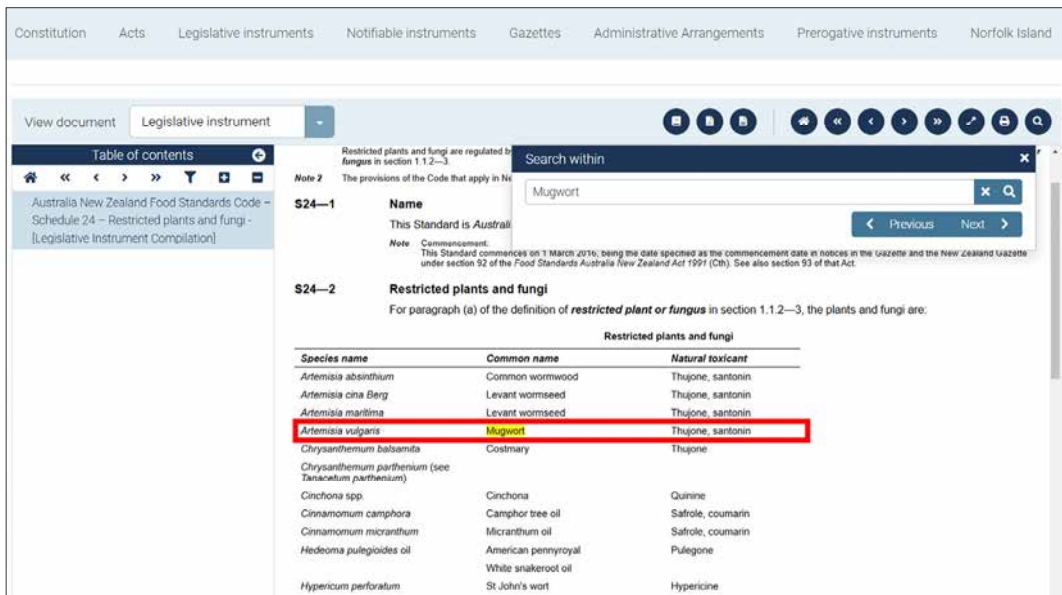
Name	Effective date	Collection	Details
Australia New Zealand Food Standards Code - Schedule 24 - Restricted plants and fungi F2015L00438 Registered: 13/04/2017	13/04/2017	U	Details

1 total Page size: 100

○ ‘돋보기’ 아이콘 클릭 후 검색하고자 하는 원료의 영문 명칭 입력 후 클릭



○ 해당 제한 식물 및 곰팡이 정보 확인



● 정보 제공 범위

- 해당 원료에 대한 증명칭, 일반명칭, 자연독소 정보를 제공하고 있으며 PDF, Word 형식으로 다운로드 가능

 예시 | 원료명: 쑥(Mugwort)

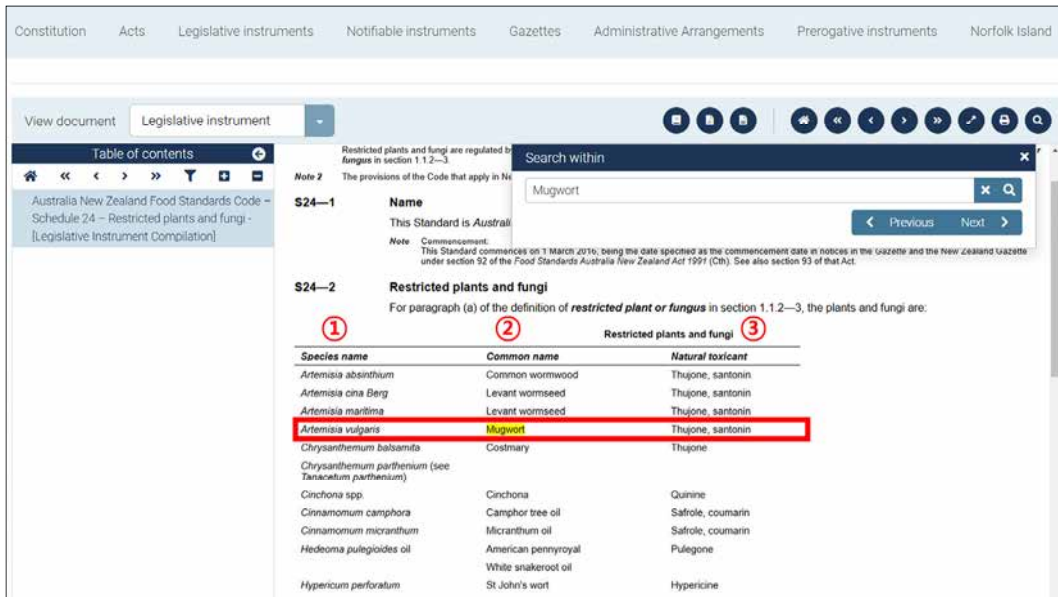


Table of contents

Search within: Mugwort

**S24-2 Restricted plants and fungi**

For paragraph (a) of the definition of *restricted plant or fungus* in section 1.1.2-3, the plants and fungi are:

① Species name	② Common name	③ Natural toxicant
<i>Artemisia absinthium</i>	Common wormwood	Thujone, santonin
<i>Artemisia cina Berg</i>	Levant wormseed	Thujone, santonin
<i>Artemisia maritima</i>	Levant wormseed	Thujone, santonin
<i>Artemisia vulgaris</i>	Mugwort	Thujone, santonin
<i>Chrysanthemum babsamita</i>	Cosmary	Thujone
<i>Chrysanthemum parthenium</i> (see <i>Tanacetum parthenium</i> )		
<i>Cinchona</i> spp.	Cinchona	Quinine
<i>Cinnamomum camphora</i>	Camphor tree oil	Safrole, coumarin
<i>Cinnamomum micranthum</i>	Micranthum oil	Safrole, coumarin
<i>Hedeoma pulegioides</i> oil	American pennyroyal	Pulegone
	White snakeroot oil	
<i>Hypericum perforatum</i>	St John's wort	Hypericine

- ① 증명칭: 아르테미시아 불가리스
- ② 일반명칭: 쑥
- ③ 자연독소: 투존, 산토닌

## 인도

### [ 식품 안전 및 기준(오염물질, 독소 및 잔류물질) 규정 ]

#### ● 개요

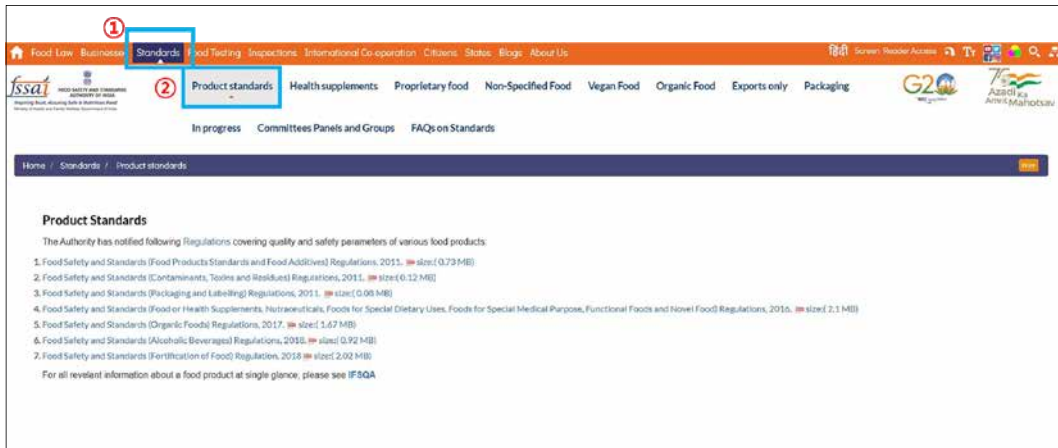
DB명	오염물질, 독소 및 잔류물질
관리기관	식품안전기준청(FSSAI)
DB 내용	품목별 식품첨가물 목록 제공
접속 주소	<a href="https://fssai.gov.in/cms/product-standards.php">https://fssai.gov.in/cms/product-standards.php</a>
정보 제공 건수	-

#### ● DB 접속 방법

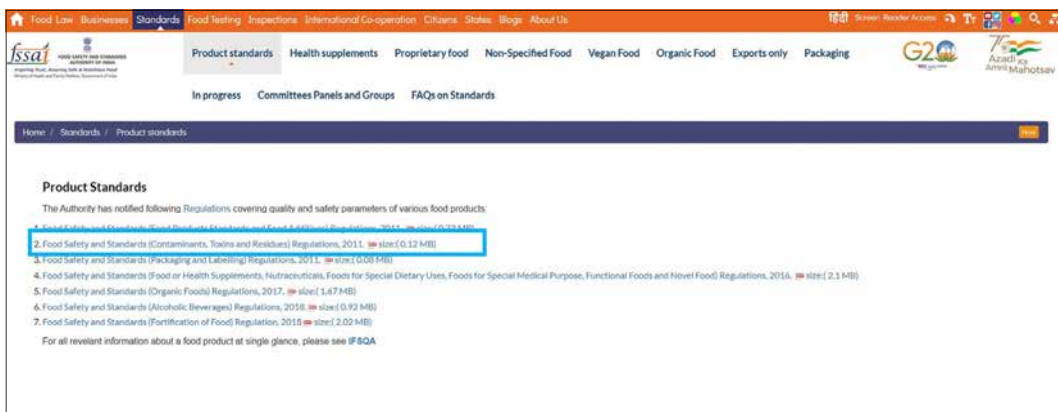
#### ● Food Safety and Standards Authority of India 접속



○ 상단의 'Standards' 클릭 후 'Product standards' 클릭



○ 목록 중 'Food Safety and Standards(Contaminants, Toxins and Residues) Regulations, 2011' 클릭



○ 해당 규정 확인(웹사이트 오류가 빈번하여 해당 파일 다운로드 권장)

1

**MINISTRY OF HEALTH AND FAMILY WELFARE**  
(Food Safety and Standards Authority of India)  
Notification

New Delhi, dated the 1<sup>st</sup> August, 2011

F.No. 2-15015/30/2010 Whereas in exercise of the powers conferred by clause (i) of sub section (2) section 92 read with section 20 of Food Safety and Standards Act, 2006 (34 of 2006) the Food Safety and Standards Authority of India proposes to make Food Safety and Standards Regulations in so far as they relate to Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011, and.

Whereas these draft Regulations were published in consolidated form at pages 1 to 776 in the Gazette of India Extraordinary Part III – Section 4 dated 20<sup>th</sup> October 2010 inviting objections and suggestions from all persons likely to be affected thereby before the expiry of the period of thirty days from the date on which the copies of the Gazette containing the said notification were made available to the public;

And whereas the copies of the Gazette were made available to the public on the 21<sup>st</sup> October 2010;

And whereas objections and suggestions received from the stakeholders within the specified period on the said draft Regulations have been considered and finalized by the Food Safety and Standards Authority of India.

Now therefore, the Food Safety and Standards Authority of India hereby make the following Regulations, namely:-

**FOOD SAFETY AND STANDARDS (CONTAMINANTS, TOXINS AND RESIDUES) REGULATIONS, 2011**

**CHAPTER 1**  
GENERAL

1.1: Short title and commencement-

1.1.1: These regulations may be called the Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011.

1.1.2: These regulations shall come into force on or after 5<sup>th</sup> August, 2011

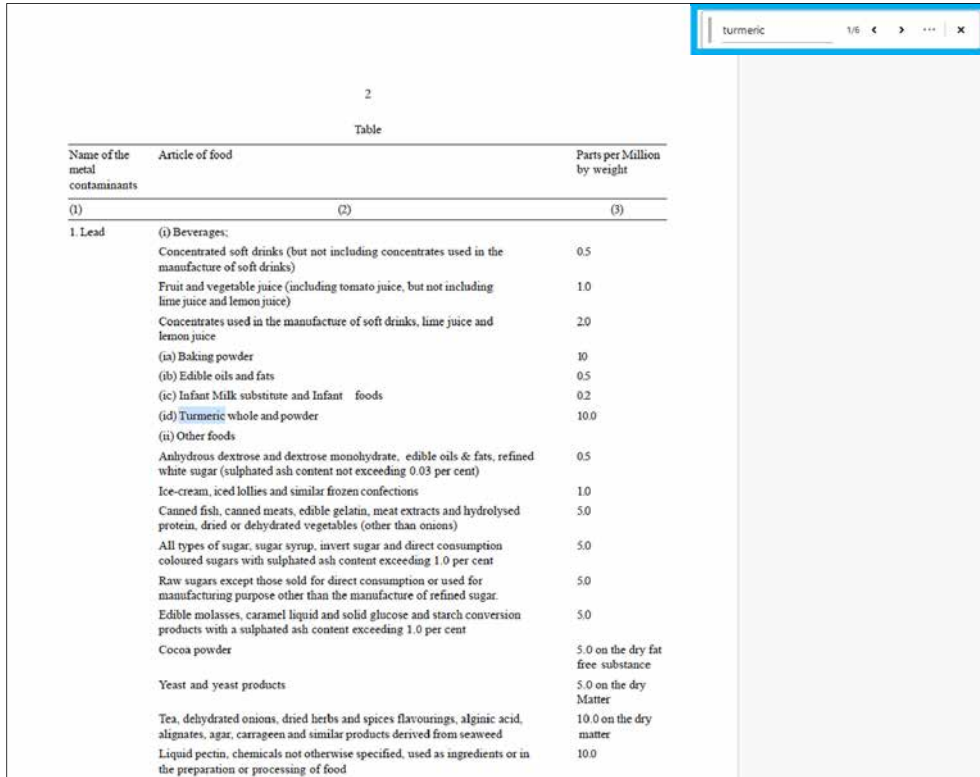
1.2: Definitions-

1.2.1: In these regulations unless the context otherwise requires:

1. "Crop contaminant" means any substance not intentionally added to food, but which gets added to articles of food in the process of their production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging transport or holding of articles of such food as a result of environmental contamination

**CHAPTER 2**  
CONTAMINANTS, TOXINS AND RESIDUES

○ Ctrl+f를 실행하여 품목 검색 후 오염물질 기준 확인



2

Table

Name of the metal contaminants	Article of food	Parts per Million by weight
(1)	(2)	(3)
1. Lead	(i) Beverages:	
	Concentrated soft drinks (but not including concentrates used in the manufacture of soft drinks)	0.5
	Fruit and vegetable juice (including tomato juice, but not including lime juice and lemon juice)	1.0
	Concentrates used in the manufacture of soft drinks, lime juice and lemon juice	2.0
	(a) Baking powder	10
	(b) Edible oils and fats	0.5
	(c) Infant Milk substitute and Infant foods	0.2
	(d) Turmeric whole and powder	10.0
	(ii) Other foods	
	Anhydrous dextrose and dextrose monohydrate, edible oils & fats, refined white sugar (sulphated ash content not exceeding 0.03 per cent)	0.5
	Ice-cream, iced lollies and similar frozen confections	1.0
	Canned fish, canned meats, edible gelatin, meat extracts and hydrolysed protein, dried or dehydrated vegetables (other than onions)	5.0
	All types of sugar, sugar syrup, invert sugar and direct consumption coloured sugars with sulphated ash content exceeding 1.0 per cent	5.0
	Raw sugars except those sold for direct consumption or used for manufacturing purpose other than the manufacture of refined sugar.	5.0
	Edible molasses, caramel liquid and solid glucose and starch conversion products with a sulphated ash content exceeding 1.0 per cent	5.0
	Cocoa powder	5.0 on the dry fat free substance
	Yeast and yeast products	5.0 on the dry Matter
	Tea, dehydrated onions, dried herbs and spices flavourings, alginic acid, alginates, agar, carrageen and similar products derived from seaweed	10.0 on the dry matter
	Liquid pectin, chemicals not otherwise specified, used as ingredients or in the preparation or processing of food	10.0

● 정보 제공 범위

- 금속오염물질 제한농도, 농작물 오염물질 및 자연 독소 제한농도 농약 잔류물질 제한농도, 금지 물질 목록을 제공함



예시 | 원료명: 강황 전체 및 분말

①	②	③
Name of the metal contaminants	Article of food	Parts per Million by weight
(1)	(2)	(3)
1. Lead	(i) Beverages;	
	Concentrated soft drinks (but not including concentrates used in the manufacture of soft drinks)	0.5
	Fruit and vegetable juice (including tomato juice, but not including lime juice and lemon juice)	1.0
	Concentrates used in the manufacture of soft drinks, lime juice and lemon juice	2.0
	(ia) Baking powder	10
	(ib) Edible oils and fats	0.5
	(ic) Infant Milk substitute and Infant foods	0.2
	(id) Turmeric whole and powder	10.0

- ① 금속오염물질: 납
- ② 식품: 강황 전체 및 분말
- ③ 허용량: 10.0 (ppm)

## 일본

### [식품 위험 허브 정보]

#### ● 개요

DB명	식품 위험 허브 정보
관리기관	식품안전위원회
DB 내용	1차 산품에 포함되는 위험, 식품의 제조 과정에서 생기는 위험, 곰팡이 독·자연 독 등의 목록 * 제공하는 DB 중 식품건강영향평가서, 국내리스크관리 항목에 식품안전위원회에서 제작한 내용뿐만 아니라 후생노동성, 농림수산성 등에서 제공하는 프로파일이 존재함. 기관에서 다루는 관점 등의 내용의 차이로 인한 고시로 보임
접속 주소	<a href="https://www.fsc.go.jp/foodsafetyinfo_map/foodhazinfohub/foodhazinfohub_poll.html">https://www.fsc.go.jp/foodsafetyinfo_map/foodhazinfohub/foodhazinfohub_poll.html</a>
정보 제공 건수	43건('24.11. 기준)

● DB 접속 방법

- 홈페이지 접속 후 ‘식품 위험정보 허브(食品ハザード情報ハブ)’ 탭 클릭



- 아래로 스크롤 후 '3) 오염물질의 페이지는 이쪽(3.「汚染物質」のページはこちら)' 링크 클릭



○ 1차산품에서 비롯된 독소 및 제조과정 중 발생하는 독소에 대한 상세 정보 및 관련 연구 확인

**【ハザード情報】**

- 一次産品に含まれるハザード（[海洋毒素](#) / [かび毒](#) / [植物に含まれる自然毒](#) / [重金属等](#) / [その他](#)）
- [食品の製造工程で生じるハザード](#)

=一次産品に含まれるハザード=

海産毒素	ハザードの説明	食品健康影響評価書	国内リスク管理等の関連情報	国際機関評価結果等	Codex規格基準
アサシロロ	<ul style="list-style-type: none"> <li>リスクプロファイル（厚生労働省）<a href="#">☞</a></li> <li>リスクプロファイル [PDF:305KB]（農林水産省）<a href="#">☞</a></li> </ul>	—	<ul style="list-style-type: none"> <li>自然由来の毒素：貝毒（農林水産省）<a href="#">☞</a></li> </ul>		
下痢性貝毒	<ul style="list-style-type: none"> <li>リスクプロファイル（厚生労働省）<a href="#">☞</a></li> <li>リスクプロファイル [PDF:249KB]（農林水産省）<a href="#">☞</a></li> </ul>	<ul style="list-style-type: none"> <li>二枚貝中のオキタケ毒 <a href="#">☞</a></li> </ul>	<ul style="list-style-type: none"> <li>近海性貝毒等により毒化した貝類の取扱いは、<a href="#">☞</a> [PDF:87KB]（厚生労働省）<a href="#">☞</a></li> <li>自然由来の毒素：貝毒（農林水産省）<a href="#">☞</a></li> </ul>	<ul style="list-style-type: none"> <li>Marine Biotoxins: Food and Nutrition Paper 80, (FAO) <a href="#">☞</a></li> <li>Assessment and management of biotoxin risks in bivalve molluscs: Fisheries and Aquaculture Technical Paper No. 551, (FAO) <a href="#">☞</a></li> <li>Report of the Joint FAO/IOC/WHO ad hoc Expert</li> </ul>	
ドゥモイロ	<ul style="list-style-type: none"> <li>リスクプロファイル（厚生労働省）<a href="#">☞</a></li> <li>リスクプロファイル [PDF:320KB]（農林水産省）<a href="#">☞</a></li> </ul>	—	—	<ul style="list-style-type: none"> <li>Assessment and management of biotoxin risks in bivalve molluscs: Fisheries and Aquaculture Technical Paper No. 551, (FAO) <a href="#">☞</a></li> <li>Report of the Joint FAO/IOC/WHO ad hoc Expert</li> </ul>	<ul style="list-style-type: none"> <li>CXS 292-2008 [PDF:415KB] <a href="#">☞</a> (Standard for Live and Raw Bivalve Molluscs)</li> <li>CXC 52-2003 [PDF:44,061KB] <a href="#">☞</a> (Code</li> </ul>

● 정보 제공 범위

- 독소명칭, 위험 설명, 식품건강영향평가서, 국내 리스크 관리 등의 관여 정보, 국제기관 평가 결과, Codex규격기준



예시 | 물질명: 테트로도톡신(テトロドトキシソ)

	シガテラ毒	<ul style="list-style-type: none"> <li>▶ 리스크프로파일 (厚生労働省) <a href="#">[PDF:232KB]</a></li> <li>▶ 리스크프로파일 (農林水産省) <a href="#">[PDF:284KB]</a></li> <li>▶ 팩트시트 (食品安全委員会) <a href="#">[PDF:284KB]</a></li> </ul>	-	-	<ul style="list-style-type: none"> <li>▶ Marine Biotoxins: Food and Nutrition Paper 80 (FAO) <a href="#">[PDF:2,337KB]</a></li> <li>▶ Report of the expert meeting on ciguatera poisoning (FAO/WHO) <a href="#">[PDF:2,337KB]</a></li> </ul>	▶ CXC 52-2003 <a href="#">[PDF:44,061KB]</a> (Code of Practice for Fish and Fishery Products)
①	테트로도톡신	<ul style="list-style-type: none"> <li>▶ 리스크프로파일: 魚類 (厚生労働省) <a href="#">[PDF:1,904]</a></li> <li>▶ 리스크프로파일: 巻貝 (厚生労働省) <a href="#">[PDF:1,904]</a></li> </ul>	-	<ul style="list-style-type: none"> <li>▶ 安全なフグを提供しよう (厚生労働省) <a href="#">[PDF:1,904]</a></li> <li>▶ 巻貝 (キンシバイ) による食中毒について (厚生労働省) <a href="#">[PDF:1,904]</a></li> </ul>	▶ JOINT FAO/WHO Technical Paper on Toxicity equivalence factors for marine biotoxins associated with bivalve molluscs <a href="#">[PDF:1,904]</a>	▶ CXC 52-2003 <a href="#">[PDF:44,061KB]</a> (Code of Practice for Fish and Fishery Products)
	バリトキシソ	<ul style="list-style-type: none"> <li>▶ 리스크프로파일 (厚生労働省) <a href="#">[PDF:1,904]</a></li> </ul>	-	-	-	▶ CXC 52-2003 <a href="#">[PDF:44,061KB]</a> (Code of Practice for Fish and Fishery Products)
	かび毒	ハザードの説明	食品健康影響評価書	国内リスク管理等の関連情報	国際機関評価結果等	Codex規格基準

- ① 독소명칭: 테트로도톡신
- ② 위험 설명: 후생노동성 페이지로 이동(첨부 이미지 확인)
- ③ 식품건강영향평가서: -
- ④ 국내 리스크관리 등의 관여 정보
- ⑤ 국제기관 평가결과
- ⑥ Codex 규격기준





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## 2. 의약품

## ■ 호주

### [ TGA eBusiness Services ]

#### ● 개요

DB명	TGA eBusiness Services
관리기관	연방의료제품청(TGA)
DB내용	원료 정보, 용도, 제한 사항 등에 대한 정보를 제공
접속 주소	<a href="https://www.ebs.tga.gov.au/">https://www.ebs.tga.gov.au/</a>
정보 제공 건수	정확한 데이터 개수는 확인 불가하나 광범위한 원료 정보를 제공하는 것으로 조사됨

#### ● DB 접속 방법

#### ○ TGA eBusiness Services 접속

The screenshot shows the TGA eBusiness Services website interface. The main content area is titled 'Ingredients' and features a search bar and a filter dropdown menu set to 'Name'. Below the search area is a table with the following columns: Name, Synonym, Identifier, Category, Reference, and CAS No. The table contains two entries:

Name	Synonym	Identifier	Category	Reference	CAS No.	Linkable
(+)-2,5,7,8-Tetrahydroquinoline	(+)-2,5,7,8-Tetrahydroquinoline	110556	AAN	CHEMID (plus National Library of Medicine)	450-41-1	Linked
Nargosin-7-pharmacopione	Nargosin-7-pharmacopione	102587	AAN	International Cosmetic Ingredient Directory	10236-47-2	Linked

The footer of the page includes the text: 'Web page last updated: Thursday, 20 November 2024 01:17pm' and the URL: 'URL: https://www.ebs.tga.gov.au/'.

Public TGA Information → Ingredients 탭 클릭 → 'Search'에 원료명 입력 후 'Go' 클릭

**Ingredients**

**Australian Approved Names List for Therapeutic Substances**

The TGA provides access to information about ingredients used in products. This Ingredients Table provides the list of approved names for chemical, biological and herbal ingredients that may be used in TGA-regulated therapeutic goods. The Ingredients Table allows you to search for a particular substance through the portal below.

The list of ingredients previously published in the TGA approved terminology for medicines document is included in this Ingredients Table.

The Ingredients Table now contains more information on the requirements when the ingredients are used in listed medicines. The legislative basis for the availability and requirements associated with the use of these ingredients in listed medicines is the [Prescription Ingredients Determination](#).

Search for:  in All Fields Go

There are two types of ingredients, active and excipient. An active ingredient is the therapeutically active component in a medicine's final formulation that is responsible for its physiological action. An excipient ingredient is any component of a finished dosage form, other than an active ingredient.

For queries about approved names for chemical or biological ingredients, contact [TSenarath@tga.gov.au](mailto:TSenarath@tga.gov.au)  
 For queries about approved names for herbal ingredients or listed medicine ingredient restrictions contact [complementary.medicines@health.gov.au](mailto:complementary.medicines@health.gov.au)

What can be searched for  
 Your search terms will find documents that match values that we store against: Name; Synonym; Identifier; Category; Reference; CAS Number; and Listed status for Ingredients.

Search Options  
 If you are not sure of the name or the exact spelling, you can enter the first few letters of the product.  
 If no results are found for what you enter, the search will automatically attempt to find words that start with your search term.  
 eg. searching for **measur**e will return results for the whole word **measures**, but searching for **meas** or **meas\*** will return results for words like **measurer** and **measuring**.

You may use \* to represent zero or more of any character, eg. \*nose to find **nose** or **noses**\* to find **conditioner**  
 You may use ? to represent any single character, eg. ?nose to find **nos**e or **nos**?

More complex searches  
**and &**  
 can be used to find documents containing all of the words linked by them, eg. **ear and nose and throat** will find documents containing all of these words.  
**or (comma)**  
 can be used to find documents containing any of the words linked by them, eg. **ear or nose or throat** will find documents containing at least one of these words.  
**not !**  
 can be used to find documents that do not contain the associated word, eg. **ear and not nose** will find documents that contain 'ear', but do not contain 'nose'.  
**()**  
 can be used to order the search terms, eg. **throat and not (sooth\* or sore)** will find documents that contain 'throat' but do not contain either 'sose' or words starting with 'sooth'.

Notes  
 To search for documents containing the special words and characters above, use "" quotes around your search term, eg. "nose & throat" will find documents that contain the exact string 'nose & throat'.  
 To search for documents containing the characters < > , use quotes around your search term, eg. "STABLED" will find documents that contain the exact string "-stabled".

Part 1 .  
2.의 양: 판

해당 원료 클릭

**Ingredients**

Search:  in All Fields Go Reset


Filter on: Name for  Go Reset

Name	Synonym	Identifier	Category	Reference	CAS No	Listed
<a href="#">ascorbic acid</a>	Vitamin C L-Ascorbic acid Ascorbic acid anhydrous	52224	AAN	British Pharmacopoeia	50-81-7	Listed

Therapeutic Goods Administration | Copyright | Privacy | Disclaimer | Security | Browser Support | [www.australia.gov.au](http://www.australia.gov.au) | [www.health.gov.au](http://www.health.gov.au)  
 For further information contact the [eBS Help Lines](mailto:eBS Help Lines), [eBS@health.gov.au](mailto:eBS@health.gov.au)


Web page last updated: Thursday, 28 November 2024 01:17am  
 URL: <https://www.ebs.tga.gov.au/>

○ 해당 원료의 상세 정보 확인

 <b>Australian Government</b> <b>Department of Health and Aged Care</b> Therapeutic Goods Administration			
<b>Ingredient Summary</b>			
<b>Ingredient Name</b>	ascorbic acid		
<b>Ingredient ID</b>	52224		
<b>Category</b>	Australian Approved Name		
<b>Synonyms</b>	Vitamin C L-Ascorbic acid Ascorbic acid anhydrous		
<b>CAS Number</b>	50-81-7		
<b>Availability</b>	<p>Available for use as an Active Ingredient in: Biologicals, Export Only, Listed Medicines, Over the Counter, Prescription Medicines</p> <p>Not available as a Homoeopathic Ingredient in Listed Medicines</p> <p>Available for use as an Excipient Ingredient in: Biologicals, Devices, Export Only, Listed Medicines, Over the Counter, Prescription Medicines</p> <p>Available for use as an Equivalent Ingredient in: Export Only, Listed Medicines, Prescription Medicines</p> <p><i>Please note: Only the name and definition of a substance have been reviewed to allow it to be included in the ingredient repository. The approval for use of the ingredient in therapeutic goods is a decision made by the relevant TGA regulatory area. This approval process may require submission of further information, for example safety data for the ingredient or for the finished goods, to meet legislative and regulatory requirements.</i></p>		
<b>Additional Information</b>			
Naming Reference			
<b>Reference</b>	<b>Edition/Year/Volume</b>	<b>Page Number(s)</b>	<b>Accessed Online</b>
British Pharmacopoeia	2008/1	186	No
Restrictions			
<b>Restriction</b>	<b>Applies To</b>		
END OF SUMMARY			

● 정보 제공 범위

- 원료 정보, 용도, 제한 사항 등에 대한 정보를 상세히 제공하고 있으며 PDF 형식으로 다운로드 가능

 예시 | 원료명: 비타민 C(Vitamin C)

Australian Government Department of Health and Aged Care Therapeutic Goods Administration	
<b>① Ingredient Summary</b>	
Ingredient Name	ascorbic acid
Ingredient ID	52224
Category	Australian Approved Name
Synonyms	Vitamin C L-Ascorbic acid Ascorbic acid anhydrous
CAS Number	50-81-7
Availability	Available for use as an Active Ingredient in: Biologicals, Export Only, Listed Medicines, Over the Counter, Prescription Medicines.  Not available as a Homeopathic Ingredient in Listed Medicines.  Available for use as an Excipient Ingredient in: Biologicals, Devices, Export Only, Listed Medicines, Over the Counter, Prescription Medicines.  Available for use as an Equivalent Ingredient in: Export Only, Listed Medicines, Prescription Medicines.  <small>Please note: Only the name and definition of a substance have been reviewed to allow it to be included in the ingredient repository. The approval for use of the ingredient in therapeutic goods is a decision made by the relevant TGA regulatory area. This approval process may require submission of further information, for example safety data for the ingredient or for the finished goods, to meet legislative and regulatory requirements.</small>
Additional Information	
<b>② Naming Reference</b>	
Reference	Edition/Year/Volume Page Number(s) Accessed Online
British Pharmacopoeia	2008/1 186 No
<b>③ Restrictions</b>	
Restriction	Applies To
END OF SUMMARY	
<small>Disclaimer: The details contained in this document reflect the information held at the nominated date and time of printing. The most recent version of this document can be accessed at <a href="http://www.tga.gov.au">www.tga.gov.au</a>. Please refer to TGA's disclaimer by clicking on the following link <a href="#">Disclaimer</a>.</small>	

① 원료 정보

원료명: Ascorbic acid

원료 ID: 52224

분류: 호주 승인 명칭

동의어: Vitamin C, L-아스코르브산, 무수 아스코르브산

CAS 번호: 50-81-7

용도: 1. 활성원료로 사용 가능

생물학적 제제, 수출전용, 등재의약품, 일반의약품, 처방의약품

2. 등재의약품의 경우 동종요법 원료로 사용 불가

3. 부형제로 사용 가능

생물학적 제제, 의료기기, 수출전용, 등재의약품, 일반의약품, 처방의약품

4. 등가원료로 사용 가능

수출전용, 등재의약품, 처방의약품

② 명칭 참조(Naming Reference): 영국 약전(British Pharmacopoeia), 2008/1권, 186페이지  
온라인으로 확인 불가

③ 제한 사항(Restrictions): -

## ■ 일본

### [ 무승인 무허가 의약품 정보 ]

#### ● 개요

DB명	무승인 무허가 의약품 정보
관리기관	후생노동성
DB 내용	의약품적 효능 효과를 표방하지 않는 경우에는 의약품이라고 판단하지 않는 원재료 목록
접속 주소	https://www.mhlw.go.jp/content/001318303.pdf
정보 제공 건수	-

#### ● DB 접속 방법

- ‘후생노동성’ 접속 후 ‘정책에 대하여(製作について)’에서 ‘분야별 정책 일람(分野別の製作一覧)’ 클릭



- ‘건강·의료(健康·医療)’ 탭의 ‘의료품·의료기기(医療品·医療機器)’ 클릭



- 아래로 스크롤 후 ‘약사감시, 약물남용대책’란의 ‘건강피해정보·무승인무허가의약품정보 (健康被害情報・無承認無許可医薬品情報)’ 탭 클릭



○ 아래로 스크롤 후, ‘참고) 관련통지[(参考) 関連通知]’란의 별첨 확인

**中国製ダイエット用健康食品等関連情報**

中国製ダイエット用健康食品等関連情報については、こちらをご覧ください。

ページの先頭へ戻る

**(参考) 関連通知**

- 無承認無許可医薬品の指導取締りについて [PDF形式: 366KB] [469KB]
- 食薬区分における成分本質 (原材料) の取扱いの例示の一部改正について (令和6年10月17日発出) [PDF形式: 179KB] [216KB]
- (参考) 別添1. 専ら医薬品として使用される成分本質 (原材料) リスト [PDF形式: 338KB] [340KB]
- (参考) 別添2. 医薬品的効能効果を標ぼうしない限り医薬品と判断しない成分本質 (原材料) リスト [PDF形式: 500KB] [502KB]**
- 新規成分本質 (原材料) の判断に関する照会の様式について [PDF形式: 277KB] [277KB]
- 別紙1. 成分本質 (原材料) の分類にかかる照会様式 (植物・動物等由来) [Word形式: 78KB] [78KB]
- 別紙2. 成分本質 (原材料) の分類にかかる照会様式 (その他 (化学物質等)) [Word形式: 71KB] [71KB]
- 別紙3. 【記載例】成分本質 (原材料) の分類にかかる照会様式 (植物・動物等由来) [PDF形式: 663KB] [663KB]
- 別紙4. 【記載例】成分本質 (原材料) の分類にかかる照会様式 (その他 (化学物質等)) [Word形式: 670KB] [670KB]
- 無承認無許可医薬品の監視指導について [PDF形式: 288KB]

ページの先頭へ戻る

○ ‘별첨2’ 클릭 후 원재료 데이터베이스 PDF 형식으로 확인 가능

三 非薬リスト 1 / 21 96% +

(別添2)  
○ 医薬品的効能効果を標ぼうしない限り医薬品と判断しない成分本質 (原材料) リスト  
I. 植物由来物等  
(例) 2024.10.17更新

名 称	他 名 等	部 位 等	備 考
アイギョクシ		寒天植物質	
アイランド苔		植物体	
アイブライト		全草	
アオギリ		種子	
アオダモ	コバトネリコ/トネリコ /Fraxinus lamuginosa/Fraxinus japonica	樹皮	
アガーベ	デキワリュウゼツ	球茎	
アカザ		葉	
アカシヨウマ		根	シヨウマの根茎は「医」
アカツメクサ	コウシヤシクソウ/ムラサキツメクサ/レッド・クローバー	葉・花穂(序)	
アカテツ		果肉・葉	
アカニレ	スリッパリーエルム	全草	
アカバナムシヨケギク		葉	
アカメガシワ		樹皮	
アガリクス	アガリクス・ブラセイ/ヒメマツタケ	子実体	
アギタケ	阿魏茸	子実体	
アキノギリソウ		全草	
アケビ	モクツウ	実	つる性の茎は「医」
アサ		発芽防止処理されている種子	発芽防止処理されていない種子は「医」

● 정보 제공 범위

- 명칭, 다른 명칭, 부위 등, 비교

 예시 | 원료명: 아선약나무(アセンヤク/阿仙藥/Gambir)



名	ラテン名	部位	備考
アキタケ	阿魏茸	子實體	
アキ/キリンソウ		全草	
アケビ	モクツウ	実	つる性の薬は「医」
アサ		発芽防止処理されている種子	発芽防止処理されていない種子は「医」
アサガオ		葉・花	種子は「医」
アサツキ		莖葉・莖茎	
アシ	ヨシ	全草(根茎を除く)	根茎は「医」
アシサイ	シヨウカ/ハチセンカ	全草	
アシタバ		葉	
アシドフィルス菌		菌体	
アズキ	セキショウズ	種子	
アスナロ		葉	
① アセロラ	② ハルバ/ドスサクラ	③ 果実	④
アセンヤク	ガンビール	葉及び若枝の乾燥水製エキス	
アッケシソウ		全草	
アップルミント	ラウンドリーミント	葉	
アニス	ピンピネラ	果実・種子・種子油・根	
アフィニソメノン		全薬	
アフリカマンゴノキ	オボノ/アボン(種子)/テイカナツツ/ブッシュマンゴノ/ワイルドマンゴノ	種子	
アボガド		果実・葉	
アマ	アマシ/アマニン/アマニ油	種子・種子油	
アマチャ		枝葉・葉	
アマチャヅル	コウコラン	全草	
アマナ	サンジロ	莖茎	
アメリカサンショウ		全草	
アメリカニンジン	カントニンジン/セイヨウニン/セイヨウニンジン/Panax	根茎・根・葉	

- ① 명칭: 아선약나무(アセンヤク)
- ② 다른 명칭: 감비르(ガンビール)
- ③ 부위 등: 잎 및 어린가지 건조 수성 추출물(葉及び若枝の乾燥水製エキス)
- ④ 비교

## [ 무승인 무허가 의약품 정보 ]

### ● 개요

DB명	무승인 무허가 의약품 정보
관리기관	후생노동성
DB 내용	오로지 의약품으로서 사용되는 성분 원재료 목록
접속 주소	https://www.mhlw.go.jp/content/001318302.pdf
정보 제공 건수	-

### ● DB 접속 방법

- ‘후생노동성’ 접속 후 ‘정책에 대하여(製作について)’에서 ‘분야별 정책 일람(分野別の製作一覧)’ 클릭



- ‘건강·의료(健康·医療)’ 탭의 ‘의료품·의료기기(医療品·医療機器)’ 클릭



Part 1  
2. 의약품

- 아래로 스크롤 후 ‘약사감시, 약물남용대책’란의 ‘건강피해정보·무승인무허가약품정보(健康被害情報·無承認無許可医薬品情報)’ 탭 클릭



○ 아래로 스크롤 후, ‘(참고) 관련통지[(参考) 関連通知]’란의 별첨 확인

**中国製ダイエット用健康食品等関連情報**

▶ 中国製ダイエット用健康食品等関連情報については、こちらをご覧ください。

▶ [ページの先頭へ戻る](#)

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**(参考) 関連通知**

- ▶ [REF 無承認無許可医薬品の指導取締りについて \[PDF形式：366KB\] \[469KB\]](#)
- ▶ [REF 食薬区分における成分本質（原材料）の取扱いの例示の一部改正について（令和6年10月17日発出） \[PDF形式：179KB\] \[216KB\]](#)
- ▶ [REF \(参考\) 別添1. 専ら医薬品として使用される成分本質（原材料）リスト \[PDF形式：338KB\] \[340KB\]](#)
- ▶ [REF \(参考\) 別添2. 医薬品的効能効果を標ぼうしない限り医薬品と判断しない成分本質（原材料）リスト \[PDF形式：500KB\] \[502KB\]](#)
- ▶ [REF 新規成分本質（原材料）の判断に関する照会の際の様式について \[PDF形式：277KB\] \[277KB\]](#)
- ▶ [▶ W 別紙1. 成分本質（原材料）の分類にかかる照会様式（植物・動物等由来） \[Word形式：78KB\] \[78KB\]](#)
- ▶ [▶ W 別紙2. 成分本質（原材料）の分類にかかる照会様式（その他（化学物質等）） \[Word形式：71KB\] \[71KB\]](#)
- ▶ [▶ REF 別紙3. 【記載例】成分本質（原材料）の分類にかかる照会様式（植物・動物等由来） \[PDF形式：663KB\] \[663KB\]](#)
- ▶ [▶ REF 別紙4. 【記載例】成分本質（原材料）の分類にかかる照会様式（その他（化学物質等）） \[Word形式：670KB\] \[670KB\]](#)
- ▶ [▶ REF 無承認無許可医薬品の監視指導について \[PDF形式：288KB\]](#)

▶ [ページ先頭へ戻る](#)

○ ‘별첨1’ 클릭 후 원재료 데이터베이스 PDF 형식으로 확인 가능

三 専ら薬リスト

1 / 8 - 98% +

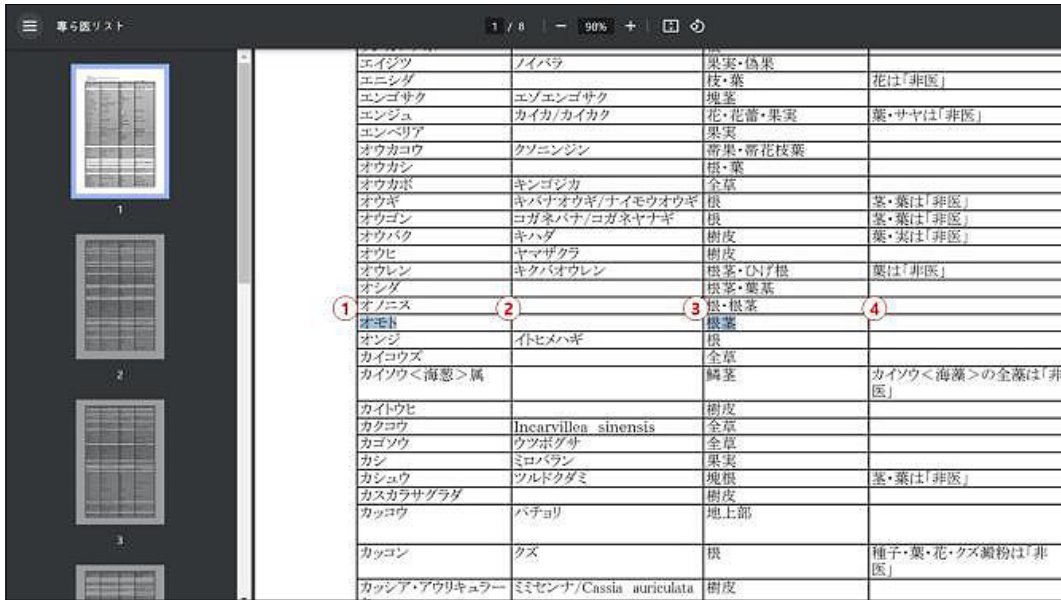
(別添1)  
○専ら医薬品として使用される成分本質(原材料)リスト  
1. 植物由来物等  
(例) 2024.10.17更新

名 称	他 名 等	部 位 等	備 考
アラビアチャノキ		葉	
アルニカ		全草	
アロエ	キュラソー・アロエ/ケーブ・アロエ	葉の液汁	根・葉肉は「非医」、キダチアロエの葉は「非医」
イチイ	アツラギ	全草	
イスサフラン		種子	
イボソウラフジ	<i>Tinospora crispa</i>	全木	
イリス		根茎	
イレイセン	シナボタンヅル	根・根茎	葉は「非医」
インヂンコウ	カワラヨモギ	花穂・蔞花全草	
インドサルサ		根	
インドジャボク属	インドジャボク/ラウオールフイア	根・根茎	
インドハマユウ	<i>Croton tatarifolium</i> Linn.	全草	
インヨウカク	イカリソウ	全草	
ウイザニア	アッシュワガンダ	全草	
ウマノスズクサ属		全草	
ウヤク	テンダイウヤク	根	葉・実は「非医」
ウワウルシ	クマユクモモ	葉	
ウンカゴリアボ		根	
エイジツ	ノイバラ	果実・偽果	
エニシダ		枝・葉	花は「非医」
エンゴサク	エゾエンゴサク	塊茎	
エンジュ	カイカ/カイカク	花・花蕾・果実	葉・サヤは「非医」

● 정보 제공 범위

- 명칭, 다른 명칭, 부위 등, 비교

 예시 | 원료명: 만년청(オモト/Rohdea japonica)



エイジツ	ノイバラ	果実・偽果	
エニシダ		枝・葉	花は「非医」
エンゴサク	エゾエンゴサク	塊茎	
エンジュ	カイカ/カイカク	花・花蕾・果実	葉・サヤは「非医」
エンペリア		果実	
オウカク	クソニンジン	新果・蕾花枝葉	
オウカシ		根・葉	
オウカボ	キンゴジカ	全草	
オウギ	キバナオウギ/ナイモウオウギ	根	茎・葉は「非医」
オウゴン	コガネバナ/コガネヤナギ	根	茎・葉は「非医」
オウバク	キハダ	樹皮	葉・実は「非医」
オウヒ	ヤマザクラ	樹皮	
オウレン	キクバオウレン	根茎・心げ根	葉は「非医」
オシダ		根茎・葉基	
① オノニス	②	③ 根・根茎	④
オモト		根茎	
オンジ	イトヒメハギ	根	
カイコウス		全草	
カイソウ<海葱>属		鱗茎	カイソウ<海藻>の全藻は「非医」
カイトウヒ		樹皮	
カクコウ	Incarvillea sinensis	全草	
カゴソウ	ウツボグサ	全草	
カシ	ミロバラン	果実	
カシユウ	ワルドクダミ	塊根	茎・葉は「非医」
カスカラサクラダ		樹皮	
カッコウ	ハチョリ	地上部	
カクコン	クズ	根	種子・葉・花・クズ澱粉は「非医」
カクシア・アウリキュラー	ミミセンナ/Cassia auriculata	樹皮	

- ① 명칭: 오모토(만년청/オモト)
- ② 다른 명칭
- ③ 부위 등: 뿌리줄기
- ④ 비교





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# 3. 생약

## ■ 유럽연합

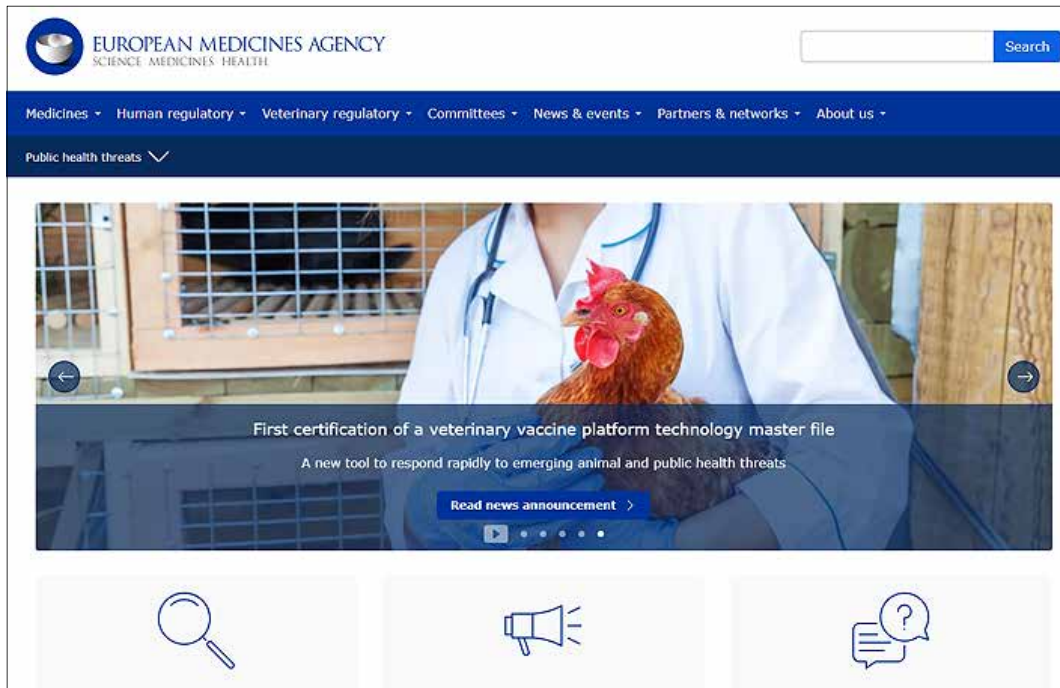
### [ 유럽연합 약초 모노그래프 ]

#### ● 개요

DB명	유럽연합 약초 모노그래프
관리기관	유럽의약품청(EMA)
DB 내용	유럽연합 약초 모노그래프 및 유럽연합 (등재된 약초) 목록 제공
접속 주소	<a href="https://www.ema.europa.eu/en/search?f%5B0%5D=ema_search_categories%3A85&amp;f%5B1%5D=herbal_outcome%3A256">https://www.ema.europa.eu/en/search?f%5B0%5D=ema_search_categories%3A85&amp;f%5B1%5D=herbal_outcome%3A256</a>
정보 제공 건수	- 유럽연합 약초 모노그래프 169건 - 유럽연합(등재된 약초) 목록 14건('24.11. 기준)

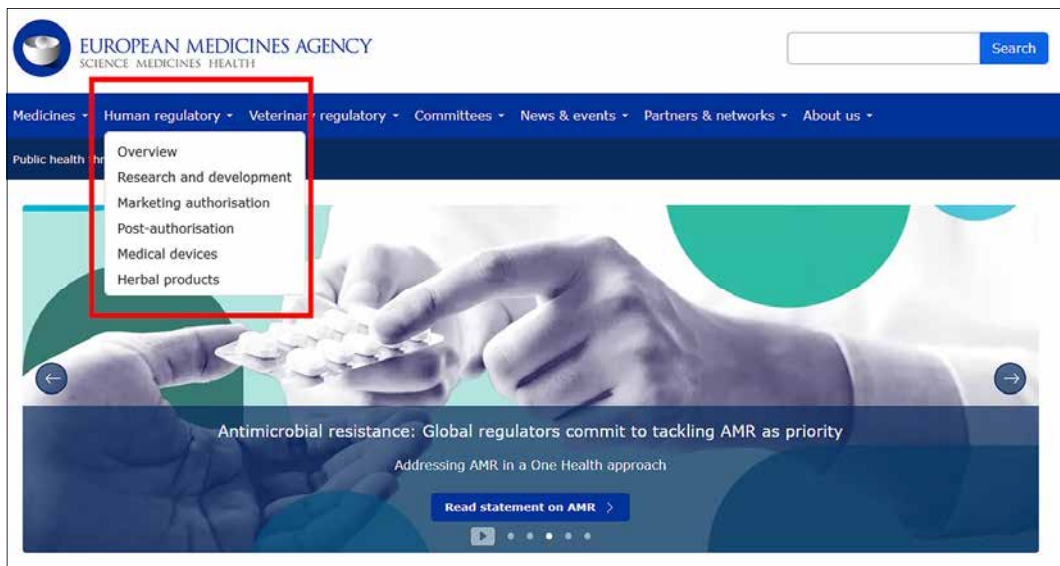
● DB 접속 방법

○ 유럽의약품청(EMA) 접속



Part 1.  
약  
3.생

○ 'Human regulatory' 클릭 후 'Herbal products' 클릭



○ ‘EU monographs and list entries’ 클릭

## Herbal medicinal products

Herbal

Page contents

In this section

Bringing herbal medicinal products to market within the EU

Establishing EU standards for national procedures

Legal framework

Related content

Related EU legislation

External links

The Committee on Herbal Medicinal Products (HMPC) issues scientific opinions on herbal substances and preparations, along with information on recommended uses and safe conditions, on behalf of the European Medicines Agency (EMA). This gives companies and national competent authorities a clear reference point when preparing or assessing an application for marketing authorisation or registration of herbal medicinal products in European Union (EU) Member States.

### In this section

#### Bringing herbal medicinal products to market within the EU

- Scientific guidelines
- Regulatory and scientific support
- Questions and answers

#### Establishing EU standards for national procedures

[EU monographs and list entries](#)

Procedures for monograph and list establishment (including calls for scientific data and public consultations)

### Bringing herbal medicinal products to market within the EU

Companies seeking to bring herbal medicinal products to the market in EU Member States should follow the national

○ 화면 중간의 ‘Herbal: European Union herbal monographs’ 클릭

When EMA publishes an HMPC opinion, this includes the monograph, the supporting assessment report and divergent positions of individual HMPC members if the monograph was not adopted by consensus (see article 7 of the HMPC [HMPC rules of procedure](#)).

For more information on the use of EU monographs in procedures for placing a herbal medicinal product on the market in a particular Member State, refer to the relevant national competent authority.

### Finding EU herbal monographs

- To view all EU herbal monographs, or to browse for existing EU herbal monographs and supporting documents by herbal substance, go to [Herbal: European Union herbal monographs](#).

### European Union list entries

To complement traditional-use monographs on herbal substances, the HMPC gradually develops the European Union list (formerly known as Community list) through 'list entries'.

Unlike EU herbal monographs, EU list entries are legally binding on applicants and national competent authorities in the Member States.

Draft list entries are developed by the HMPC, but the **final list entries are adopted and published by the European Commission**.

○ 유럽연합 약초 모노그래프 및 등재된 약초 정보 확인

**Search results (14)**

Remove all filters ● Herbal ● European Union list entry ●

**Vitis viniferae folium - herbal medicinal product**  
Grapevine Leaf, *Vitis vinifera* L.  
C: ongoing call for scientific data  
**Last updated:** 2 April 2024  
Herbal product Human Herbal

**Calendulae flos - herbal medicinal product**  
Calendula Flower, *Calendula officinalis* L.  
C: ongoing call for scientific data  
**Last updated:** 4 March 2024  
Herbal product Human Herbal

**Foeniculi dulcis fructus - herbal medicinal product**  
Sweet Fennel, *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Mill.) Batt. & Trab.  
F: Assessment finalised  
**Last updated:** 1 March 2024  
Herbal product Human Herbal

Part 1.  
약  
3. 생

● 정보 제공 범위

- ▲ 라틴어명칭, ▲ 영문명칭, ▲ 학명, ▲ 치료분야, ▲ 상태, ▲ 자료목록에 추가된 날짜, ▲ 우선순위 목록에 추가된 날짜, ▲ 유럽평가결과, ▲ 추가정보 등을 제공함



예시 | 원료명: 포도나무 잎

Key facts	
① Latin name	Vitis viniferae folium
② English common name	Grapevine Leaf
③ Botanical name	<i>Vitis vinifera</i> L.
④ Therapeutic area	Circulatory disorders
⑤ Status	C: ongoing call for scientific data
⑥ Date added to the inventory	01/11/2007
⑦ Date added to priority list	01/11/2008
⑧ Outcome of European assessment	<ul style="list-style-type: none"> <li>• <a href="#">European Union herbal monograph</a></li> <li>• <a href="#">European Union list entry</a></li> </ul>
⑨ Additional information	<ul style="list-style-type: none"> <li>• Date of adoption of Community list entry by HMPC: 15/07/2010</li> <li>• <a href="#">Commission decisions on Community list entries</a> </li> </ul>

- ① 라틴어명칭: Vitis viniferae folium
- ② 영문명칭: 포도나무 잎
- ③ 학명: Vitis vinifera L.
- ④ 치료분야: 순환계 질환
- ⑤ 상태: C. 과학적 데이터 추가 요청 진행 중
- ⑥ 자료목록에 추가된 날짜: 2007년 11월 1일
- ⑦ 우선순위 목록에 추가된 날짜: 2008년 11월 1일
- ⑧ 유럽평가결과: - 유럽연합 약초 모노그래프  
- 유럽연합 목록 항목
- ⑨ 추가정보: - 약초제품위원회(HMPC)가 목록 등재한 날짜: 2010년 7월 15일  
- 목록 등재에 대한 위원회 결정(링크)

## ■ 일본

### [ 생약 목록 ]

#### ● 개요

DB명	생약 목록
관리기관	독립행정법인 의약품의료기기종합기구
DB 내용	제18개정 일본약국방_생약 목록
접속 주소	- <a href="https://www.pmda.go.jp/rs-std-jp/standards-development/jp/0192.html">https://www.pmda.go.jp/rs-std-jp/standards-development/jp/0192.html</a> - <a href="https://www.mhlw.go.jp/content/11120000/000788459.pdf">https://www.mhlw.go.jp/content/11120000/000788459.pdf</a>
정보 제공 건수	-

#### ● DB 접속 방법

- 홈페이지 접속 후 '규제과학·기준작성조사·일본약국방(レギュラトリーサイエンス・基準作成調査・日本薬局方)' 탭의 '기준 작성조사 업무의 개요(基準作成調査業務の概要)' 클릭



○ 하단 스크롤 후 우측 메뉴탭의 '일본약국방(日本薬局方)'의 '제18개정(第十八改正)' 클릭



○ 하단 스크롤 후 '의약품조각 생약 등(医薬品各条 生薬等)' 선택



○ 원재료 상세 정보 확인 가능



Part 1.  
약  
3. 생

● 정보 제공 범위

- 생약의 상성, 확인시험, 회분(재 함량), 산 불용성 회분, 추출물 함량, 저장법

 예시 | 원료명: 회향(уй키요우/Fennel)

<p>量 (0.0) 香エタノールエキス 15.0%以上</p> <p>製 表面容器</p> <p><b>Iウカク</b> am Herb H HERBA</p> <p>はキオナイカワノ <i>Epimedium auratum</i> Nakai, <i>Epimedium grandiflorum</i> Morin var. <i>argutum</i> Nakai, <i>Epimedium pubescens</i> Ledeb., <i>Epimedium brevicornis</i> Maximowicz, <i>Epimedium wushanense</i> T. S. Yang, <i>Epimedium sagittatum</i> Maximowicz 又は トキウイカワノ <i>Epimedium sempervirens</i> Nakai (<i>Berberisdiversa</i>) の根上部分</p> <p>状 本品は葉及び1~3割3出根葉からなる。小葉は卵形又は卵状心形、長さ3~20cm、幅2~8cm、小葉柄は長さ1.5~7cmである。葉面は粗くとがり、は長さ0.1~0.2cmの刺毛がある。基部は心臓形~深で、三小葉の葉脈では掌形である。表面は緑色~緑ときに艶があり、裏面は淡緑色~淡黄褐色を呈し、ば有毛で、葉脈が顕著である。葉は縦管か又は草質で葉柄及び葉は円柱形で淡黄褐色~黄褐色を呈し、すい。</p> <p>は僅かににおいがあり、味は僅かに苦い。</p> <p>の葉の横切片を鏡檢 (0.0) するとき、主脈部には3の維管束があり、葉肉部は上面表皮、1層の柱状組織、組織、下皮表皮からなる。葉縁部は円形~楕円形で厚で埋まる。表皮には多数腺毛がある。葉柄には8~小葉柄には16~15本の維管束がある。本品の茎の横切層 (0.0) するとき、下皮は1~数細胞層で、皮層組織は4~10細胞層である。維管束は13~30本あり、円形~楕円形である。</p> <p>本品の粗粉2.0gにエタノール(20) mLを加えて15分間</p>	<p><b>ウイキョウ</b> Fennel <b>FOENICULI FRUCTUS</b> 茴香</p> <p>1 本品はウイキョウ <i>Foeniculum vulgare</i> Miller (<i>Seselinifera</i>) の果実である。</p> <p>主要性状 本品は双懸果で長円柱形を呈し、長さ3.5~8mm、幅1~2.5mmである。外面は灰黄緑色~灰黄色で、互いに接する2個の果室の脊々には本本の長稜線がある。双懸果はしばしば長さ2~10mmの果柄を付ける。</p> <p>本品は物質なしにおい及び味がある。</p> <p>本品の横切片を鏡檢 (0.0) するとき、裏面に近い縁部には背腹のものより著しく隆起し、各隆起線間に1個の小さな油室があり、裏面に12個の油室がある。</p> <p>精製試験 本品の粗粉30.0gにヘキサセン10 mLを加えて時々振り混ぜながら5分間放置した後、ろ過し、ろ液を試験溶液とする。この液につき、薄層クロマトグラフィー (2.0) により試験を行う。試験溶液5 µLを薄層クロマトグラフィー用シリカゲル(蛍光入り)を用いて調製した薄層板にスポットする。次にヘキサセン/酢酸エチル(20:1)を展開溶媒として約7 cm展開した旨、薄層板を風乾する。これに紫外線(主波長254 nm)を照射するとき、黄緑0.4付近にスポットを認める。</p> <p>3 純度試験</p> <p>(1) 水分 本品は、真物 (0.0) に近い試験を行うとき、水分3.0%以上を含まない。</p> <p>(2) 真物 (0.0) 本品は葉以外の真物1.0%以上を含まない。</p> <p>4 灰分 (0.0) 10.0%以下。</p> <p>5 糖不溶性成分 (0.0) 1.5%以下。</p> <p>6 精油含量 (0.0) 本品の粗末50.0gをとり、試験を行うとき、その量は0.7 mL以上である。</p> <p>7 貯法 容器 表面容器。</p>
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① 생약의 상성: 본 제품은 쌍현과(双懸果)로 타원기둥 모양을 보이며 길이 3.5~8 mm, 폭 1~ 2.5 mm이다. 외면은 회황록색~회황색이며, 서로 밀접한 2개의 분과 각각에는 5개의 융기선이 있다. (이하 생략)

② 확인시험

③ 순도시험

④ 회분: 10.0% 이하

⑤ 산 불용성 회분: 1.5% 이하

⑥ 추출물 함량: 본 제품의 분말 50.0g을 취하여 시험할 때, 그 양은 0.7 mL 이상이다.

⑦ 저장법: 용기, 밀폐용기

## [ 약용식물 종합 데이터베이스 ]

### ● 개요

DB명	약용식물 종합 데이터베이스
관리기관	국립건강영양연구소
DB 내용	한약·생약에 이용되는 약용 식물에 관한 다양한 정보를 간단한 조작으로 검색·열람할 수 있는, 약용 식물의 「종합 도감」
접속 주소	<a href="https://www.wts9.nibiohn.go.jp/mpdb.html">https://www.wts9.nibiohn.go.jp/mpdb.html</a>
정보 제공 건수	157건('24.11. 기준)

### ● DB 접속 방법

- 홈페이지 접속 후 ‘산관학 연계(産官学連携)’ 탭 클릭



○ ‘각종 데이터베이스와 자원뱅크(各種データベースと資源バンク)’ 클릭



○ 아래로 스크롤 후 ‘약용식물종합정보 데이터베이스(薬用植物総合情報データベース)’ 링크 클릭



- ‘약용식물자원연구센터(藥用植物資源研究センター)’ 페이지에 들어가서 ‘약용식물 종합정보 데이터베이스’ 클릭

国立研究開発法人 医薬基盤・健康・栄養研究所  
National Institutes of Biomedical Innovation, Health and Nutrition  
Research Center for Medicinal Plant Resources

センターについて    業務内容の紹介    研究部の紹介    情報発信    サイトマップ

● 薬用植物総合情報データベース

「薬用植物総合情報データベース」は、漢方薬・生薬に用いられる薬用植物に関するさまざまな情報を、簡単な操作で検索・閲覧することができる、薬用植物の「総合図鑑」です。薬用植物の情報、生薬の情報、成分・遺伝子に関する情報、栽培法に関する情報等に加え、国内に流通する代表的な生薬を「モデル生薬」として集め、これらの成分等について実際に測定、解析したデータを収載しています。また、薬用植物の栽培や増殖に関する情報、生薬の内部形態の情報なども充実しています。下の入口ボタンよりデータベースにお進みください。

**薬用植物総合情報データベース (クリックで開始)**

「薬用植物総合情報データベース」の詳しい説明はこちらです

Part 1.  
3. 생약

- ‘검색하기(検索する)’ 클릭

国立研究開発法人 医薬基盤・健康・栄養研究所

NIBIOHN  
薬用植物  
総合情報データベース

この「総合情報データベース」は、漢方薬・生薬に用いられる薬用植物に関するさまざまな情報を、簡単な操作で検索・閲覧することができる、薬用植物の「総合図鑑」です。薬用植物の情報、生薬の情報、成分・遺伝子に関する情報、栽培法に関する情報等に加え、国内に流通する代表的な生薬を「モデル生薬」として集め、これらの成分等について実際に測定、解析したデータを収載しています。また、薬用植物の栽培や増殖に関する情報、生薬の内部形態の情報なども充実しています。下の「検索する」ボタンより検索画面にお進みください。

このデータベースについて詳細情報を見る

**検索する**

漢方薬に使用される薬用植物の総合情報データベース | 厚生労働科学研究費 | Copyright © 2012-2016 Research Center for Medicinal Plant Resources, NIBIOHN

- 상단 바의 '생약정보(生薬情報)' 클릭



- 검색 서비스 및 히라가나 순 정보 열람 가능





## ■ 대만

### [ 대만중약전 ]

#### ● 개요

DB명	대만중약전[Taiwan Herbal Pharmacopeia(THP)]
관리기관	위생복지부 중의약사
DB 내용	중약 검사규격 및 검사방법이 수록된 국가표준규범으로 중약재 정보 제공
접속 주소	<a href="https://dep.mohw.gov.tw/DOCMAP/cp-759-63293-108.html">https://dep.mohw.gov.tw/DOCMAP/cp-759-63293-108.html</a>
정보 제공 건수	394건('24.11. 기준) - 중약재: 355건 - 중약재 음편: 30건 - 중약제제: 9건
기타	'대만중약전 및 중약·양약 병용 조회시스템'*이 있으나 현재('24.11. 기준) 연결되지 않아 pdf 파일로 확인 가능함. 2022년 6월 1일 발효된 제4판이 최신 버전이며, 영문 번역본을 제공하고 있음. 제·개정 상황에 따라 수시로 업데이트될 수 있음 * 대만 위생복지부 중의약사( <a href="https://www.cmthp.mohw.gov.tw/">https://www.cmthp.mohw.gov.tw/</a> )

● DB 접속 방법

- ‘위생복지부 중의약사’ 홈페이지 메인 접속 후 ‘대만중약전(臺灣中藥典)’ 클릭



Part 1.  
3. 생약

- ‘대만중약전’ 화면으로 이동 후 ‘대만중약전 제4판 공고, 2022년 6월 1일 발효 (公告臺灣中藥典第四版，並自111年6月1日生效。)’ 클릭



※ 초록색 표시부분 클릭 시 영문버전 pdf 파일 다운로드 가능

- 화면 이동 후 ‘대만중약전 제4판-전자책(0929)[臺灣中藥典第四版-電子書(0929)]’ pdf 파일 다운로드

公告臺灣中藥典第四版，並自111年6月1日生效。

- 資料來源：中醫藥司
- 建檔日期：110-09-24
- 更新時間：110-09-29

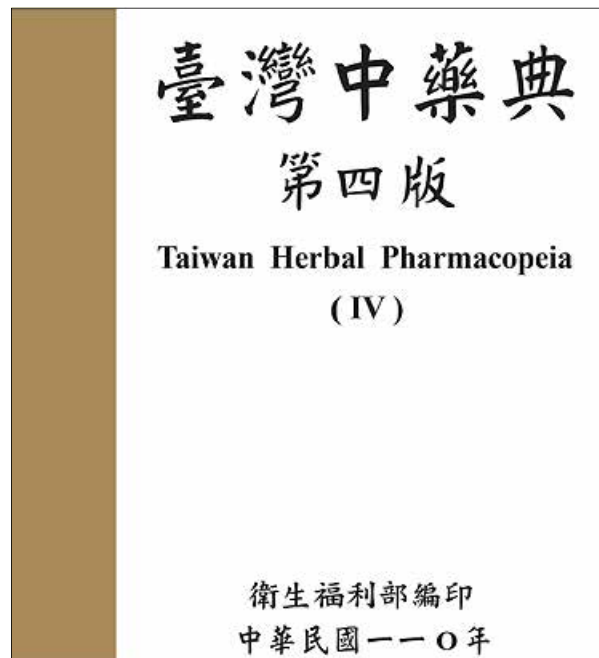
發文日期：中華民國110年9月13日  
發文字號：衛部中字第1101861154號  
附件：臺灣中藥典第四版

附件下載

- [臺灣中藥典第四版-電子書\(0929\).pdf](#)

◀ 回上一頁

- ‘대만중약전 제4판(臺灣中藥典第四版)’ pdf 파일 실행



- pdf 쪽수 기준 155쪽 '품목 목차 중약재(品項目次 中藥材)' 화면으로 이동 후 검색하고자 하는 중약재명 클릭



Part 1.  
3. 생약

- 해당 중약재의 상세 정보 확인



● 정보 제공 범위

- 종약재의 중문 및 영문 명칭, 라틴어 생약명, 기원, 함량, 성상, 감별, 불순물 검사 및 기타 규정, 기능, 용도 및 용량, 주의사항 등 정보 제공

**예시 | 종약재명: 인삼**

丁 香

CARYOPHYLLI FLOS

Clove

本品為桃金娘科 *Mystecina* 植物丁香 *Elettaria amomum* (L.) Merr & L.M.Perry 之乾燥花蕾。

本品所含丁香油不得少於 15.0%(w/w)。

**性状:**

1. 一般性状——本品為 1~2.5mm 呈線形或卵形紅色。其花冠無足扁平具四稜之柱狀。上部有 2 室之子房。中軸部上有多數短而平展之葉。每一葉之葉柄寬而平。葉內有多數散生之油室。葉片之葉脈呈羽狀。葉片之葉脈呈羽狀。葉片之葉脈呈羽狀。葉片之葉脈呈羽狀。
2. 組織——本品花冠上部(子房部分)橫切面。顯線性。表皮細胞為等徑之厚壁細胞。其外圍層以厚壁之角質層。具有向外放射氣孔。外圍層細胞中有多數巨大之長橢圓形晶。晶之直徑約 200µm。內層厚角化細胞之內層有晶。晶之直徑約 100µm。內層厚角化細胞之內層有晶。晶之直徑約 100µm。內層厚角化細胞之內層有晶。晶之直徑約 100µm。
3. 粉末——本品花冠上部(子房部分)橫切面。顯線性。表皮細胞為等徑之厚壁細胞。其外圍層以厚壁之角質層。具有向外放射氣孔。外圍層細胞中有多數巨大之長橢圓形晶。晶之直徑約 200µm。內層厚角化細胞之內層有晶。晶之直徑約 100µm。內層厚角化細胞之內層有晶。晶之直徑約 100µm。

**鑑別:**

1. 取本品粉末 1.0g，加甲醇 10 mL，照液相色譜法測定。保留時間約 10 分鐘。作為檢品溶液。取本品對照藥材 1.0g，同法製成對照藥材溶液。將取丁香油(Ginsenoside)對照標準品，加甲醇製成 1 mL 含 10 µg 的溶液。作為檢品溶液。將取本品對照藥材 1.0g，同法製成對照藥材溶液。將取丁香油(Ginsenoside)對照標準品，加甲醇製成 1 mL 含 10 µg 的溶液。作為檢品溶液。

靈 芝

GINSENG RADIX ET RHIZOMA

Ginseng Root

本品為五加科 *Araliaceae* 植物人參 *Panax ginseng* C.A.Mey. 之乾燥根及根莖。栽培者稱「園參」，野生者稱「野山參」。

本品含人參皂苷  $R_g$  (Ginsenoside  $R_g$ ) 的人參皂苷  $Re$  (Ginsenoside  $Re$ ) 的總量不得少於 0.3%。含人參皂苷  $Rb_1$  (Ginsenoside  $Rb_1$ ) 不得少於 0.2%。

**性状:**

1. 一般性状——
  - (1) 園參: 本品呈類(參)圓形，表面淡黃色，上部有環紋，根莖(蘆頭)直徑 2~6 cm，直徑 0.5~1.5 cm，有橫紋或縱紋(蘆頭)及 1 室數輪不定根。支根 2~8 條，支根多分枝，有偏折。
  - (2) 野山參: 本品呈類(參)圓形，表面淡黃色，上部有環紋，根莖(蘆頭)直徑 2~6 cm，直徑 0.5~1.5 cm，有橫紋或縱紋(蘆頭)及 1 室數輪不定根。支根 2~8 條，支根多分枝，有偏折。
2. 組織——本品切片(參)圓形，顯線性。表皮細胞為等徑之厚壁細胞。其外圍層以厚壁之角質層。具有向外放射氣孔。外圍層細胞中有多數巨大之長橢圓形晶。晶之直徑約 200µm。內層厚角化細胞之內層有晶。晶之直徑約 100µm。內層厚角化細胞之內層有晶。晶之直徑約 100µm。
3. 粉末——本品花冠上部(子房部分)橫切面。顯線性。表皮細胞為等徑之厚壁細胞。其外圍層以厚壁之角質層。具有向外放射氣孔。外圍層細胞中有多數巨大之長橢圓形晶。晶之直徑約 200µm。內層厚角化細胞之內層有晶。晶之直徑約 100µm。內層厚角化細胞之內層有晶。晶之直徑約 100µm。

**鑑別:**

1. 取本品粉末 1.0g，加甲醇 10 mL，照液相色譜法測定。保留時間約 10 分鐘。作為檢品溶液。取本品對照藥材 1.0g，同法製成對照藥材溶液。將取丁香油(Ginsenoside)對照標準品，加甲醇製成 1 mL 含 10 µg 的溶液。作為檢品溶液。將取本品對照藥材 1.0g，同法製成對照藥材溶液。將取丁香油(Ginsenoside)對照標準品，加甲醇製成 1 mL 含 10 µg 的溶液。作為檢品溶液。

- ① 중문 명칭: 인삼(人參)
- ② 라틴어 생약명: GINSENG RADIX ET RHIZOMA
- ③ 영문 명칭: Ginseng Root
- ④ 기원: 오가과(Araliaceae) 식물 인삼(*Panax ginseng* C.A.Mey.)의 건조 뿌리 및 뿌리 줄기이며, 재배종은 '원삼(園參)' 야생종은 '야산삼(野山參)'이라 부름
- ⑤ 함량: Ginsenoside  $R_g$ 과 Ginsenoside  $Re$ 의 총량은 0.3%보다 적지 않아야 하며, Ginsenoside  $Rb_1$ 은 0.2%보다 적지 않아야 함
- ⑥ 성상: 1. 일반성상 2. 조직 3. 분말 (이하 생략)
- ⑦ 감별: 본품 분말 1.0 g을 취하여 에탄올 10 mL를 가하고 30분간 초음파 진탕 후 여과하여 검액으로 함 (이하 생략)

同標準品溶液。取檢品溶液及對照標準品溶液各 5 mL，對照標準品溶液 1 mL，分別加於含有螢光劑之矽膠薄層板上，按薄層分析法(通則 1421.3)，以下步驟：無水乙醇：水 1:1 為展開劑。展佈之，使液面距離上端定距約 10~12 cm 時，取出薄板或試液。以 125% 飽和乙醇溶液(50:50:1000 TS)洗滌後，105°C 加熱至顯色清晰。置於可見光下檢視之。檢品與對照標準品及對照標準品溶液所呈現斑點之  $R_f$  值及色澤均一致。

- 8. 雜質檢査及其他規定:**
1. 二氧化硫——本品之二氧化硫殘留量不得超過 150 ppm。(通則 2323-4503)
  2. 砷(Ar)——本品之砷含量 3.0 ppm。(通則 2211-4301)
  3. 總砷(G)——本品之總砷量 1.0 ppm。(通則 4501)
  4. 汞(Hg)——本品之汞含量 0.2 ppm。(通則 4501)
  5. 鉛(Pb)——本品之鉛含量 5.0 ppm。(通則 2211-4301)
  6. 總糖類——
    - (1) 本品之總 DDT 之含量在 1.0 ppm 以下。(通則 4505)
    - (2) 本品之總 BHC 之含量在 0.5 ppm 以下。(通則 4505)
    - (3) 本品之總 PCNB 之含量在 1.0 ppm 以下。(通則 4505)

- 9. 含量測定:**
1. 人參皂苷  $R_{g_1}$ 、人參皂苷  $R_e$ 、人參皂苷  $R_b_1$  ——  
 移動相與顯色——以乙醇為移動相 A，以水為移動相 B。  
 對照標準品溶液——取人參皂苷  $R_{g_1}$  對照標準品、人參皂苷  $R_e$  對照標準品及人參皂苷  $R_b_1$  對照標準品適量，精確稱定，加正醇萃取液 1 mL，各含 0.2 mg 的混合液，搖勻，即得。  
 檢品溶液——取本品粉末 0.5 g，置 50 mL 量瓶中，精確加入 75% 乙醇 25 mL，加正醇萃取液 4 mL，冷卻後，以濾紙過濾，取

濾液，殘渣部分重複提取 3 次，合併濾液，移入 100 mL 量瓶中，濃縮至少量，移入 10 mL 量瓶中，加 75% 乙醇至刻度，搖勻，過濾，取濾液。移置檢品溶液。濾紙留置——取正醇萃取液，其定長 200 mm 檢測器，定長 1.1 之紫外管，進行速度掃描的 35°C 移動相流速 1 mL/min。按下表中的規定進行測定。理論數值按人參皂苷  $R_{g_1}$ 、人參皂苷  $R_e$ 、人參皂苷  $R_b_1$  總計算應不低於 8500。

時間 (分鐘)	移動相 A(%)	移動相 B(%)
0-30	59	41
30-45	19-22	81-78
45-60	22-29	78-71
60-75	29	71
75-110	29-40	71-60

測定法——分別稱取對照標準品溶液與檢品溶液各 10  $\mu$ L，注入層析裝置進行之。測定，即得。  
 人參皂苷  $R_{g_1}$ 、人參皂苷  $R_e$ 、人參皂苷  $R_b_1$  (%) =  $C_{\text{檢品}} / C_{\text{對照}} \times 100$   
 $C_{\text{檢品}}$  = 檢品溶液中人參皂苷  $R_{g_1}$ 、人參皂苷  $R_e$ 、人參皂苷  $R_b_1$  之濃度  
 $C_{\text{對照}}$  = 對照標準品溶液中人參皂苷  $R_{g_1}$ 、人參皂苷  $R_e$ 、人參皂苷  $R_b_1$  之濃度  
 $C_{\text{對照}}$  = 人參皂苷  $R_{g_1}$ 、人參皂苷  $R_e$ 、人參皂苷  $R_b_1$  對照標準品之濃度(mg/mL)  
 註：檢品量(g) 以總計之

10. 的驗法：本品應含總或關於總的總成，並含有
11. 的驗法：本品應含總或關於總的總成，並含有
12. 的驗法：本品應含總或關於總的總成，並含有
13. 的驗法：本品應含總或關於總的總成，並含有
14. 的驗法：本品應含總或關於總的總成，並含有
15. 的驗法：本品應含總或關於總的總成，並含有

**【收引】白參**  
 本品含人參皂苷  $R_{g_1}$  和人參皂苷  $R_b_1$  的總量不得少於 0.3%，所含人參皂苷  $R_e$  不得少於 0.2%。

本品收引為藥材除去雜質、淨製、乾燥、切斷、乾燥、成塊或粉狀。塊狀，多為圓形或圓形薄片，外表面灰白色，切面淡黃色或淡白色；外表面粗糙，形成縱紋或粉白色，切面有黃棕色或粉紅色。體輕、質脆、香氣特異，味微甘、微苦。  
 鑑別：同藥材方法。  
 雜質檢査及其他規定：同藥材方法及條載。  
 含量測定：同藥材方法。  
 的驗法：同藥材方法。  
 性味與歸經：甘、微苦、微溫。歸脾、肺、心經。  
 功能：大補元氣，復脈固脫，補神益精，生津止渴，安神益智。  
 用法與用量：3~21.5 g。  
 注意事項：從藥量。

**【收引】紅參**  
 本品含人參皂苷  $R_{g_1}$  和人參皂苷  $R_b_1$  的總量不得少於 0.3%，所含人參皂苷  $R_e$  不得少於 0.2%。  
 本品收引為藥材除去雜質、淨製、乾燥、切斷、乾燥、成塊或粉狀。塊狀，多為圓形或圓形薄片，外表面灰白色，切面淡紅色或淡紅色；外表面粗糙，形成縱紋或粉白色，切面有黃棕色或粉紅色。體輕、質脆、香氣特異，味微甘、微苦。  
 鑑別：同藥材方法。  
 雜質檢査及其他規定：同藥材方法及條載。  
 含量測定：同藥材方法。  
 的驗法：同藥材方法。  
 性味與歸經：甘、微苦、微溫。歸脾、肺、心經。  
 功能：大補元氣，復脈固脫，補神益精，生津止渴，安神益智。  
 用法與用量：3~21.5 g。  
 注意事項：從藥量。

**八角茴香**  
**ANISI STYLLATI FRUCTUS**  
**Star Anise Fruit**

本品為木質對 *Magnoliaceae* 植物八角茴香 *Illicium verum* Hook.f 之乾燥成熟果實。  
 本品之種之乾燥後不得少於 38.0%，水抽提物不得少於 18.0%，含揮發油不得少於 4.0% (v/w)。所含反式茴香腦(trans-Anethole)不得少於 4.0%。

- 性狀:**
1. 一般性狀——本品呈聚合果，由 8 個果葉果組成，果葉果排列於中軸上，下有 1 個對稱的果柄，長 3~4 cm，果葉果呈三角形，長 5~15 mm，寬約 5 mm，厚 5~10 mm，上端尖突。該種果實，外表面灰棕色，多皺紋，內表面灰棕色，有光澤，種子 1 枚，呈扁形，長 7 mm，寬 4 mm，厚 2 mm，種皮紅棕色，老熟光澤，一端有凹下殘留及明顯的孔，另一端有凸點，中間有長條形縫隙，種仁白色，含油質，味香、甜。
  2. 組織——本品外果皮為 1 列皮細胞，內果皮有 1~2 列皮細胞，中果皮有 1~2 列皮細胞，內果皮有 1 列網狀細胞，種皮外層為 1 列緊密之石細胞，呈長方形，其內為數層薄壁細胞，胚乳細胞內含糊粉粒及脂肪油。
  3. 粉末——本品粉末紅褐色。外果皮皮細胞呈多角形，內果皮石細胞呈方形或三角形，長 90~400  $\mu$ m，寬 40~120  $\mu$ m，壁厚，可見層紋及孔溝。內果皮網狀細胞，長 120~450  $\mu$ m，寬 50~80  $\mu$ m。種皮木質化，具粒孔，種皮石細胞呈方形或三角形，長 50~80  $\mu$ m，內含棕色物質。纖維呈梭形，木質化，有紋孔。內胚乳細胞呈多角形，內含糊粉粒及脂肪油。
- 鑑別:**
1. 取本品粉末 3.0 g，加石油醚(30~60°C) 2 mL (1:1) 混合液 15 mL，置震，振搖 15 分鐘，過濾，殘渣加水 2 mL，使之溶解，作為檢品溶液。取八角茴香對照標準品 1.0 g，同法製成對照標準品溶液，另取茴香腦 (Anethole) 對照標準品，加無水乙醇製成 1 mL 含 10  $\mu$ g 的溶液，作為對照標準品溶液。取檢品溶液、對照標準品溶液及對照標準品溶液各 2~5  $\mu$ L，按薄層分析法(通則 1421.3)。

- 8. 불순물 검사 및 기타 규정:** 1. 이산화황 2. 비소 3. 카드뮴 4. 수은 5. 납 6. 농약잔류 (이하 생략)
- 9. 함량측정:** 1. Ginsenoside  $R_{g_1}$ , Ginsenoside  $R_e$ , Ginsenoside  $R_{b_1}$  (이하 생략)
- 10. 저장법:** 본품은 벌레 방지를 위해 밀폐용기에 담아 냉장 또는 그늘지고 서늘하며 건조한 곳에 보관해야 함
- 11. 용도 분류:** 보약(補益藥) (원기 보충)
- 12. 성미 및 귀경:** 달고 약간 쓰며 약간 따뜻함. 비장, 폐장, 심장에 귀경
- 13. 기능:** 대보원기(大補元氣), 복맥고탈(復脈固脫) (이하 생략)
- 14. 용도 및 용량:** 3~11.5 g
- 15. 주의사항:** 여로(藜蘆)와 상반
- ※ 빨간색 네모칸 표시부분은 음편 '백삼'과 '홍삼' 내용임

Part 1.  
3. 생약

## [ 식품에 동시 사용 가능한 중약재 품목 ]

### ● 개요

DB명	식품에 동시 사용 가능한 중약재 품목
관리기관	위생복지부 중의약사
DB 내용	식품에 사용 가능한 중약재 정보 제공
접속 주소	<a href="https://dep.mohw.gov.tw/DOCMAP/cp-754-39873-108.html">https://dep.mohw.gov.tw/DOCMAP/cp-754-39873-108.html</a>
정보 제공 건수	37건('24.11. 기준)
기타	법규 공고를 통해 pdf 파일로 제공되며 최신 공고는 2018년 2월 22일에 발효됨. 제·개정 상황에 따라 수시로 업데이트될 수 있음

● DB 접속 방법

- ‘위생복지부 중의약사’ 홈페이지 접속 후 ‘법령규장 카테고리(法令規章區)’ 클릭



Part 1.  
3. 생약

- ‘법령규장 카테고리’ 화면으로 이동 후 ‘중약업무 관련 법규(中藥業務相關法規)’ 클릭



- ‘중약업무 관련 법규’ 화면으로 이동 후 ‘식품에 동시 사용 가능한 중약재(可同時提供食品使用之中藥材)’ 클릭

...首頁 / 法令規章區 / 中藥業務相關法規

←

中藥業務相關法規

- 一般公告與法規
- 中藥材與飲片
- 中藥製劑藥品
- 可同時提供食品使用之中藥材
- 藥廠(商)管理
- 修法預告、草案
- 廣告
- 表單下載
- 異常物質限量基準

- 화면 이동 후 ‘식품에 동시 사용 가능한 중약재 품목 공고, 2018년 2월 22일 발효(公告「可同時提供食品使用之中藥材」品項, 自中華民國107年2月22日生效)’ 클릭

...首頁 / 法令規章區 / 中藥業務相關法規 / 可同時提供食品使用之中藥材

←

可同時提供食品使用之中藥材 顯示條件查詢

共 9 筆資料, 第 1/1 頁, 1

- 公告「可同時提供食品使用之中藥材」品項, 自中華民國107年2月22日生效。 107-02-14
- 訂定藥事法第二十一條第三款所稱「藥品中一部或全部含有污穢或異物者」, 於菊花、蓮子、白木耳、雞眼肉、烏梅乾、百合、枸杞、山萸、薄荷、艾實、山楂、肉豆蔻、草豆蔻、砂仁、黃芩、絞股藍(七葉膽)、小茴香及八角茴香等市售中藥材, 其異常物質限量基準及檢驗方法比照食品安全衛生管理等相關標準及規定, 並自中華民國一百零五年三月一日生效。 105-03-01
- 215種『可同時提供食品使用之中藥材』 102-06-10
- 公告增列蓮藕等21種品項為「可同時提供食品使用之中藥材」 102-06-10
- 公告『本草綱目』內之五穀雜糧、蔬果及畜牧漁獸類等一百六十一種品項「可同時提供食品使用之中藥材」 102-06-10

- 화면 이동 후 '식품에 동시 사용 가능한 중약재 품목(可同時提供食品使用之中藥材品項)' pdf 파일 다운로드

公告「可同時提供食品使用之中藥材」品項，自中華民國107年2月22日生效。

● 資料來源：中醫藥司 ● 建檔日期：107-02-14 ● 更新時間：107-02-14

發文日期：107年2月13日  
發文字號：衛部中字第1071860124號  
附件：如文

主旨：公告「可同時提供食品使用之中藥材」品項如附件，自中華民國一百零七年二月二十二日生效；行政院衛生署八十九年七月十五日衛署中會字第八九〇四〇一一九號、九十二年八月七日署授藥字第〇九二〇〇〇一五三四號、九十三年二月十日署授藥字第〇九三〇〇〇〇五四五號、九十五年三月二十四日署授藥字第〇九五〇〇〇〇八九五號、九十七年十一月二十四日署授藥字第〇九七〇〇〇三六九一號及一百零一年四月二十六日署授藥字第一〇一〇〇〇一六七〇號等六號公告，自同日停止適用。

附件下載

- 公告.pdf
- 總說明.pdf
- 可同時提供食品使用之中藥材品項.pdf

- ‘식품에 동시 사용 가능한 중약재 품목’ pdf 파일 실행

**「可同時提供食品使用之中藥材」品項**

序號	品名	基原	部位
1	百合	卷丹 <i>Lilium lancifolium</i> Thunb. 百合 <i>Lilium brownii</i> F. E. Brown var. <i>viridulum</i> Baker 細葉百合 <i>Lilium pomilum</i> DC.	乾燥內質鱗莖
2	荷葉	蓮 <i>Nelumbo nucifera</i> Gaertn.	乾燥葉
3	銀耳 (白木耳)	銀耳 <i>Tremella luciformis</i> Berk.	乾燥子實體
4	山藥	薯蕷 <i>Dioscorea opposita</i> Thunb. 懷柔薯蕷 <i>Dioscorea doryophora</i> Bance 基 陸 山 藥 <i>Dioscorea japonica</i> Thunb. var. <i>pseudojaponica</i> (Hay.) Yamam	乾燥根莖
5	生薑	薑 <i>Zingiber officinale</i> Rosc.	新鮮根莖
6	昆布	海帶 <i>Laminaria japonica</i> Aresch. 昆布 <i>Ecklonia kurama</i> Okun.	乾燥葉狀體
7	蒜	小根蒜 <i>Allium macrostemon</i> Bge. 蒜 <i>Allium chinense</i> G. Don.	乾燥鱗莖
8	馬齒莧	馬齒莧 <i>Portulaca oleracea</i> L.	乾燥地上部分
9	蒜 (小蒜)	小蒜 <i>Allium macrostemon</i> Bunge.	乾燥鱗莖
10	海藻	海蒿子 <i>Sargassum pallidum</i> (Turn.) C. Ag. 羊棲菜 <i>Sargassum fusiforme</i> (Harv.) Setch.	乾燥基體
11	小 茴 香 (子)	茴香 <i>Foeniculum vulgare</i> Mill.	乾燥成熟果實
12	八角茴香 (大茴香)	八角茴香 <i>Illicium verum</i> Hook. f.	乾燥成熟果實
13	薄荷	薄荷 <i>Ocimum basilicum</i>	全草
14	龍眼肉	龍眼 <i>Pinnocarpus longus</i> Lour. <i>Eugenia longus</i> (Lour.) Steudel (synonym) <i>Nephelium longanum</i> Cambess. (synonym)	乾燥之中果皮 及果肉
15	枸杞子	枸杞 <i>Lycium chinense</i> Mill. 寧夏枸杞 <i>Lycium barbarum</i> L.	乾燥果實
16	烏梅	梅 <i>Prunus mume</i> (Sieb.) Sieb. et Zucc.	乾燥近成熟果 實，經陳製而成

第 1 頁 / 共 3 頁

● 정보 제공 범위

- 식품에 동시 사용 가능한 중약재 품명, 기원, 부위 정보 제공



예시 | 중약재명: 백합

**「可同時提供食品使用之中藥材」品項**

序號	品名	基原	部位
1	① 百合	② 卷丹 <i>Lilium lancifolium</i> Thunb. 百合 <i>Lilium brownii</i> F. E. Brown var. <i>viridulum</i> Baker 細葉百合 <i>Lilium pumilum</i> DC.	③ 乾燥肉質鱗莖
2	荷葉	蓮 <i>Nelumbo nucifera</i> Gaertn.	乾燥葉
3	銀耳 (白木耳)	銀耳 <i>Tremella fuciformis</i> Berk.	乾燥子實體
4	山藥	薯蕷 <i>Dioscorea opposita</i> Thunb. 恆春薯蕷 <i>Dioscorea doryophora</i> Hance 基隆山藥 <i>Dioscorea japonica</i> Thunb. var. <i>pseudojaponica</i> (Hay.) Yamam	乾燥根莖
5	生薑	薑 <i>Zingiber officinale</i> Rosc.	新鮮根莖

① 품명: 백합(百合)

② 기원: 권단(卷丹) *Lilium lancifolium* Thunb.

백합(百合) *Lilium brownii* F. E. Brown var. *viridulum* Baker

세엽백합(細葉百合) *Lilium pumilum* DC.

③ 부위: 건조 육질 인경





+

## 3. 첨가물

## ■ 미국

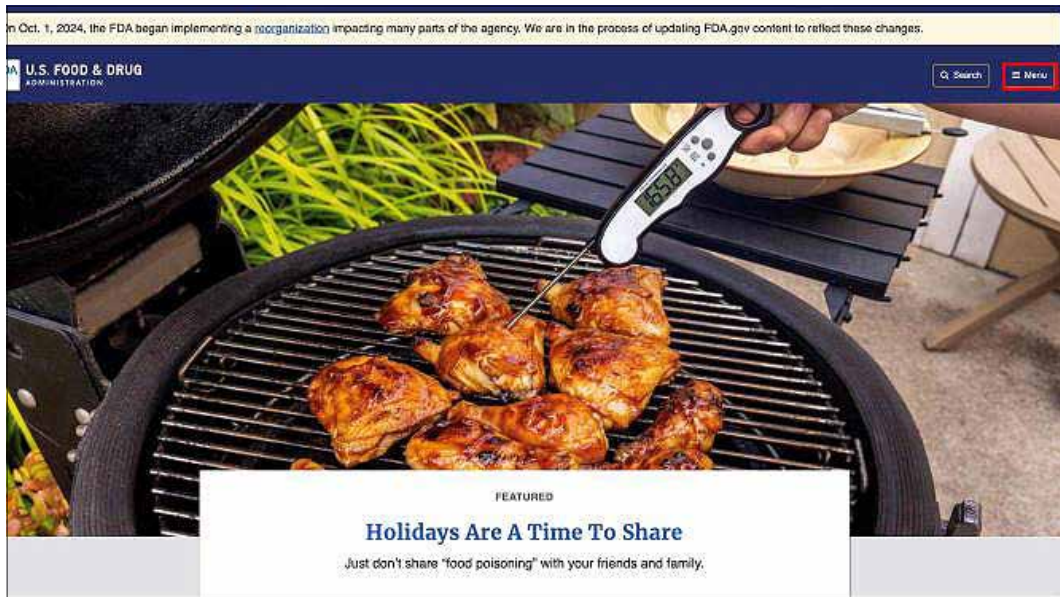
### [ 색소첨가물 규제 상태 ]

#### ● 개요

DB명	색소첨가물 규제 상태(Regulatory Status of Color Additives)
관리기관	식품의약품청(FDA)
DB 내용	색소첨가물 규제 상태를 표시하며 '영구등재', '임시등재', '삭제'로 구분하며, '영구등재', '임시등재' 구분만 지정 용도로 사용 허가
접속 주소	<a href="https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=ColorAdditives">https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=ColorAdditives</a>
정보 제공 건수	총 298건 중 식품 56건('24.11. 기준) - 영구등재 146건, 임시등재 2건, 삭제 150건

● DB 접속 방법

○ ‘FDA’ 메인 홈페이지 접속 후 우측 상단의 ‘메뉴(Menu)’ 클릭



○ ‘메뉴(Menu)’ 화면으로 이동 후 ‘Food’ 항목 클릭



Part 1.  
4.원 가 메

- ‘Food’ 화면에서 ‘성분&포장(Ingredients & Packaging)’ 항목 클릭

NAVIGATE THE FOOD SECTION

<p><a href="#">Labeling &amp; Nutrition</a></p> <p>Additional Facts Label, Label Claims, Menu &amp; Packaging Machine Labeling, Gluten-Free Labeling</p>	<p><a href="#">Ingredients &amp; Packaging</a></p> <p>Food &amp; Color Additives, GRAS, Food Allergens, Food Contact Substances, New Plant Varieties</p>	<p><a href="#">Food Defense</a></p> <p>Protecting the Food Supply, Intentional Adulteration, Food Defense Plan Builder</p>	<p><a href="#">Dietary Supplements</a></p> <p>Products &amp; Ingredients, New Dietary Ingredients Notification Process, Structure/Function Claim Notifications</p>
<p><a href="#">Science &amp; Research</a></p> <p>Laboratory Methods, Whole Genome Sequencing, Risk Analysis, Total Diet Study, Cancer Research</p>	<p><a href="#">Compliance &amp; Enforcement</a></p> <p>Reportable Food Registry, Warning Letters, Inspections, Compliance Programs, Adverse Event Reporting</p>	<p><a href="#">International &amp; Interagency Coordination</a></p> <p>International Outreach, Visitor's Program, Trade Agreements, Interagency Agreements</p>	<p><a href="#">Chemical Contaminants &amp; Pesticides</a></p> <p>Acrylamide, Arsenic, Chemical Contaminants, Toxins &amp; Pesticides in Food</p>
INDUSTRY GUIDANCE & REGULATION			
<p><a href="#">Guidance for Industry by Topic</a></p>	<p><a href="#">Imports &amp; Exports</a></p>	<p><a href="#">Registration of Food Facilities/Other Submissions</a></p>	<p><a href="#">Retail Food Protection</a></p>
<p><a href="#">Food Safety Modernization Act (FSMA)</a></p>	<p><a href="#">Hazard Analysis Critical Control Point (HACCP)</a></p>	<p><a href="#">Current Good Manufacturing Practices (CGMPs)</a></p>	<p><a href="#">Federal/State Food Program</a></p>

[Top](#)

- ‘성분&포장(Ingredients & Packaging)’ 화면에서 ‘모든성분&포장(All Ingredients & Packaging Inventories)’ 항목 클릭

- [Environmental Decisions](#)
- [Food from New Plant Varieties](#)
- [Human Food Made with Cultured Animal Cells](#)
- [Food Chemical Safety](#)

**Guidance**

- [Ingredients, Additives, GRAS, and Packaging Guidance](#)
- [Food Allergens Guidance](#)
- [Code of Federal Regulations Citations for Color Additives, Food Ingredients, and Packaging](#)

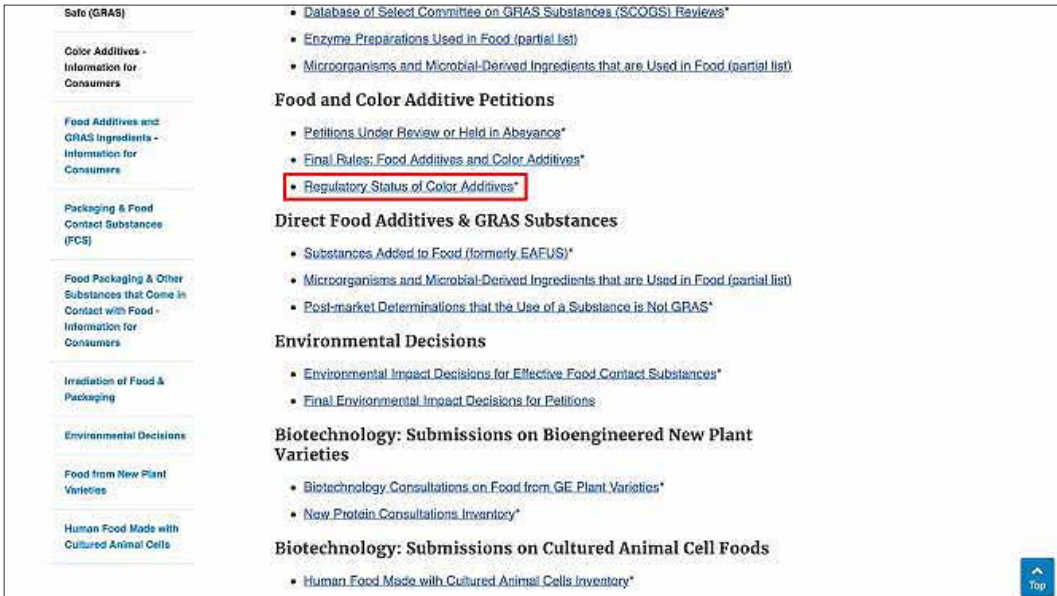
**Inventories**

- [All Ingredients & Packaging Inventories](#)
- [Substances Added to Food \(formerly EAFUS\)](#)
- [GRAS Notice Inventory](#)
- [Effective Food Contact Substance Notifications](#)
- [Inventory of Food Contact Substances Listed in 21 CFR](#)

**Related Content**

- [Overview of Food Ingredients, Additives & Colors](#) [↗](#) (archived)

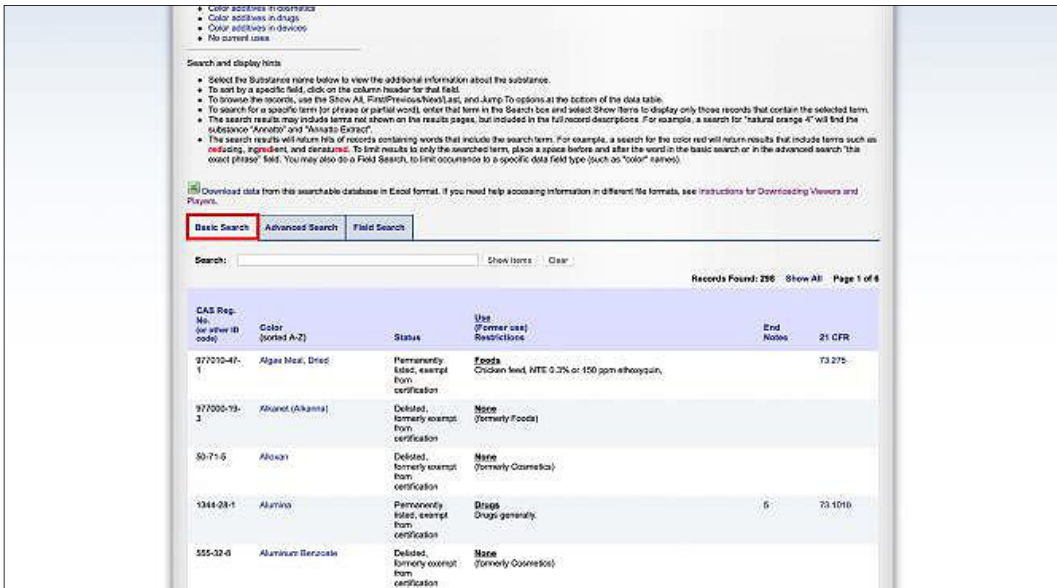
- ‘모든 성분&포장(All Ingredients & Packaging Inventories)’ 화면에서 ‘색소첨가물 규제 상태(Regulatory Status of Color Additives)’ 항목 클릭



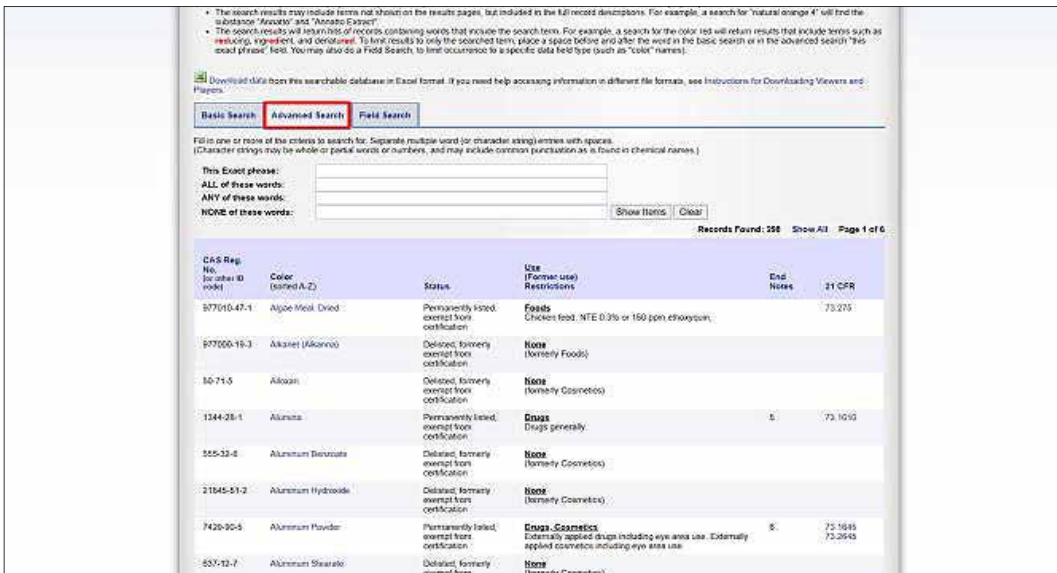
- 색소첨가물 규제 상태(Regulatory Status of Color Additives) 접속 완료



○ ‘기본검색(Basic Search)’, ‘고급검색(Advanced Search)’, ‘범주검색(Field Search)’ 기능 제공



○ ‘고급검색(Advanced Search)’에서는 완전 일치어구(ThisExactPhrase), 모든 단어 포함(All of these words), 하나라도 포함(Any of these words), 포함 시 제외(None of these words) 등의 기능 사용 가능



○ ‘범주검색(Field Search)’에서는 제공범위 범주를 선택해 검색 가능

Download data from this searchable database in Excel format. If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Basic Search   **Advanced Search**   **Field Search**

Choose a field to search. (An asterisk (\*) indicates that the field is found on an individual record's detail page and is not shown below.)

Field:  Show Items   Clear

Records Found: 298   Show All   Page 1 of 6

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes	21 CFR
977010-47-1	Algae Meal, Dried	Permanently listed, exempt from certifi-	<b>Food</b> Chicken feed, NTE 0.3% or 150 ppm ethoxyquin,		73.276
977001-19-3	Alkanet (Alkanet)	Deleted, formerly exempt from certification	<b>None</b> (Formerly Foods)		
50-71-5	Alkoxan	Deleted, formerly exempt from certification	<b>None</b> (Formerly Cosmetics)		
1344-28-1	Alumina	Permanently listed, exempt from certification	<b>Drug</b> Drugs generally;	5	73.1010
555-32-8	Aluminum Benzoin	Deleted, formerly exempt from certification	<b>None</b> (Formerly Cosmetics)		
21945-51-2	Aluminum Hydroxide	Deleted, formerly exempt from certification	<b>None</b> (Formerly Cosmetics)		
7420-93-5	Aluminum Powder	Permanently listed, exempt from certification	<b>Drug, Cosmetics</b> Externally applied drugs including eye area use. Externally applied cosmetics including eye area use	6	73.1645 73.2545
837-12-7	Aluminum Silicate	Deleted, formerly exempt from certification	<b>None</b> (Formerly Cosmetics)		
1323-03-4	Aniseed Extract / Aniseed	Permanently listed, exempt from certification	<b>Food, Drug, Cosmetics</b> Foods generally, insected drugs generally, external drugs	5, 6	73.1000 73.2030

○ ‘검색(Search)’에 검색하고자 하는 원료의 영문 명칭 입력 후 ‘결과보기(Show Items)’ 버튼 클릭

Search and display hints

- Select the Substance name below to view the additional information about the substance.
- To sort by a specific field, click on the column header for that field.
- To browse the records, use the Show All, First/Previous/Next/Last, and Jump To options at the bottom of the data table.
- To search for a specific term (or phrase or partial word), enter that term in the Search box and select Show Items to display only those records that contain the selected term.
- The search results may include terms not shown on the results pages, but included in the full record descriptions. For example, a search for "natural orange 4" will find the substance "Anatto" and "Anatto Extract".
- The search results will return hits of records containing words that include the search term. For example, a search for the color red will return results that include terms such as redness, pigment, and denatured. To limit results to only the searched term, place a space before and after the word in the basic search or in the advanced search "this exact phrase" field. You may also do a Field Search, to limit occurrence to a specific data field type (such as "color" names).

Download data from this searchable database in Excel format. If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Basic Search   **Advanced Search**   **Field Search**

Search:  Show Items   Clear

Records Found: 298   Show All   Page 1 of 6

CAS Reg. No. (or other ID code)	Color (sorted A-Z)	Status	Use (Former use) Restrictions	End Notes	21 CFR
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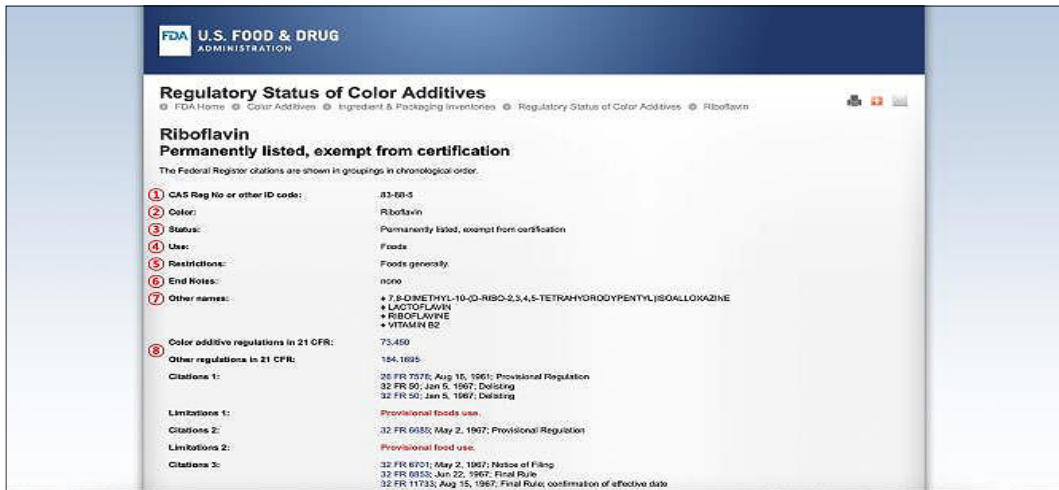
Part 1  
4.원 가 명

● 정보 제공 범위

- CAS 등록번호, 색소(물질명), 규제상태, 사용용도(과거용도) 및 제한사항, 주석, 관련 21 CFR 규정 등의 정보제공



예시 | 원료명: Vitamin B2



- ① CAS 등록번호: 83-88-5
- ② 색소(물질명): Riboflavin
- ③ 규제상태: 영구 등재(Permanently listed) 및 인증 면제(Exempt from certification)
- ④ 사용용도(과거용도): 식품(Food)
- ⑤ 제한사항: 일반적으로 식품(Foods generally)
- ⑥ 주석: 없음
- ⑦ 동의어
  - 7,8-DIMETHYL-10-(D-RIBO-2,3,4,5 TETRAHYDRODYPENTYL) ISOALLOXAZINE
  - LACTOFLAVIN
  - RIBOFLAVINE
  - VITAMIN B2
- ⑧ 관련 21 CFR 규정: 73.450
  - 기타 21 CFR 규정: 184.1695
  - Citation은 4차례에 걸쳐 수정
  - Limitations 1, 2: Provisional foods에만 사용 가능
  - Limitations 3: GMP 하에서 일반 식품에 사용 가능
  - Limitations 4: 식품화학물질규격(Food Chemicals Codex)에 명시된 규격을 준수해야 함

<b>Citations 4:</b>	49 FR 3704; Jan 30, 1984; Incorporation by Reference, proposed updating of list 49 FR 10087 (at 10089); Mar 19, 1984, Final Rule 49 FR 23002; Jun 5, 1984, Final Rule, confirmation of effective date
<b>Limitations 4:</b>	<b>Food use:</b> Incorporated by reference the Food Chemicals Codex, 5d Ed. (1981), identify, specifications; no substantive changes to regulations.
<b>EEC No.:</b>	E101
<b>9 Definitions of Terms Used</b>	<ul style="list-style-type: none"> <li>• <b>FDI</b> Food Inspection Decision (issued by USDA prior to 1927)</li> <li>• <b>CAS Reg. No. or other ID</b> Chemical Abstract Service (CAS) Registry® Number for the substance or a numerical code assigned by CFSAN (077mm-rrn-series) to those substances that do not have a CAS Reg. No.</li> <li>• <b>Other Names</b> Recognized synonyms for color additives</li> <li>• <b>Lakes</b> Insoluble pigments formed by chemically reacting water-soluble straight colors with precipitants and substrata.</li> </ul>
<b>10 End Notes</b>	<ol style="list-style-type: none"> <li>1. The color additives <i>Azarcote</i>, <i>Irill meal</i>, <i>Azoxanthin</i>, <i>Azoxanthin dimethylsuccinate</i>, <i>Ultramarine blue</i>, <i>Certhaxanthin</i>, <i>Haematochromum algae meal</i>, <i>Synthetic iron oxide</i>, <i>Dried algae meal</i>, <i>Tagetes (Azoo marigold) meal and extract</i>, <i>Corn endosperm oil</i>, <i>Paraoxocoumarin</i>, and <i>PhaPa yeast</i> are approved for specific uses in animal food (see 21 CFR 73.32, 73.35, 73.37, 73.50, 73.75, 73.165, 73.200, 73.215, 73.255, 73.315, 73.352, and 73.355, respectively).</li> <li>2. The year approved is based on the date listed in the "Confirmation of Effective Date" notice for the action as published in the Federal Register.</li> <li>3. Withdrawn for use after the 1960 amendments; never provisionally listed.</li> <li>4. Color additives listed in 21 CFR Parts 74 and 82 must be analyzed and batch certified by FDA before they can be used in any FDA-regulated product marketed in the U.S. This requirement applies to products imported into this country as well as those manufactured domestically. Manufacturers of certified color additives must include on the label the name of the certified color additive, a statement indicating general use limitations, any quantitative limitations in products, and the certification lot number assigned to the batch. Straight colors required to be certified are listed in 21 CFR Part 74. Most lakes are provisionally listed under 21 CFR 81.1 for use as listed in 21 CFR 82.51 (food, drugs, and cosmetics), 21 CFR 82.1091 (drugs and cosmetics), or 21 CFR 82.2051 (externally applied drugs and cosmetics). All FD&amp;C Red No. 40 lakes are permanently listed under 21 CFR 74.345 (food), 74.1340 (drugs), and 74.2340 (cosmetics); FD&amp;C Blue No. 1 and FD&amp;C Yellow No. 5 aluminum lakes for drug and cosmetic use are permanently listed in 21 CFR sections 74.1101, 74.1705, 74.2101, and 74.2705.</li> <li>5. Color additives that are permitted for general use may not be used in the area of the eye, in injections, or in surgical sutures unless such use is specified in the color additive listing regulation. Currently no color additives are listed for use in injected products (such as tattoos or permanent makeup).</li> <li>6. Color additives that are permitted for external application may not be used in the area of the eye, in injections, or in surgical sutures unless such use is specified in the color additive listing regulation. Currently no color additives are listed for use in injected products (such as tattoos or permanent makeup). Some color additives that are permitted for external application also may be permitted in mouthwashes, dentifrices, or lipsticks in limited amounts specified in the color additive listing regulation.</li> <li>7. N/E - not to exceed.</li> <li>8. The listed color additives are the reaction products produced by copolymerizing the reactive dyes with various monomers such that the dyes are chemically bound in the resulting polymer matrix.</li> </ol>
<p>Page Last Updated: 10/30/2024          Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.          Language Assistance Available: Español   繁體中文   Tiếng Việt   한국어   Tagalog   Русский   العربية   Кreyòl Ayisyen   Français   Polski   Português   Italiano   Deutsch   日本語   العربية   English</p>	

⑨ 사용된 용어 설명

- 식품 검사 결정(Food Inspection Decision)
- 화학물질 등록번호[Chemical Abstract Service Registry Number(CAS)]
- 다른이름
- LAKE

⑩ 각주

## ■ 캐나다

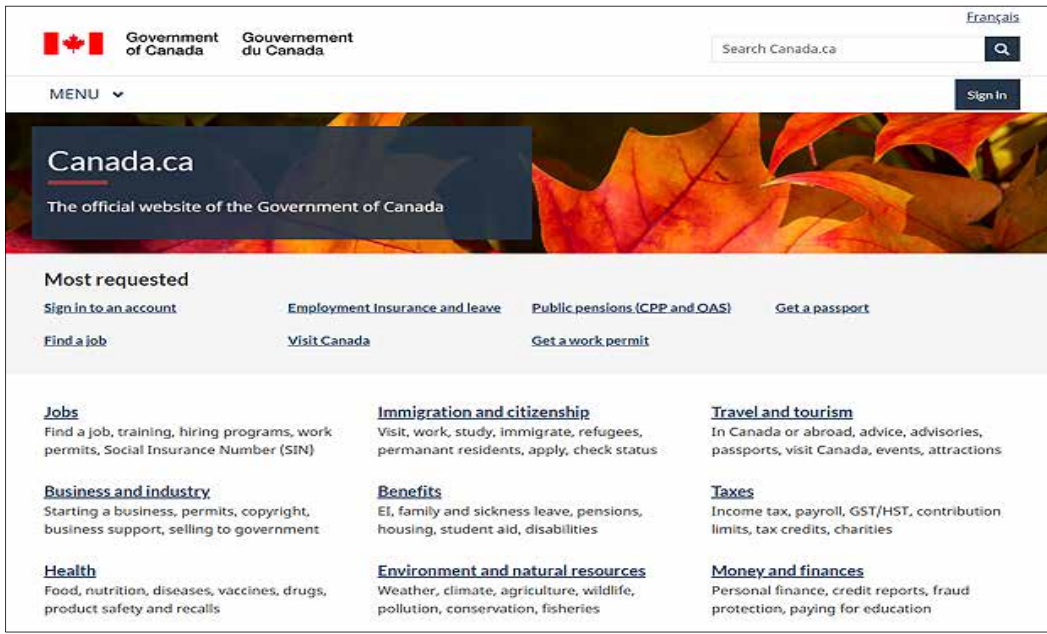
### [ 허용된 식품첨가물(고결방지제) 목록 ]

#### ● 개요

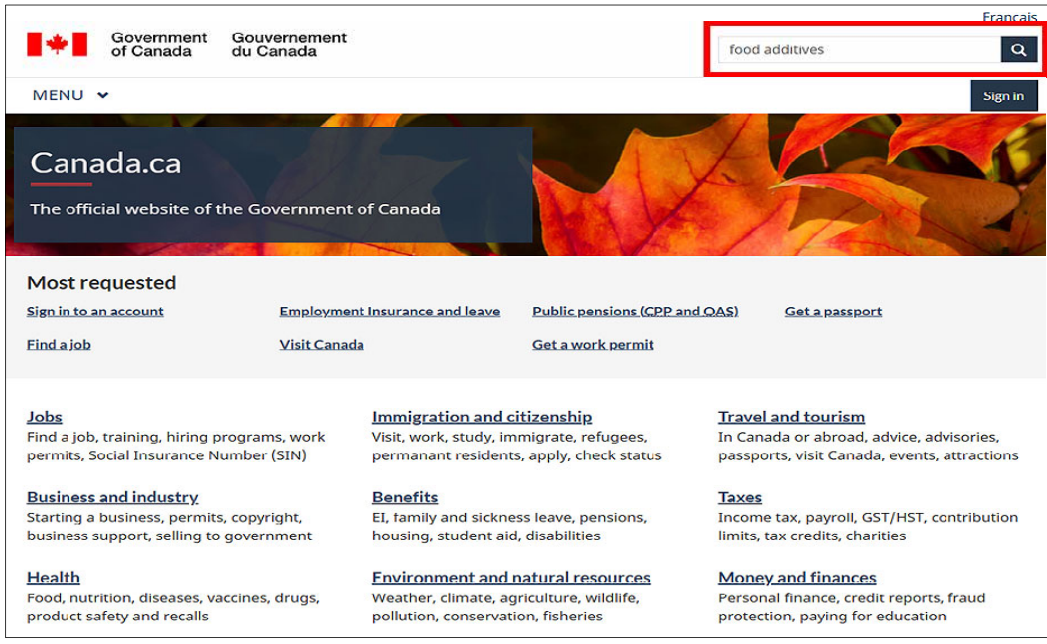
DB명	허용 식품첨가물 목록 - 허용된 고결방지제 목록
관리기관	캐나다 보건부(HC)
DB 내용	허용된 식품첨가물 목록, 첨가 허용 식품, 허용기준 및 조건
접속 주소	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/1-antickaking-agents.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/1-antickaking-agents.html</a>
정보 제공 건수	15건('24.11. 기준)

● DB 접속 방법

○ 캐나다 보건부 'Health Canada' 접속



○ 우측 상단란에 'Food Additives' 검색



○ ‘Food Additives’ 클릭

**Search results**

food additives

Don't include personal information (telephone, email, SIN, financial, medical, or work details).

55,888 search results for "food additives"

**Food Additives**

Health Canada

<https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives.html>

Dec 14, 2016 - ... and their regulation in Canada. What is a **food additive**? How are **food additives** regulated? **Food** colour labelling Specific Topics on **Food Additives** In this section ... **food** ingredients such as salt, sugar, starch; ... **Food additives** must be of suitable quality, must be effective for their intended purpose, and, when used according to the ...

○ ‘Lists of Permitted Food Additives’ 클릭

Government of Canada / Gouvernement du Canada

Search Canada.ca

Franglais

MENU

Canada.ca > Departments and agencies > Health Canada > Food and nutrition > Food Safety

**Food Safety**

- Chemical Contaminants
- Food Additives**
- Caffeine in Foods
- ARCHIVED - Food Additive Dictionary
- Lists of Permitted Food Additives
- Sugar Substitutes
- ARCHIVED - Health Canada Requests Information from Industry on the Use of Aluminum-Containing Food Additives
- ARCHIVED - Health Canada Review of Dietary Exposure to Aluminum
- Questions and Answers

**Food Additives**

This section provides information on food additives and their regulation in Canada.

[What is a food additive?](#)

[How are food additives regulated?](#)

[Food colour labelling](#)

[Specific Topics on Food Additives](#)

**In this section**

- [Food Additive Submission Preparation - Abridged Guidance](#)
- **[Lists of Permitted Food Additives](#)**
  - [Transition Guide: Understanding and Using the Lists of Permitted Food Additives](#)
- [Food Additive Dictionary](#)
- [Policy for Differentiating Food Additives and Processing Aids](#)
- [August 2016 - Results of the Consultation on the Food Directorate's Proposed Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods](#)
- (2016) [The Food Directorate's Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods](#)
- [Priority Scheduling and Expedited Handling of Submissions that have the Capacity to](#)

- 해당 목록 클릭

## Lists

- [1. List of Permitted Anticaking Agents](#)
- [2. List of Permitted Bleaching, Maturing or Dough Conditioning Agents](#)
- [3. List of Permitted Colouring Agents](#)
- [4. List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#)
- [5. List of Permitted Food Enzymes](#)
- [6. List of Permitted Firming Agents](#)
- [7. List of Permitted Glazing or Polishing Agents](#)
- [8. List of Permitted Food Additives with Other Accepted Uses](#)
- [9. List of Permitted Sweeteners](#)
- [10. List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents](#)
- [11. List of Permitted Preservatives](#)
- [12. List of Permitted Sequestering Agents](#)
- [13. List of Permitted Starch Modifying Agents](#)
- [14. List of Permitted Yeast Foods](#)
- [15. List of Permitted Carrier or Extraction Solvents](#)

[Archived Lists](#)

● 정보 제공 범위

- 허용된 식품첨가물 목록, 첨가 허용 식품, 최대허용기준 및 조건



예시 | 원료명: 칼슘 알루미늄 실리케이트

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
C.1	Calcium Aluminum Silicate	(1) Salt	(1) 1.0%, except in the case of fine grained salt 2.0%, in accordance with the requirement of paragraph B.17.001(1)(a)
		(2) Garlic salt; Onion salt	(2) 2.0% in accordance with the requirements of paragraphs B.07.020(b) and B.07.027(b) respectively
		(3) Unstandardized dry mixes	(3) Good Manufacturing Practice

항목 번호	식품첨가물	첨가 허용 식품 또는 물질	최대허용기준 및 조건
C.1	칼슘 알루미늄 실리케이트	(1) 소금	(1) 1.0%, 단, 미세 입자 소금의 경우 B.17.001(1)(a)의 요구사항에 따라 2.0%
		(2) 마늘소금, 양파소금	(2) B.07.020(b) 및 B.07.027(b)의 요구사항에 따라 2.0%
		(3) 비표준 건조 혼합물	(3) GMP 기준

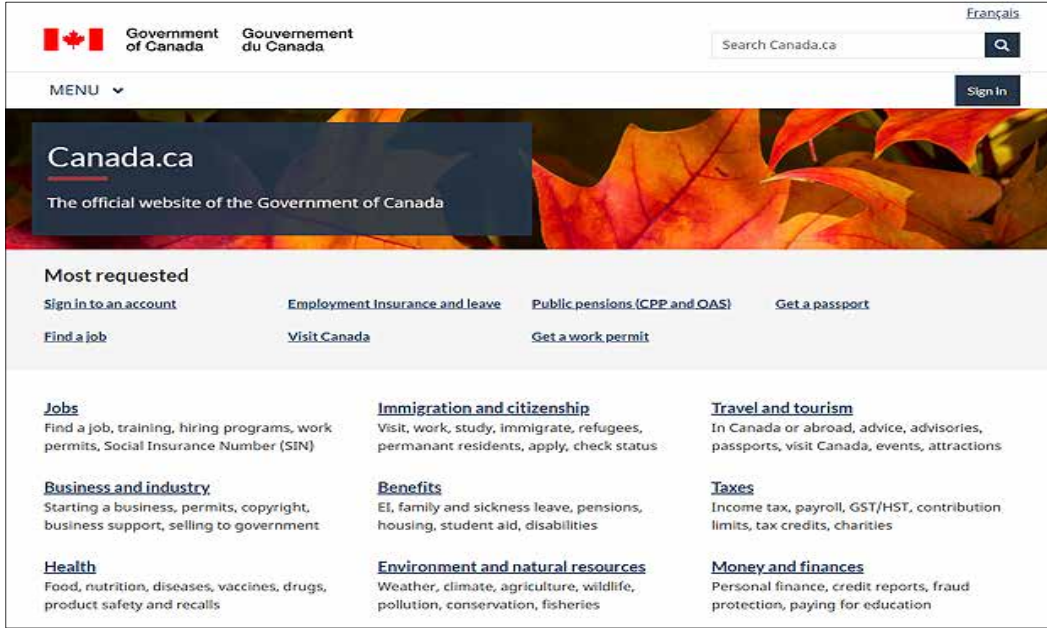
## [ 허용된 식품첨가물(밀가루 개량제) 목록 ]

### ● 개요

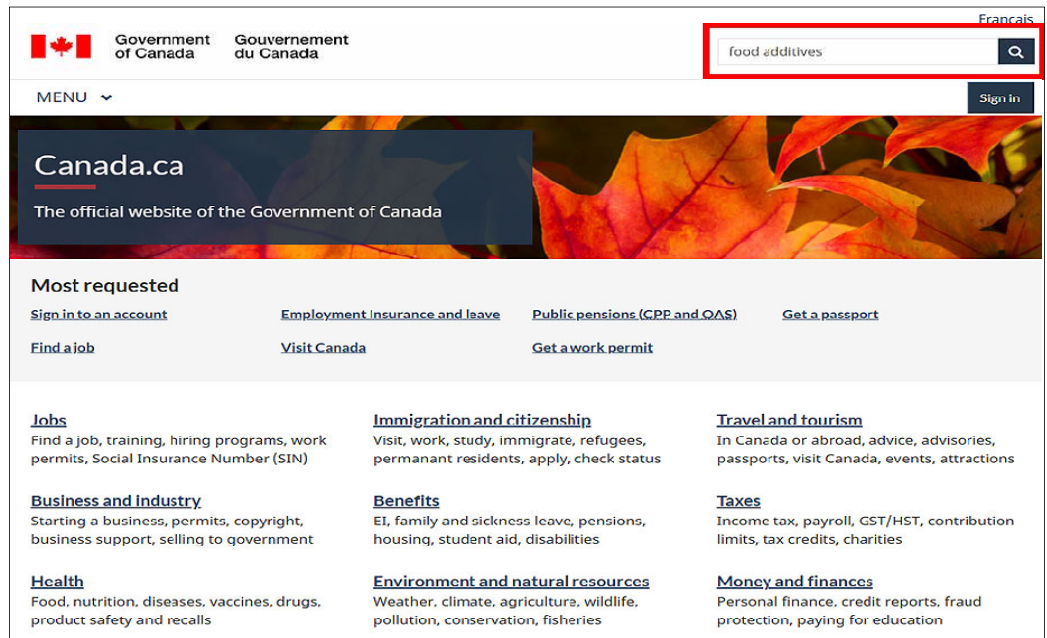
<b>DB명</b>	허용 식품첨가물 목록 - 허용된 밀가루 개량제 목록
<b>관리기관</b>	캐나다 보건부(HC)
<b>DB 내용</b>	허용된 식품첨가물 목록, 첨가 허용 식품, 허용기준 및 조건
<b>접속 주소</b>	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/2-bleaching-maturing-dough-conditioning-agents.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/2-bleaching-maturing-dough-conditioning-agents.html</a>
<b>정보 제공 건수</b>	16건('24.11. 기준)

● DB 접속 방법

○ 캐나다 보건부 'Health Canada' 접속



○ 우측 상단란에 'Food Additives' 검색



○ ‘Food Additives’ 클릭

**Search results**

food additives

Don't include personal information (telephone, email, SIN, financial, medical, or work details).

55,888 search results for "food additives"

**Food Additives**

Health Canada

<https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives.html>

Dec 14, 2016 - ... and their regulation in Canada. What is a **food additive**? How are **food additives** regulated? **Food** colour labelling Specific Topics on **Food Additives** In this section ... **food** ingredients such as salt, sugar, starch; ... **Food additives** must be of suitable quality, must be effective for their intended purpose, and, when used according to the ...

○ ‘Lists of Permitted Food Additives’ 클릭

Government of Canada / Gouvernement du Canada

Search Canada.ca

Franglais

MENU

Canada.ca > Departments and agencies > Health Canada > Food and nutrition > Food Safety

**Food Safety**

- Chemical Contaminants
- Food Additives**
- Caffeine in Foods
- ARCHIVED - Food Additive Dictionary
- Lists of Permitted Food Additives
- Sugar Substitutes
- ARCHIVED - Health Canada Requests Information from Industry on the Use of Aluminum-Containing Food Additives
- ARCHIVED - Health Canada Review of Dietary Exposure to Aluminum
- Questions and Answers

**Food Additives**

This section provides information on food additives and their regulation in Canada.

[What is a food additive?](#)  
[How are food additives regulated?](#)  
[Food colour labelling](#)  
[Specific Topics on Food Additives](#)

**In this section**

- [Food Additive Submission Preparation - Abridged Guidance](#)
- **[Lists of Permitted Food Additives](#)**
  - [Transition Guide: Understanding and Using the Lists of Permitted Food Additives](#)
- [Food Additive Dictionary](#)
- [Policy for Differentiating Food Additives and Processing Aids](#)
- [August 2016 - Results of the Consultation on the Food Directorate's Proposed Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods](#)
- [\(2016\) The Food Directorate's Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods](#)
- [Priority Scheduling and Expedited Handling of Submissions that have the Capacity to](#)

Part 1  
4. 원 가 문

○ 해당 목록 클릭

### Lists

1. [List of Permitted Anticaking Agents](#)
2. [List of Permitted Bleaching, Maturing or Dough Conditioning Agents](#)
3. [List of Permitted Colouring Agents](#)
4. [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#)
5. [List of Permitted Food Enzymes](#)
6. [List of Permitted Firming Agents](#)
7. [List of Permitted Glazing or Polishing Agents](#)
8. [List of Permitted Food Additives with Other Accepted Uses](#)
9. [List of Permitted Sweeteners](#)
10. [List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents](#)
11. [List of Permitted Preservatives](#)
12. [List of Permitted Sequestering Agents](#)
13. [List of Permitted Starch Modifying Agents](#)
14. [List of Permitted Yeast Foods](#)
15. [List of Permitted Carrier or Extraction Solvents](#)

[Archived Lists](#)

● 정보 제공 범위

- 허용된 식품첨가물 목록, 첨가 허용 식품, 최대허용기준 및 조건

**예시** | 원료명: 아세톤 퍼옥사이드

List of Permitted Bleaching, Maturing or Dough Conditioning Agents			
Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
A.1	Acetone Peroxide	(1) Bread; Flour; Whole wheat flour	(1) Good Manufacturing Practice
		(2) Unstandardized bakery products	(2) Good Manufacturing Practice

항목 번호	식품첨가물	첨가 허용 식품 또는 물질	최대허용기준 및 조건
A.1	아세톤 퍼옥사이드	(1) 빵, 밀가루, 통밀가루 (2) 비표준 베이커리 제품	(1) GMP 기준 (2) GMP 기준

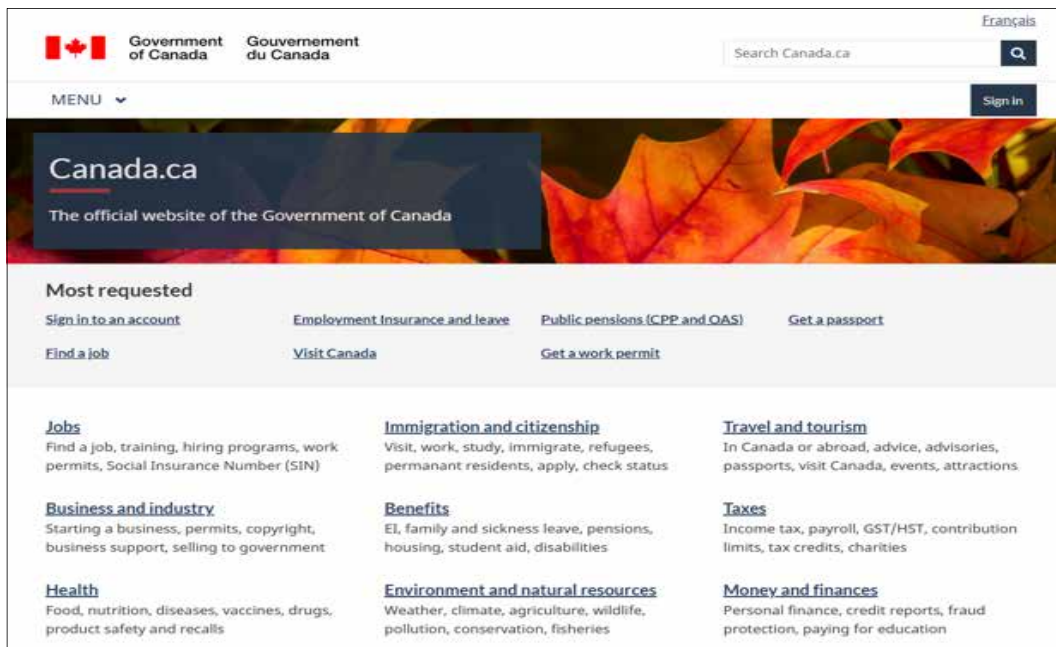
## [ 허용된 식품첨가물(색소) 목록 ]

### ● 개요

<b>DB명</b>	허용 식품첨가물 목록 - 허용된 색소 목록
<b>관리기관</b>	캐나다 보건부(HC)
<b>DB 내용</b>	허용된 식품첨가물 목록, 첨가 허용 식품, 허용기준 및 조건
<b>접속 주소</b>	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/3-coloring-agents.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/3-coloring-agents.html</a>
<b>정보 제공 건수</b>	-

### ● DB 접속 방법

#### ○ 캐나다 보건부 'Health Canada' 접속



○ 우측 상단란에 'Food Additives' 검색

Government of Canada / Gouvernement du Canada

food additives

Canada.ca  
The official website of the Government of Canada

Most requested

Sign in to an account   Employment Insurance and leave   Public pensions (CPP and OAS)   Get a passport

Find a job   Visit Canada   Get a work permit

**Jobs**  
Find a job, training, hiring programs, work permits, Social Insurance Number (SIN)

**Immigration and citizenship**  
Visit, work, study, immigrate, refugees, permanent residents, apply, check status

**Travel and tourism**  
In Canada or abroad, advice, advisories, passports, visit Canada, events, attractions

**Business and industry**  
Starting a business, permits, copyright, business support, selling to government

**Benefits**  
EI, family and sickness leave, pensions, housing, student aid, disabilities

**Taxes**  
Income tax, payroll, GST/HST, contribution limits, tax credits, charities

**Health**  
Food, nutrition, diseases, vaccines, drugs, product safety and recalls

**Environment and natural resources**  
Weather, climate, agriculture, wildlife, pollution, conservation, fisheries

**Money and finances**  
Personal finance, credit reports, fraud protection, paying for education

○ 'Food Additives' 클릭

Search results

food additives

Don't include personal information (telephone, email, SIN, financial, medical, or work details).

55,888 search results for "food additives"

**Food Additives**  
Health Canada

https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives.html

Dec 14, 2016 - ... and their regulation in Canada. What is a **food additive**? How are **food additives** regulated? **Food** colour labelling Specific Topics on **Food Additives** In this section ... **food** ingredients such as salt, sugar, starch; ... **Food additives** must be of suitable quality, must be effective for their intended purpose, and, when used according to the ...

○ ‘Lists of Permitted Food Additives’ 클릭

The screenshot shows the Government of Canada website. At the top, there is a search bar and the text 'Français'. Below the search bar is a 'MENU' dropdown. The breadcrumb trail reads: 'Canada.ca > Departments and agencies > Health Canada > Food and nutrition > Food Safety'. On the left, a sidebar menu lists various categories under 'Food Safety', with 'Food Additives' selected. The main content area is titled 'Food Additives' and includes a description, several informational links, and a section titled 'In this section' which contains a bulleted list of resources. The link 'Lists of Permitted Food Additives' is highlighted with a red box, and a sub-link 'Transition Guide: Understanding and Using the Lists of Permitted Food Additives' is also visible.

○ 해당 목록 클릭

The screenshot shows a page titled 'Lists' containing a numbered list of 15 links. The third link, 'List of Permitted Colouring Agents', is highlighted with a red box. Below the list is a link for 'Archived Lists'.

- [1. List of Permitted Anticaking Agents](#)
- [2. List of Permitted Bleaching, Maturing or Dough Conditioning Agents](#)
- [3. List of Permitted Colouring Agents](#)
- [4. List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#)
- [5. List of Permitted Food Enzymes](#)
- [6. List of Permitted Firming Agents](#)
- [7. List of Permitted Glazing or Polishing Agents](#)
- [8. List of Permitted Food Additives with Other Accepted Uses](#)
- [9. List of Permitted Sweeteners](#)
- [10. List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents](#)
- [11. List of Permitted Preservatives](#)
- [12. List of Permitted Sequestering Agents](#)
- [13. List of Permitted Starch Modifying Agents](#)
- [14. List of Permitted Yeast Foods](#)
- [15. List of Permitted Carrier or Extraction Solvents](#)

[Archived Lists](#)

Part 1.  
4. 원 가 문

● 정보 제공 범위

- 허용된 식품첨가물 목록, 첨가 허용 식품, 최대허용기준 및 조건



예시 | 원료명: 1번 항목의 허용된 착색제 및 첨가 허용 식품

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
1.	Alkanet; Aluminum Metal; Annatto; Anthocyanins; Beet Red; Canthaxanthin; Carbon Black; Carotene; Charcoal; Chlorophyll; Cochineal; Iron Oxide; Orchil; Paprika; Riboflavin; Saffron; Saunderswood; Silver Metal; Titanium Dioxide; Turmeric; Xanthophyll	(1) Apple (or rhubarb) and (naming the fruit) jam; Bread; Butter; Concentrated (naming the fruit) juice except frozen concentrated orange juice; Fig marmalade with pectin; Fish roe (caviar); Ice cream mix; Ice milk mix; Icing sugar; Liqueur; Lobster paste; (naming the flavour) Milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Partly skimmed milk with added milk solids; (naming the flavour) Skim milk; (naming the flavour) Skim milk with added milk solids; (naming the fruit) Jam with pectin; (naming the fruit) Jelly with pectin; Pickles; Pineapple marmalade with pectin; Relishes; Sherbet; Smoked fish; Tomato catsup	(1) Good Manufacturing Practice
		(2) Unstandardized foods	(2) Good Manufacturing Practice
		(3) A blend of prepared fish and prepared meat referred to in paragraph B.21.006(n)	(3) Good Manufacturing Practice

항목번호	식품첨가물	첨가 허용 식품 또는 물질	최대허용기준 및 조건
1	알카넷 알루미늄 금속 안나토 안토시아닌 비트 레드 캔타잔틴 카본 블랙 카로틴 숯 엽록소 코치닐 산화철 오르칠 파프리카 리보플라빈 사프란 산더스우드 은 금속 이산화티타늄 강황 잔토펜	(1) 사과 또는 (루바브)잼 (과일)잼; 빵; 버터; 농축 과일 주스(냉동 농축 오렌지 주스 제외); 펙틴 함유 무화과 잼; 어란(캐비어); 아이스크림 믹스; 아이스 밀크 믹스; 설탕 아이싱; 리큐어; 바닷가재 페이스트; (맛 명시한)우유; (맛 명시한)저지방 우유; 저지방 우유 + 우유; (맛 명시한)고형분; (맛 명시한)탈지유; (맛 명시한)탈지유 + 우유 고형분; 펙틴 함유 과일 잼; 펙틴 함유 과일 젤리; 피클; 펙틴 함유 파인애플 잼; 렐리시; 소스; 셔벗; 훈제 생선; 토마토 케첩	(1) GMP 기준
		(2) 비표준 식품	(2) GMP 기준
		(3) B.21.006(n) 항에 명시된 준비된 생선 및 육류 혼합물	(3) GMP 기준

## [ 허용된 식품첨가물(유화제, 겔화제, 안정제 및 증점제) 목록 ]

### ● 개요

<b>DB명</b>	허용 식품첨가물 목록 - 허용된 유화제, 겔화제, 안정제 및 증점제 목록
<b>관리기관</b>	캐나다 보건부(HC)
<b>DB 내용</b>	허용된 식품첨가물 목록, 첨가 허용 식품, 허용기준 및 조건
<b>접속 주소</b>	https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/4-emulsifying-gelling-stabilizing-thickening-agents.html
<b>정보 제공 건수</b>	-

### ● DB 접속 방법

#### ○ 캐나다 보건부 'Health Canada' 접속

The screenshot shows the official website of the Government of Canada. At the top, there is a header with the Canadian flag, the text 'Government of Canada / Gouvernement du Canada', a search bar with 'Search Canada.ca', and a 'Français' language selector. Below the header is a 'MENU' dropdown and a 'Sign In' button. The main content area features a large banner with the text 'Canada.ca The official website of the Government of Canada'. Below the banner, there is a 'Most requested' section with links for 'Sign in to an account', 'Find a job', 'Employment Insurance and leave', 'Visit Canada', 'Public pensions (CPP and OAS)', 'Get a work permit', and 'Get a passport'. The bottom section is organized into a grid of service categories: 'Jobs', 'Business and industry', 'Health', 'Immigration and citizenship', 'Benefits', 'Environment and natural resources', 'Travel and tourism', 'Taxes', and 'Money and finances', each with a brief description of the services provided.

○ 우측 상단란에 'Food Additives' 검색

Government of Canada / Gouvernement du Canada

Francis

food additives

MENU

Sign in

Canada.ca  
The official website of the Government of Canada

**Most requested**

- [Sign in to an account](#)
- [Employment Insurance and leave](#)
- [Public pensions \(CPP and OAS\)](#)
- [Get a passport](#)
- [Find a job](#)
- [Visit Canada](#)
- [Get a work permit](#)

<p><b>Jobs</b> Find a job, training, hiring programs, work permits, Social Insurance Number (SIN)</p>	<p><b>Immigration and citizenship</b> Visit, work, study, immigrate, refugees, permanent residents, apply, check status</p>	<p><b>Travel and tourism</b> In Canada or abroad, advice, advisories, passports, visit Canada, events, attractions</p>
<p><b>Business and industry</b> Starting a business, permits, copyright, business support, selling to government</p>	<p><b>Benefits</b> EI, family and sickness leave, pensions, housing, student aid, disabilities</p>	<p><b>Taxes</b> Income tax, payroll, GST/HST, contribution limits, tax credits, charities</p>
<p><b>Health</b> Food, nutrition, diseases, vaccines, drugs, product safety and recalls</p>	<p><b>Environment and natural resources</b> Weather, climate, agriculture, wildlife, pollution, conservation, fisheries</p>	<p><b>Money and finances</b> Personal finance, credit reports, fraud protection, paying for education</p>

○ 'Food Additives' 클릭

**Search results**

food additives

Don't include personal information (telephone, email, SIN, financial, medical, or work details).

55,888 search results for "food additives"

**Food Additives**

Health Canada

<https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives.html>

Dec 14, 2016 - ... and their regulation in Canada. What is a **food additive**? How are **food additives** regulated? **Food** colour labelling Specific Topics on **Food Additives** In this section ... **food** ingredients such as salt, sugar, starch; ... **Food additives** must be of suitable quality, must be effective for their intended purpose, and, when used according to the ...

○ ‘Lists of Permitted Food Additives’ 클릭

The screenshot shows the Government of Canada website. The breadcrumb trail is: Canada.ca > Departments and agencies > Health Canada > Food and nutrition > Food Safety. The main heading is 'Food Additives'. Below it, there is a list of links: 'What is a food additive?', 'How are food additives regulated?', 'Food colour labelling', and 'Specific Topics on Food Additives'. Under 'In this section', there is a list of links, with 'Lists of Permitted Food Additives' highlighted in a red box. Below this link is a sub-link: 'Transition Guide: Understanding and Using the Lists of Permitted Food Additives'. Other links in the list include 'Food Additive Submission Preparation - Abridged Guidance', 'Food Additive Dictionary', 'Policy for Differentiating Food Additives and Processing Aids', 'August 2016 - Results of the Consultation on the Food Directorate's Proposed Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods', '(2016) The Food Directorate's Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods', and 'Priority Scheduling and Expedited Handling of Submissions that have the Capacity to...'. On the left side, there is a navigation menu with 'Food Additives' selected.

○ 해당 목록 클릭

The screenshot shows a list of 15 links under the heading 'Lists'. The 4th link, 'List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents', is highlighted with a red box. The list includes: 1. List of Permitted Anticaking Agents, 2. List of Permitted Bleaching, Maturing or Dough Conditioning Agents, 3. List of Permitted Colouring Agents, 4. List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents, 5. List of Permitted Food Enzymes, 6. List of Permitted Firming Agents, 7. List of Permitted Glazing or Polishing Agents, 8. List of Permitted Food Additives with Other Accepted Uses, 9. List of Permitted Sweeteners, 10. List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents, 11. List of Permitted Preservatives, 12. List of Permitted Sequestering Agents, 13. List of Permitted Starch Modifying Agents, 14. List of Permitted Yeast Foods, 15. List of Permitted Carrier or Extraction Solvents. Below the list is a link for 'Archived Lists'.

Part 1.  
4.원 가  
문

● 정보 제공 범위

- 허용된 식품첨가물 목록, 첨가 허용 식품, 최대허용기준 및 조건



예시 | 원료명: 아카시아 검(Acacia gum)

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
A.1	Acacia Gum	(1) Cream; French dressing; Mincemeat; (naming the flavour) Milk; Mustard pickles; (naming the flavour) Partly skimmed milk; (naming the flavour) Partly skimmed milk with added milk solids; Relishes; Salad dressing; (naming the flavour) Skim milk; (naming the flavour) Skim milk with added milk solids	(1) Good Manufacturing Practice
		(2) Ice milk mix; Ice milk	(2) 0.5% in accordance with the requirements of section B.08.071
		(3) Ice cream mix; Ice cream	(3) 0.5% in accordance with the requirements of section B.08.061
		(4) Sherbet	(4) 0.75% in accordance with the requirements of section B.08.063
		(5) Unstandardized foods	(5) Good Manufacturing Practice
		(6) Calorie-reduced margarine	(6) 0.5%. If used in combination with other food additives permitted by this list in this food except gelatin, lecithin, monoglycerides, mono- and diglycerides, and sorbitan tristearate, the total amount not to exceed 0.5%
		(7) Canned asparagus; Canned green beans; Canned peas; Canned wax beans	(7) 1.0% in accordance with the requirements of clause B.11.002(d) (viii)(C)

항목번호	식품첨가물	첨가 허용 식품 또는 물질	최대허용기준 및 조건
A.1	아카시아 검	(1) 크림, 프렌치 드레싱, 미트 파이, (맛 명시한) 우유, 겨자 피클, (맛 명시한) 저지방 우유, (맛 명시한) 저지방 우유 + 우유 고형분, 소스, 샐러드 드레싱, (맛 명시한) 탈지유, (맛 명시한) 탈지유 + 우유 고형분	(1) GMP 기준
		(2) 아이스 밀크 믹스, 아이스 밀크	(2) B.08.071의 요구사항에 따라 0.5%
		(3) 아이스크림 믹스, 아이스크림	(3) B.08.061의 요구사항에 따라 0.5%
		(4) 셔벗	(4) B.08.063의 요구사항에 따라 0.75%
		(5) 비표준 식품	(5) GMP 기준
		(6)저칼로리 마가린	(6) 이 목록에서 허용된 다른 식품 첨가물(젤라틴, 레시틴, 모노 글리세리드, 모노-디글리세리드, 소르비탄 트리스테아레이트 등)과 조합 시 0.5%를 초과하지 않는 조건 하에 사용
		(7) 아스파라거스 통조림, 그린빈 통조림, 완두콩 통조림, 왁스빈 통조림	(7) B.11.002(d)(viii)(C)의 요구 사항에 따라 1.0%

## [ 허용된 식품첨가물(효소제제) 목록 ]

### ● 개요

DB명	허용 식품첨가물 목록 - 허용된 식품 효소 목록
관리기관	캐나다 보건부(HC)
DB 내용	허용된 식품첨가물 목록, 첨가 허용 식품, 허용기준 및 조건
접속 주소	https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/5-enzymes.html
정보 제공 건수	-

### ● DB 접속 방법

#### ○ 캐나다 보건부 'Health Canada' 접속

The screenshot shows the top portion of the Canada.ca website. At the top left, there are logos for the Government of Canada and the Government of Canada in French. A search bar is located at the top right. Below the search bar is a 'MENU' dropdown and a 'Sign In' button. The main header area features the 'Canada.ca' logo and the tagline 'The official website of the Government of Canada'. Below this, there is a 'Most requested' section with links to 'Sign in to an account', 'Employment Insurance and leave', 'Public pensions (CPP and OAS)', and 'Get a passport'. Further down, there are several service categories: 'Jobs', 'Business and industry', 'Health', 'Immigration and citizenship', 'Benefits', 'Environment and natural resources', 'Travel and tourism', 'Taxes', and 'Money and finances', each with a brief description of the services provided.

○ 우측 상단란에 'Food Additives' 검색

Government of Canada / Gouvernement du Canada

Francis

food additives

MENU

Sign in

Canada.ca  
The official website of the Government of Canada

**Most requested**

[Sign in to an account](#)   [Employment Insurance and leave](#)   [Public pensions \(CPP and OAS\)](#)   [Get a passport](#)

[Find a job](#)   [Visit Canada](#)   [Get a work permit](#)

<p><b>Jobs</b> Find a job, training, hiring programs, work permits, Social Insurance Number (SIN)</p>	<p><b>Immigration and citizenship</b> Visit, work, study, immigrate, refugees, permanent residents, apply, check status</p>	<p><b>Travel and tourism</b> In Canada or abroad, advice, advisories, passports, visit Canada, events, attractions</p>
<p><b>Business and industry</b> Starting a business, permits, copyright, business support, selling to government</p>	<p><b>Benefits</b> EI, family and sickness leave, pensions, housing, student aid, disabilities</p>	<p><b>Taxes</b> Income tax, payroll, GST/HST, contribution limits, tax credits, charities</p>
<p><b>Health</b> Food, nutrition, diseases, vaccines, drugs, product safety and recalls</p>	<p><b>Environment and natural resources</b> Weather, climate, agriculture, wildlife, pollution, conservation, fisheries</p>	<p><b>Money and finances</b> Personal finance, credit reports, fraud protection, paying for education</p>

○ 'Food Additives' 클릭

**Search results**

food additives

Don't include personal information (telephone, email, SIN, financial, medical, or work details).

55,888 search results for "food additives"

**Food Additives**

Health Canada

<https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives.html>

Dec 14, 2016 - ... and their regulation in Canada. What is a **food additive**? How are **food additives** regulated? **Food** colour labelling Specific Topics on **Food Additives** In this section ... **food** ingredients such as salt, sugar, starch; ... **Food additives** must be of suitable quality, must be effective for their intended purpose, and, when used according to the ...

Part 1  
4. 원 가 문

○ ‘Lists of Permitted Food Additives’ 클릭

The screenshot shows the Government of Canada website. At the top, there are logos for the Government of Canada and the Government of Canada in French, along with a search bar. Below the navigation bar, there is a 'MENU' dropdown and a breadcrumb trail: Canada.ca > Departments and agencies > Health Canada > Food and nutrition > Food Safety. On the left, a sidebar menu lists various food safety topics, with 'Food Additives' selected. The main content area is titled 'Food Additives' and includes an introductory paragraph, several links for more information, and a list of resources under the heading 'In this section'. The link 'Lists of Permitted Food Additives' is highlighted with a red box.

○ 해당 목록 클릭

The screenshot shows a list of 15 permitted food additives. The items are:

1. [List of Permitted Anticaking Agents](#)
2. [List of Permitted Bleaching, Maturing or Dough Conditioning Agents](#)
3. [List of Permitted Colouring Agents](#)
4. [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#)
5. [List of Permitted Food Enzymes](#)
6. [List of Permitted Firming Agents](#)
7. [List of Permitted Glazing or Polishing Agents](#)
8. [List of Permitted Food Additives with Other Accepted Uses](#)
9. [List of Permitted Sweeteners](#)
10. [List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents](#)
11. [List of Permitted Preservatives](#)
12. [List of Permitted Sequestering Agents](#)
13. [List of Permitted Starch Modifying Agents](#)
14. [List of Permitted Yeast Foods](#)
15. [List of Permitted Carrier or Extraction Solvents](#)

Below the list, there is a link for [Archived Lists](#).

● 정보 제공 범위

- 허용된 식품첨가물 목록, 첨가 허용 식품, 최대허용기준 및 조건



예시 | 원료명:  $\alpha$ -아세토락테이트 탈카복실레이스

Item No.	Column 1 Additive	Column 2 Permitted Source	Column 3 Permitted in or Upon	Column 4 Maximum Level of Use and Other Conditions
A.01	$\alpha$ -Acetolactate decarboxylase	Bacillus subtilis ToC46 (pUW235)	(1) Brewers' Mash	(1) Good Manufacturing Practice
			(2) Distillers' Mash	(2) Good Manufacturing Practice

항목 번호	식품첨가물	허용 공급원	첨가 허용 식품 또는 물질	최대허용기준 및 조건
A.01	$\alpha$ -아세토락테이트 탈카복실레이스	바실러스 서브틸리스 ToC46 (pUW235)	(1) 맥주 제조용 매쉬	(1) GMP 기준
			(2) 증류주 제조용 매쉬	(2) GMP 기준

## [ 허용된 식품첨가물(경화제) 목록 ]

### ● 개요

<b>DB명</b>	허용 식품첨가물 목록 - 허용된 경화제 목록
<b>관리기관</b>	캐나다 보건부(HC)
<b>DB 내용</b>	허용된 식품첨가물 목록, 첨가 허용 식품, 허용기준 및 조건
<b>접속 주소</b>	https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/6-firming-agents.html
<b>정보 제공 건수</b>	11건('24.11. 기준)

### ● DB 접속 방법

#### ○ 캐나다 보건부 'Health Canada' 접속

The screenshot shows the official website of the Government of Canada. At the top, there is a header with the Canadian flag, the text 'Government of Canada' and 'Gouvernement du Canada', a search bar labeled 'Search Canada.ca', and a 'Français' link. Below the header is a 'MENU' dropdown and a 'Sign In' button. The main content area features a large banner with the text 'Canada.ca' and 'The official website of the Government of Canada'. Below the banner, there is a 'Most requested' section with links to 'Sign in to an account', 'Employment Insurance and leave', 'Public pensions (CPP and OAS)', 'Get a passport', 'Find a job', 'Visit Canada', and 'Get a work permit'. The bottom section is organized into a grid of service categories: 'Jobs', 'Business and industry', 'Health', 'Immigration and citizenship', 'Benefits', 'Environment and natural resources', 'Travel and tourism', 'Taxes', and 'Money and finances'. Each category includes a brief description of the services provided.

○ 우측 상단란에 'Food Additives' 검색

The screenshot shows the top navigation bar of the Government of Canada website. On the left, there is the Canadian flag and the text 'Government of Canada' and 'Gouvernement du Canada'. On the right, there is a search bar containing the text 'food additives', which is highlighted with a red rectangular box. To the right of the search bar is a magnifying glass icon. Below the search bar is a 'Sign in' button. The main header area features the text 'Canada.ca' and 'The official website of the Government of Canada' over a background image of autumn leaves. Below this is a 'Most requested' section with links to 'Sign in to an account', 'Employment Insurance and leave', 'Public pensions (CPP and OAS)', 'Get a passport', 'Find a job', 'Visit Canada', and 'Get a work permit'. Further down, there are several category links: 'Jobs', 'Business and industry', 'Health', 'Immigration and citizenship', 'Benefits', 'Environment and natural resources', 'Travel and tourism', 'Taxes', and 'Money and finances', each with a brief description of the services provided.

○ 'Food Additives' 클릭

The screenshot shows the search results page for 'Food Additives'. At the top, there is a search bar with 'food additives' entered and a magnifying glass icon. Below the search bar, there is a message: 'Don't include personal information (telephone, email, SIN, financial, medical, or work details)'. The search results are displayed as '55,888 search results for "food additives"'. The first result is 'Food Additives' from Health Canada, which is highlighted with a red rectangular box. Below the title is the URL: 'https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives.html'. The snippet of the search result reads: 'Dec 14, 2016 - ... and their regulation in Canada. What is a **food additive**? How are **food additives** regulated? **Food** colour labelling Specific Topics on **Food Additives** In this section ... **food** ingredients such as salt, sugar, starch; ... **Food additives** must be of suitable quality, must be effective for their intended purpose, and, when used according to the ...'.

Part 1.  
4. 원 가 문

○ ‘Lists of Permitted Food Additives’ 클릭

The screenshot shows the Government of Canada website. At the top, there is a search bar and a language selector for 'Français'. Below the navigation bar, a breadcrumb trail reads: Canada.ca > Departments and agencies > Health Canada > Food and nutrition > Food Safety. On the left, a sidebar menu lists various categories under 'Food Safety', with 'Food Additives' selected. The main content area is titled 'Food Additives' and includes introductory text, several informational links (e.g., 'What is a food additive?', 'How are food additives regulated?'), and a section titled 'In this section' containing a bulleted list of resources. The link 'Lists of Permitted Food Additives' is highlighted with a red rectangular box, and a sub-link 'Transition Guide: Understanding and Using the Lists of Permitted Food Additives' is also visible.

○ 해당 목록 클릭

The screenshot shows a page titled 'Lists' containing a numbered list of 15 links to various food additive categories. The list items are: 1. List of Permitted Anticaking Agents, 2. List of Permitted Bleaching, Maturing or Dough Conditioning Agents, 3. List of Permitted Colouring Agents, 4. List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents, 5. List of Permitted Food Enzymes, 6. List of Permitted Firming Agents (highlighted with a red box), 7. List of Permitted Glazing or Polishing Agents, 8. List of Permitted Food Additives with Other Accepted Uses, 9. List of Permitted Sweeteners, 10. List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents, 11. List of Permitted Preservatives, 12. List of Permitted Sequestering Agents, 13. List of Permitted Starch Modifying Agents, 14. List of Permitted Yeast Foods, and 15. List of Permitted Carrier or Extraction Solvents. Below the list, there is a link for 'Archived Lists'.

● 정보 제공 범위

- 허용된 식품첨가물 목록, 첨가 허용 식품, 최대허용기준 및 조건



예시 | 원료명: 알루미늄 황산염

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
A.1	Aluminum Sulphate	(1) Canned crabmeat, lobster, salmon, shrimp and tuna; Pickles and relishes	(1) Good Manufacturing Practice
		(2) Unstandardized foods	(2) Good Manufacturing Practice

항목번호	식품첨가물	첨가 허용 식품 또는 물질	최대허용기준 및 조건
A.1	알루미늄 황산염	(1) 통조림 게살, 바닷가재, 연어, 새우 및 참치; 피클 및 소스류	(1) GMP 기준
		(2) 비표준 식품	(2) GMP 기준

## [ 허용된 식품첨가물(광택제) 목록 ]

### ● 개요

DB명	허용 식품첨가물 목록 - 허용된 광택제 목록
관리기관	캐나다 보건부(HC)
DB 내용	허용된 식품첨가물 목록, 첨가 허용 식품, 허용기준 및 조건
접속 주소	https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/7-glazing-polishing-agents.html
정보 제공 건수	12건('24.11. 기준)

### ● DB 접속 방법

#### ○ 캐나다 보건부 'Health Canada' 접속

The screenshot shows the official website of the Government of Canada. At the top, there are logos for the Government of Canada in English and French, a search bar, and a 'Sign In' button. Below the header is a 'MENU' dropdown. The main content area features a banner with 'Canada.ca' and the tagline 'The official website of the Government of Canada'. Underneath, there is a 'Most requested' section with links like 'Sign in to an account', 'Employment Insurance and leave', 'Public pensions (CPP and OAS)', and 'Get a passport'. The bottom section is organized into a grid of service categories: Jobs, Immigration and citizenship, Travel and tourism, Business and industry, Benefits, Taxes, Health, Environment and natural resources, and Money and finances, each with a brief description of the services provided.

○ 우측 상단란에 'Food Additives' 검색

Government of Canada / Gouvernement du Canada

Francis

food additives

MENU

Sign in

Canada.ca  
The official website of the Government of Canada

**Most requested**

[Sign in to an account](#)   [Employment Insurance and leave](#)   [Public pensions \(CPP and OAS\)](#)   [Get a passport](#)

[Find a job](#)   [Visit Canada](#)   [Get a work permit](#)

**Jobs**  
Find a job, training, hiring programs, work permits, Social Insurance Number (SIN)

**Immigration and citizenship**  
Visit, work, study, immigrate, refugees, permanent residents, apply, check status

**Travel and tourism**  
In Canada or abroad, advice, advisories, passports, visit Canada, events, attractions

**Business and industry**  
Starting a business, permits, copyright, business support, selling to government

**Benefits**  
EI, family and sickness leave, pensions, housing, student aid, disabilities

**Taxes**  
Income tax, payroll, GST/HST, contribution limits, tax credits, charities

**Health**  
Food, nutrition, diseases, vaccines, drugs, product safety and recalls

**Environment and natural resources**  
Weather, climate, agriculture, wildlife, pollution, conservation, fisheries

**Money and finances**  
Personal finance, credit reports, fraud protection, paying for education

○ 'Food Additives' 클릭

**Search results**

food additives

Don't include personal information (telephone, email, SIN, financial, medical, or work details).

55,888 search results for "food additives"

**Food Additives**

Health Canada

<https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives.html>

Dec 14, 2016 - ... and their regulation in Canada. What is a **food additive**? How are **food additives** regulated? **Food** colour labelling Specific Topics on **Food Additives** In this section ... **food** ingredients such as salt, sugar, starch; ... **Food additives** must be of suitable quality, must be effective for their intended purpose, and, when used according to the ...

Part 1  
4. 원 가 문

○ ‘Lists of Permitted Food Additives’ 클릭

The screenshot shows the Government of Canada website. At the top, there is a search bar and a language selector for 'Français'. Below the search bar is a 'MENU' dropdown. The breadcrumb trail reads: Canada.ca > Departments and agencies > Health Canada > Food and nutrition > Food Safety. On the left, a navigation menu lists various categories under 'Food Safety', with 'Food Additives' selected. The main content area is titled 'Food Additives' and includes an introductory paragraph, several links for more information, and a list of resources under the heading 'In this section'. The link 'Lists of Permitted Food Additives' is highlighted with a red box, and its sub-link 'Transition Guide: Understanding and Using the Lists of Permitted Food Additives' is also highlighted.

○ 해당 목록 클릭

The screenshot shows a page titled 'Lists' containing a numbered list of 15 links. The 7th link, 'List of Permitted Glazing or Polishing Agents', is highlighted with a red box. Below the list is a link for 'Archived Lists'.

● 정보 제공 범위

- 허용된 식품첨가물 목록, 첨가 허용 식품, 최대허용기준 및 조건



예시 | 원료명: 아세틸화 모노글리세리드

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
A.1	Acetylated Monoglycerides	(1) Unstandardized confectionery	(1) 0.4%
		(2) Glaze for frozen fish	(2) Good Manufacturing Practice

항목번호	식품첨가물	첨가 허용 식품 또는 물질	최대허용기준 및 조건
A.1	아세틸화 모노글리세리드	(1) 비표준 과자류	(1) GMP 기준
		(2) 냉동 생선 글레이징	(2) GMP 기준

## [ 허용된 식품첨가물(기타) 목록 ]

### ● 개요

<b>DB명</b>	허용 식품첨가물 목록 - 허용된 식품첨가물(기타) 목록
<b>관리기관</b>	캐나다 보건부(HC)
<b>DB 내용</b>	허용된 식품첨가물 목록, 첨가 허용 식품, 허용기준 및 조건
<b>접속 주소</b>	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/8-other-accepted-uses.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/8-other-accepted-uses.html</a>
<b>정보 제공 건수</b>	-

### ● DB 접속 방법

#### ○ 캐나다 보건부 'Health Canada' 접속

The screenshot shows the official website of the Government of Canada. At the top, there are logos for the Government of Canada in English and French, a search bar, and a 'Sign In' button. Below the header is a 'MENU' dropdown. The main content area features a banner with the text 'Canada.ca The official website of the Government of Canada'. Underneath, there is a 'Most requested' section with links for 'Sign in to an account', 'Employment Insurance and leave', 'Public pensions (CPP and OAS)', and 'Get a passport'. Below this, there are several categorized service links: 'Jobs', 'Business and industry', 'Health', 'Immigration and citizenship', 'Benefits', 'Environment and natural resources', 'Travel and tourism', 'Taxes', and 'Money and finances'.

○ 우측 상단란에 'Food Additives' 검색

○ 'Food Additives' 클릭

Part 1.  
4.원 가 문

○ ‘Lists of Permitted Food Additives’ 클릭

The screenshot shows the Government of Canada website. At the top, there is a search bar and a language selector for 'Français'. Below the search bar is a 'MENU' dropdown. The breadcrumb trail reads: Canada.ca > Departments and agencies > Health Canada > Food and nutrition > Food Safety. On the left, a navigation menu lists various food safety topics, with 'Food Additives' selected. The main content area is titled 'Food Additives' and includes a description, several informational links (e.g., 'What is a food additive?', 'How are food additives regulated?'), and a section titled 'In this section' containing a list of links. The link 'Lists of Permitted Food Additives' is highlighted with a red box.

○ 해당 목록 클릭

The screenshot shows a page titled 'Lists' containing a numbered list of 15 links. The 8th link, 'List of Permitted Food Additives with Other Accepted Uses', is highlighted with a red box. Below the list is a link for 'Archived Lists'.

● 정보 제공 범위

- 허용된 식품첨가물 목록, 첨가 허용 식품, 최대허용기준 및 조건



예시 | 원료명: 아카시아 검

List of Permitted Food Additives with Other Accepted Uses

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Purpose of Use	Column 4 Maximum Level of Use and Other Conditions
A.01	Acacia Gum	Ale; Beer; Light beer; Malt liquor; Porter; Stout; Wine	Fining agent	Good Manufacturing Practice

항목번호	식품첨가물	첨가 허용 식품 또는 물질	사용 목적	최대허용기준 및 조건
A.01	아카시아검	에일, 맥주, 라이트 맥주, 맥아주, 포터, 스타우트, 와인	정제제	GMP 기준

## [ 허용된 식품첨가물(감미료) 목록 ]

### ● 개요

<b>DB명</b>	허용 식품첨가물 목록 - 허용된 감미료 목록
<b>관리기관</b>	캐나다 보건부(HC)
<b>DB 내용</b>	허용된 식품첨가물 목록, 첨가 허용 식품, 허용기준 및 조건
<b>접속 주소</b>	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/9-sweeteners.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/9-sweeteners.html</a>
<b>정보 제공 건수</b>	23건('24.11. 기준)

### ● DB 접속 방법

#### ○ 캐나다 보건부 'Health Canada' 접속

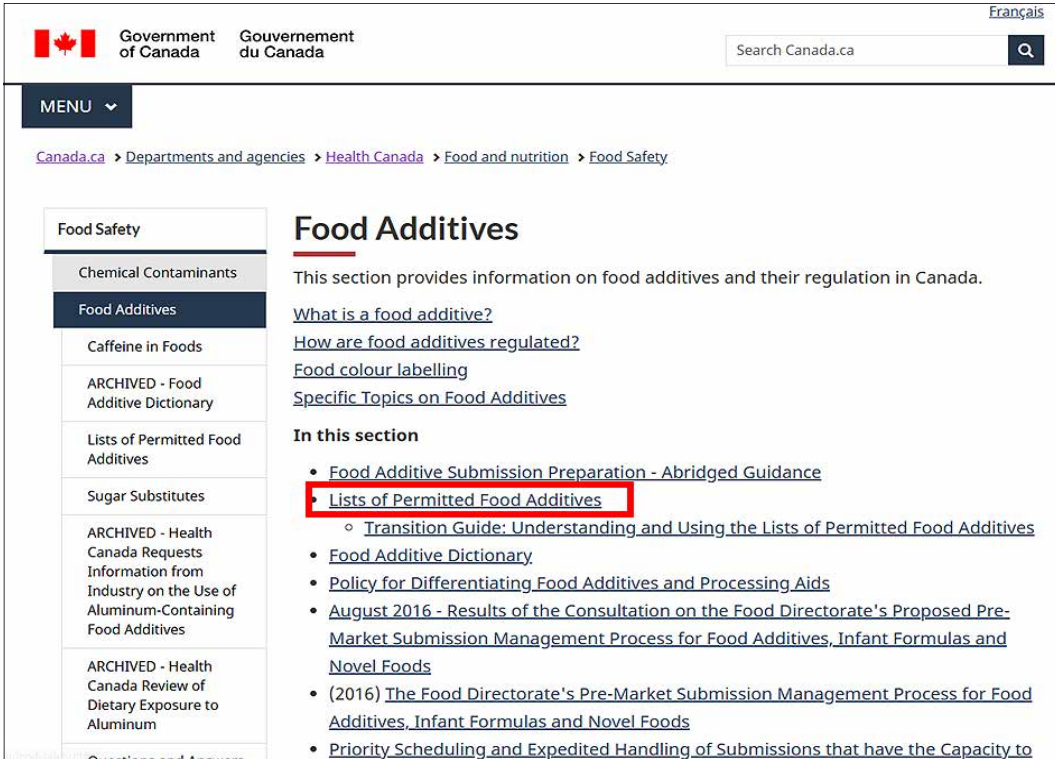
The screenshot shows the official website of the Government of Canada. At the top, there are logos for the Government of Canada in English and French, a search bar, and a 'Sign In' button. Below the header is a 'MENU' dropdown. The main content area features a large banner with the text 'Canada.ca The official website of the Government of Canada'. Underneath, there is a 'Most requested' section with links to 'Sign in to an account', 'Employment Insurance and leave', 'Public pensions (CPP and OAS)', and 'Get a passport'. Below this, there are several categorized service sections: 'Jobs', 'Business and industry', 'Health', 'Immigration and citizenship', 'Benefits', 'Environment and natural resources', 'Travel and tourism', 'Taxes', and 'Money and finances'. Each section provides a brief description of the services offered.

○ 우측 상단란에 'Food Additives' 검색

○ 'Food Additives' 클릭

Part 1.  
4. 원 가 문

## ○ ‘Lists of Permitted Food Additives’ 클릭



Government of Canada / Gouvernement du Canada

Search Canada.ca

Franglais

MENU

Canada.ca > Departments and agencies > Health Canada > Food and nutrition > Food Safety

### Food Safety

- Chemical Contaminants
- Food Additives**
- Caffeine in Foods
- ARCHIVED - Food Additive Dictionary
- Lists of Permitted Food Additives
- Sugar Substitutes
- ARCHIVED - Health Canada Requests Information from Industry on the Use of Aluminum-Containing Food Additives
- ARCHIVED - Health Canada Review of Dietary Exposure to Aluminum
- Questions and Answers

## Food Additives

This section provides information on food additives and their regulation in Canada.

[What is a food additive?](#)  
[How are food additives regulated?](#)  
[Food colour labelling](#)  
[Specific Topics on Food Additives](#)

**In this section**

- Food Additive Submission Preparation - Abridged Guidance
- Lists of Permitted Food Additives**
  - Transition Guide: Understanding and Using the Lists of Permitted Food Additives
- Food Additive Dictionary
- Policy for Differentiating Food Additives and Processing Aids
- August 2016 - Results of the Consultation on the Food Directorate's Proposed Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods
- (2016) The Food Directorate's Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods
- Priority Scheduling and Expedited Handling of Submissions that have the Capacity to

## ○ 해당 목록 클릭

## Lists

- [List of Permitted Anticaking Agents](#)
- [List of Permitted Bleaching, Maturing or Dough Conditioning Agents](#)
- [List of Permitted Colouring Agents](#)
- [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#)
- [List of Permitted Food Enzymes](#)
- [List of Permitted Firming Agents](#)
- [List of Permitted Glazing or Polishing Agents](#)
- [List of Permitted Food Additives with Other Accepted Uses](#)
- [List of Permitted Sweeteners](#)**
- [List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents](#)
- [List of Permitted Preservatives](#)
- [List of Permitted Sequestering Agents](#)
- [List of Permitted Starch Modifying Agents](#)
- [List of Permitted Yeast Foods](#)
- [List of Permitted Carrier or Extraction Solvents](#)

[Archived Lists](#)

● 정보 제공 범위

- 허용된 식품첨가물 목록, 첨가 허용 식품, 최대허용기준 및 조건



예시 | 원료명: 아스파탐(Aspartame)

Item No.	Column 1 - Additive	Column 2 - Permitted in or Upon	Column 3 - Maximum Level of Use and Other Conditions
A.1	Aspartame	(1) Table-top sweeteners	(1) Good Manufacturing Practice
		(2) Breakfast cereals	(2) 0.5%
		(3) Unstandardized beverage concentrates; Unstandardized beverage mixes; Unstandardized beverages	(3) 0.1% in beverages as consumed
		(4) Filling mixes; Fillings; Topping mixes; Toppings; Unstandardized dessert mixes; Unstandardized desserts; Yogurt	(4) 0.3% in products as consumed
		(5) Breath freshener products; Chewing gum	(5) 1.0%
		(6) Unstandardized fruit spreads; Unstandardized purées; Unstandardized sauces; Unstandardized table syrups	(6) 0.2%
		(7) Nut spreads; Peanut spreads; Unstandardized salad dressings	(7) 0.05%
		(8) Unstandardized condiments	(8) 0.2%
		(9) Confectionery glazes for snack foods; Sweetened seasonings or coating mixes for snack foods	(9) 0.1%
		(10) Unstandardized confectionery; Unstandardized confectionery coatings	(10) 0.3%

항목번호	식품첨가물	첨가 허용 식품 또는 물질	최대허용기준 및 조건
A.01	아스파탐	(1) 테이블용 감미료	(1) GMP 기준
		(2) 아침식사 대용 시리얼	(2) 0.5%
		(3) 비표준 음료 농축액, 음료 믹스, 음료	(3) 소비 음료 0.1%
		(4) 필링 믹스, 필링, 토핑 믹스, 토핑, 비표준 디저트 믹스, 비표준화 디저트, 요구르트	(4) 소비 제품 0.3%
		(5) 구강 청량제 제품, 껌	(5) 1.0%
		(6) 비표준 과일 스프레드, 푸레, 소스, 테이블 시럽	(6) 0.2%
		(7) 견과류 스프레드, 땅콩 스프레드, 비표준 샐러드드레싱	(7) 0.05%
		(8) 비표준 조미료	(8) 0.2%
		(9) 간식용 당의, 감미료로 맛을 낸 간식용 시즈닝 또는 코팅 믹스	(9) 0.1%
		(10) 비표준화 과자류, 비표준화 과자 코팅	(10) 0.3%

## [ 허용된 식품첨가물(산도조절제) 목록 ]

### ● 개요

<b>DB명</b>	허용 식품첨가물 목록 - 허용된 pH 조정제, 산 반응 물질 및 물 보정제 목록
<b>관리기관</b>	캐나다 보건부(HC)
<b>DB 내용</b>	허용된 식품첨가물 목록, 첨가 허용 식품, 허용기준 및 조건
<b>접속 주소</b>	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/10-adjusting-agents.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/10-adjusting-agents.html</a>
<b>정보 제공 건수</b>	-

### ● DB 접속 방법

#### ○ 캐나다 보건부 'Health Canada' 접속

The screenshot shows the official website of the Government of Canada. At the top, there is a header with the Canadian flag, the text 'Government of Canada' and 'Gouvernement du Canada', a search bar labeled 'Search Canada.ca', and a 'Français' link. Below the header is a 'MENU' dropdown and a 'Sign In' button. The main content area features a large banner with the text 'Canada.ca' and 'The official website of the Government of Canada'. Below the banner, there is a 'Most requested' section with links to 'Sign in to an account', 'Employment Insurance and leave', 'Public pensions (CPP and OAS)', 'Get a passport', 'Find a job', 'Visit Canada', and 'Get a work permit'. The bottom section is organized into a grid of service categories: 'Jobs', 'Immigration and citizenship', 'Travel and tourism', 'Business and industry', 'Benefits', 'Taxes', 'Health', 'Environment and natural resources', and 'Money and finances'. Each category includes a brief description of the services provided.

○ 우측 상단란에 'Food Additives' 검색

The screenshot shows the top navigation bar of the Government of Canada website. On the left, there is the Canadian flag and the text 'Government of Canada' and 'Gouvernement du Canada'. On the right, there is a search bar containing the text 'food additives' and a magnifying glass icon. A red box highlights the search bar. Below the search bar, there is a 'Sign in' button. The main content area features a banner with the text 'Canada.ca' and 'The official website of the Government of Canada'. Below the banner, there is a 'Most requested' section with links to 'Sign in to an account', 'Employment Insurance and leave', 'Public pensions (CPP and OAS)', 'Get a passport', 'Find a job', 'Visit Canada', and 'Get a work permit'. There are also sections for 'Jobs', 'Business and industry', 'Health', 'Immigration and citizenship', 'Benefits', 'Environment and natural resources', 'Travel and tourism', 'Taxes', and 'Money and finances'.

○ 'Food Additives' 클릭

The screenshot shows the search results page for 'Food Additives'. At the top, there is a search bar with 'food additives' entered and a magnifying glass icon. Below the search bar, there is a message: 'Don't include personal information (telephone, email, SIN, financial, medical, or work details)'. The search results section shows '55,888 search results for "food additives"'. The first result is 'Food Additives' from Health Canada, which is highlighted with a red box. Below the result, there is a link to the page: 'https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives.html'. The snippet of the page content is: 'Dec 14, 2016 - ... and their regulation in Canada. What is a **food additive**? How are **food additives** regulated? **Food** colour labelling Specific Topics on **Food Additives** In this section ... **food** ingredients such as salt, sugar, starch; ... **Food additives** must be of suitable quality, must be effective for their intended purpose, and, when used according to the ...'.

Part 1.  
4. 원 가 문

○ ‘Lists of Permitted Food Additives’ 클릭

Government of Canada / Gouvernement du Canada

Search Canada.ca

Franglais

MENU

Canada.ca > Departments and agencies > Health Canada > Food and nutrition > Food Safety

**Food Safety**

- Chemical Contaminants
- Food Additives**
- Caffeine in Foods
- ARCHIVED - Food Additive Dictionary
- Lists of Permitted Food Additives
- Sugar Substitutes
- ARCHIVED - Health Canada Requests Information from Industry on the Use of Aluminum-Containing Food Additives
- ARCHIVED - Health Canada Review of Dietary Exposure to Aluminum
- Questions and Answers

## Food Additives

This section provides information on food additives and their regulation in Canada.

[What is a food additive?](#)  
[How are food additives regulated?](#)  
[Food colour labelling](#)  
[Specific Topics on Food Additives](#)

**In this section**

- Food Additive Submission Preparation - Abridged Guidance
- Lists of Permitted Food Additives**
  - Transition Guide: Understanding and Using the Lists of Permitted Food Additives
- Food Additive Dictionary
- Policy for Differentiating Food Additives and Processing Aids
- August 2016 - Results of the Consultation on the Food Directorate's Proposed Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods
- (2016) The Food Directorate's Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods
- Priority Scheduling and Expedited Handling of Submissions that have the Capacity to

○ 해당 목록 클릭

## Lists

- [List of Permitted Anticaking Agents](#)
- [List of Permitted Bleaching, Maturing or Dough Conditioning Agents](#)
- [List of Permitted Colouring Agents](#)
- [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#)
- [List of Permitted Food Enzymes](#)
- [List of Permitted Firming Agents](#)
- [List of Permitted Glazing or Polishing Agents](#)
- [List of Permitted Food Additives with Other Accepted Uses](#)
- [List of Permitted Sweeteners](#)
- [List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents](#)**
- [List of Permitted Preservatives](#)
- [List of Permitted Sequestering Agents](#)
- [List of Permitted Starch Modifying Agents](#)
- [List of Permitted Yeast Foods](#)
- [List of Permitted Carrier or Extraction Solvents](#)

[Archived Lists](#)

● 정보 제공 범위

- 허용된 식품첨가물 목록, 첨가 허용 식품, 최대허용기준 및 조건



예시 | 원료명: 아세트산

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
A.1	Acetic Acid	(1) Cold-pack cheese food; Cold-pack (naming the variety) cheese; Cold-pack (naming the variety) cheese with (naming the added ingredients); Cold-pack cheese food with (naming the added ingredients); Cream cheese spread; Cream cheese spread with (naming the added ingredients); Processed cheese food; Processed cheese food with (naming the added ingredients); Processed cheese spread; Processed cheese spread with (naming the added ingredients); Processed (naming the variety) cheese; Processed (naming the variety) cheese with (naming the added ingredients); (naming the variety) Whey cheese	(1) Good Manufacturing Practice
		(2) Canned Asparagus	(2) Good Manufacturing Practice
		(3) Gelatin	(3) Good Manufacturing Practice
		(4) Unstandardized foods	(4) Good Manufacturing Practice

항목 번호	식품첨가물	첨가 허용 식품 또는 물질	최대허용기준 및 조건
A.1	아세트산	(1) 콜드팩 치즈 식품, 특정 종류의 콜드팩 치즈(종류를 명시), 특정 종류의 콜드팩 치즈와 추가된 성분이 포함된 제품(추가 성분을 명시), 추가된 성분이 포함된 콜드팩 치즈 푸드(추가 성분을 명시), 크림치즈 스프레드, 추가된 성분이 포함된 크림치즈 스프레드(추가 성분을 명시), 가공 치즈 식품, 추가된 성분이 포함된 가공 치즈 푸드(추가 성분을 명시), 가공 치즈 스프레드, 추가된 성분이 포함된 가공 치즈 스프레드 (추가 성분을 명시), 특정 종류의 가공 치즈(종류를 명시), 추가된 성분이 포함된 특정 종류의 가공 치즈(종류 및 추가 성분을 명시), 특정 종류의 유청 치즈(종류를 명시)	(1) GMP 기준
		(2) 아스파라거스 통조림	(2) GMP 기준
		(3) 젤라틴	(3) GMP 기준
		(4) 비표준 식품	(4) GMP 기준

## [ 허용된 식품첨가물(보존제) 목록 ]

### ● 개요

<b>DB명</b>	허용 식품첨가물 목록 - 허용된 보존제 목록
<b>관리기관</b>	캐나다 보건부(HC)
<b>DB 내용</b>	허용된 식품첨가물 목록, 첨가 허용 식품, 허용기준 및 조건
<b>접속 주소</b>	https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/11-preservatives.html
<b>정보 제공 건수</b>	-

### ● DB 접속 방법

#### ○ 캐나다 보건부 'Health Canada' 접속

The screenshot shows the official website of the Government of Canada. At the top, there are logos for the Government of Canada in English and French, a search bar, and a 'Sign In' button. Below the header is a 'MENU' dropdown. The main content area features a banner with the text 'Canada.ca The official website of the Government of Canada'. Underneath, there is a 'Most requested' section with links for 'Sign in to an account', 'Employment Insurance and leave', 'Public pensions (CPP and OAS)', and 'Get a passport'. Below this, there are several categorized service links: 'Jobs', 'Business and industry', 'Health', 'Immigration and citizenship', 'Benefits', 'Environment and natural resources', 'Travel and tourism', 'Taxes', and 'Money and finances'. Each category includes a brief description of the services provided.

○ 우측 상단란에 'Food Additives' 검색

The screenshot shows the top navigation bar of the Government of Canada website. On the left, there is the Canadian flag and the text 'Government of Canada' and 'Gouvernement du Canada'. On the right, there is a search bar containing the text 'food additives', which is highlighted with a red rectangular box. To the right of the search bar is a magnifying glass icon. Further right, there is a 'Français' link and a 'Sign in' button. Below the navigation bar is a 'MENU' dropdown arrow. The main header area features a large image of autumn leaves with the text 'Canada.ca' and 'The official website of the Government of Canada'. Below this is a 'Most requested' section with links to 'Sign in to an account', 'Employment Insurance and leave', 'Public pensions (CPP and OAS)', 'Get a passport', 'Find a job', 'Visit Canada', and 'Get a work permit'. The main content area is divided into three columns of categories: 'Jobs', 'Business and industry', 'Health', 'Immigration and citizenship', 'Benefits', 'Environment and natural resources', 'Travel and tourism', 'Taxes', and 'Money and finances', each with a brief description of the services provided.

○ 'Food Additives' 클릭

The screenshot shows the search results page for 'Food Additives'. At the top, there is a search bar with 'food additives' entered and a magnifying glass icon. Below the search bar, there is a note: 'Don't include personal information (telephone, email, SIN, financial, medical, or work details)'. The search results are displayed as '55,888 search results for "food additives"'. The first result is 'Food Additives' from Health Canada, which is highlighted with a red rectangular box. Below the title is the URL: 'https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives.html'. The snippet of the search result reads: 'Dec 14, 2016 - ... and their regulation in Canada. What is a **food additive**? How are **food additives** regulated? **Food** colour labelling Specific Topics on **Food Additives** In this section ... **food** ingredients such as salt, sugar, starch; ... **Food additives** must be of suitable quality, must be effective for their intended purpose, and, when used according to the ...'.

Part 1.  
4. 원 가 문

○ ‘Lists of Permitted Food Additives’ 클릭

The screenshot shows the Government of Canada website. At the top, there is a search bar and the text 'Français'. Below the search bar is a 'MENU' dropdown. The breadcrumb trail reads: 'Canada.ca > Departments and agencies > Health Canada > Food and nutrition > Food Safety'. On the left, a sidebar menu lists various topics under 'Food Safety', with 'Food Additives' selected. The main content area is titled 'Food Additives' and includes a description, several links (e.g., 'What is a food additive?', 'How are food additives regulated?'), and a section titled 'In this section' containing a list of links. The link 'Lists of Permitted Food Additives' is highlighted with a red box, and a sub-link 'Transition Guide: Understanding and Using the Lists of Permitted Food Additives' is also visible.

○ 해당 목록 클릭

The screenshot shows a page titled 'Lists' containing a numbered list of 15 links. The 11th item, 'List of Permitted Preservatives', is highlighted with a red box. Below the list is a link for 'Archived Lists'.

1. [List of Permitted Anticaking Agents](#)
2. [List of Permitted Bleaching, Maturing or Dough Conditioning Agents](#)
3. [List of Permitted Colouring Agents](#)
4. [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#)
5. [List of Permitted Food Enzymes](#)
6. [List of Permitted Firming Agents](#)
7. [List of Permitted Glazing or Polishing Agents](#)
8. [List of Permitted Food Additives with Other Accepted Uses](#)
9. [List of Permitted Sweeteners](#)
10. [List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents](#)
11. [List of Permitted Preservatives](#)
12. [List of Permitted Sequestering Agents](#)
13. [List of Permitted Starch Modifying Agents](#)
14. [List of Permitted Yeast Foods](#)
15. [List of Permitted Carrier or Extraction Solvents](#)

[Archived Lists](#)

● 정보 제공 범위

- 허용된 식품첨가물 목록, 첨가 허용 식품, 최대허용기준 및 조건



예시 | 원료명: 아세트산

Part 1 - Class 1 Preservatives			
Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
A.1	Acetic Acid	(1) Preserved fish; Preserved meat; Preserved meat by-product; Preserved poultry meat; Preserved poultry meat by-product; Pumping pickle, cover pickle and dry cure employed in the curing of preserved meat or preserved meat by-product	(1) Good Manufacturing Practice
		(2) Unstandardized foods	(2) Good Manufacturing Practice

항목 번호	식품첨가물	첨가 허용 식품 또는 물질	최대허용기준 및 조건
A.1	아세트산	(1) 보존된 생선, 보존된 육류, 보존된 육류 부산물, 보존된 가금류 육류, 보존된 가금류 육류 부산물, 염장 과정에서 사용되는 펌핑 피클, 커버 피클 및 건조 염장제(보존된 육류 또는 육류 부산물의 염장에 사용)	(1) GMP 기준
		(2) 비표준 식품	(2) GMP 기준

Part 1.  
4. 첨가물

## [ 허용된 식품첨가물(제조용제) 목록 ]

### ● 개요

<b>DB명</b>	허용 식품첨가물 목록 - 허용된 제조용제 목록
<b>관리기관</b>	캐나다 보건부(HC)
<b>DB 내용</b>	허용된 식품첨가물 목록, 첨가 허용 식품, 허용기준 및 조건
<b>접속 주소</b>	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/12-sequestering-agents.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/12-sequestering-agents.html</a>
<b>정보 제공 건수</b>	26건('24.11. 기준)

### ● DB 접속 방법

#### ○ 캐나다 보건부 'Health Canada' 접속

The screenshot shows the official website of the Government of Canada. At the top, there are logos for the Government of Canada in English and French, a search bar, and a 'Sign In' button. Below the header is a 'MENU' dropdown. The main content area features a banner with the text 'Canada.ca The official website of the Government of Canada' over a background of autumn leaves. Underneath, there is a 'Most requested' section with links to 'Sign in to an account', 'Employment Insurance and leave', 'Public pensions (CPP and OAS)', 'Get a passport', 'Find a job', 'Visit Canada', and 'Get a work permit'. The bottom section is organized into a grid of service categories: 'Jobs', 'Immigration and citizenship', 'Travel and tourism', 'Business and industry', 'Benefits', 'Taxes', 'Health', 'Environment and natural resources', and 'Money and finances', each with a brief description of the services provided.

○ 우측 상단란에 'Food Additives' 검색

○ 'Food Additives' 클릭

Part 1.  
4.원 가 문

○ ‘Lists of Permitted Food Additives’ 클릭

The screenshot shows the Government of Canada website. At the top, there is a search bar and a language selector for 'Français'. Below the navigation bar, a breadcrumb trail reads: Canada.ca > Departments and agencies > Health Canada > Food and nutrition > Food Safety. On the left, a sidebar menu is open, showing 'Food Safety' as the main category, with sub-items like 'Chemical Contaminants', 'Food Additives', 'Caffeine in Foods', 'ARCHIVED - Food Additive Dictionary', 'Lists of Permitted Food Additives', 'Sugar Substitutes', 'ARCHIVED - Health Canada Requests Information from Industry on the Use of Aluminum-Containing Food Additives', 'ARCHIVED - Health Canada Review of Dietary Exposure to Aluminum', and 'Questions and Answers'. The 'Food Additives' sub-item is selected. The main content area is titled 'Food Additives' and contains introductory text, several links (e.g., 'What is a food additive?', 'How are food additives regulated?'), and a section 'In this section' with a bulleted list. The link 'Lists of Permitted Food Additives' is highlighted with a red box, and a sub-link 'Transition Guide: Understanding and Using the Lists of Permitted Food Additives' is also visible.

○ 해당 목록 클릭

The screenshot shows a list of 15 permitted food additive categories. The items are: 1. List of Permitted Anticaking Agents, 2. List of Permitted Bleaching, Maturing or Dough Conditioning Agents, 3. List of Permitted Colouring Agents, 4. List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents, 5. List of Permitted Food Enzymes, 6. List of Permitted Firming Agents, 7. List of Permitted Glazing or Polishing Agents, 8. List of Permitted Food Additives with Other Accepted Uses, 9. List of Permitted Sweeteners, 10. List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents, 11. List of Permitted Preservatives, 12. List of Permitted Sequestering Agents (highlighted with a red box), 13. List of Permitted Starch Modifying Agents, 14. List of Permitted Yeast Foods, and 15. List of Permitted Carrier or Extraction Solvents. Below the list is a link for 'Archived Lists'.

● 정보 제공 범위

- 허용된 식품첨가물 목록, 첨가 허용 식품, 최대허용기준 및 조건



원료명: 이염기성 시트르산 암모늄, 일염기성 시트르산 암모늄, 시트르산 칼슘

List of Permitted Sequestering Agents			
Item No:	Column 1 Additive	Column 2 Permitted In or Upon	Column 3 Maximum Level of use and Other Conditions
A.1	Ammonium Citrate, dibasic	Unstandardized foods	Good Manufacturing Practice
A.2	Ammonium Citrate, monobasic	Unstandardized foods	Good Manufacturing Practice
C.1	Calcium Citrate	Unstandardized foods	Good Manufacturing Practice

항목 번호	식품첨가물	첨가 허용 식품 또는 물질	최대허용기준 및 조건
A.1	이염기성 시트르산 암모늄	비표준 식품	GMP 기준
A.2	일염기성 시트르산 암모늄	비표준 식품	GMP 기준
C.1	시트르산 칼슘	비표준 식품	GMP 기준

## [ 허용된 식품첨가물(변성전분 제제) 목록 ]

### ● 개요

<b>DB명</b>	허용 식품첨가물 목록 - 허용된 변성전분 제제 목록
<b>관리기관</b>	캐나다 보건부(HC)
<b>DB 내용</b>	허용된 식품첨가물 목록, 첨가 허용 식품, 허용기준 및 조건
<b>접속 주소</b>	https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/13-starch-modifying-agents.html
<b>정보 제공 건수</b>	25건('24.11. 기준)

### ● DB 접속 방법

#### ○ 캐나다 보건부 'Health Canada' 접속

The screenshot shows the official website of the Government of Canada. At the top, there are logos for the Government of Canada in English and French, a search bar, and a 'Sign In' button. Below the header is a 'MENU' dropdown. The main content area features a banner with the text 'Canada.ca The official website of the Government of Canada' over a background of autumn leaves. Underneath, there is a 'Most requested' section with links to 'Sign in to an account', 'Employment Insurance and leave', 'Public pensions (CPP and OAS)', 'Get a passport', 'Find a job', 'Visit Canada', and 'Get a work permit'. The bottom section is organized into a grid of service categories: 'Jobs', 'Business and industry', 'Health', 'Immigration and citizenship', 'Benefits', 'Environment and natural resources', 'Travel and tourism', 'Taxes', and 'Money and finances', each with a brief description of the services provided.

○ 우측 상단란에 'Food Additives' 검색

Government of Canada / Gouvernement du Canada

Francis

food additives

MENU

Sign in

Canada.ca  
The official website of the Government of Canada

**Most requested**

[Sign in to an account](#)   [Employment Insurance and leave](#)   [Public pensions \(CPP and OAS\)](#)   [Get a passport](#)

[Find a job](#)   [Visit Canada](#)   [Get a work permit](#)

<p><b>Jobs</b> Find a job, training, hiring programs, work permits, Social Insurance Number (SIN)</p>	<p><b>Immigration and citizenship</b> Visit, work, study, immigrate, refugees, permanent residents, apply, check status</p>	<p><b>Travel and tourism</b> In Canada or abroad, advice, advisories, passports, visit Canada, events, attractions</p>
<p><b>Business and industry</b> Starting a business, permits, copyright, business support, selling to government</p>	<p><b>Benefits</b> EI, family and sickness leave, pensions, housing, student aid, disabilities</p>	<p><b>Taxes</b> Income tax, payroll, GST/HST, contribution limits, tax credits, charities</p>
<p><b>Health</b> Food, nutrition, diseases, vaccines, drugs, product safety and recalls</p>	<p><b>Environment and natural resources</b> Weather, climate, agriculture, wildlife, pollution, conservation, fisheries</p>	<p><b>Money and finances</b> Personal finance, credit reports, fraud protection, paying for education</p>

○ 'Food Additives' 클릭

Search results

food additives

Don't include personal information (telephone, email, SIN, financial, medical, or work details).

55,888 search results for "food additives"

**Food Additives**

Health Canada

<https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives.html>

Dec 14, 2016 - ... and their regulation in Canada. What is a **food additive**? How are **food additives** regulated? **Food** colour labelling Specific Topics on **Food Additives** In this section ... **food** ingredients such as salt, sugar, starch; ... **Food additives** must be of suitable quality, must be effective for their intended purpose, and, when used according to the ...

Part 1  
4. 원 가 문

○ ‘Lists of Permitted Food Additives’ 클릭

The screenshot shows the Government of Canada website. At the top, there is a navigation bar with the Canadian flag, the text 'Government of Canada / Gouvernement du Canada', and a search box labeled 'Search Canada.ca'. Below the navigation bar is a 'MENU' dropdown. The main content area has a breadcrumb trail: 'Canada.ca > Departments and agencies > Health Canada > Food and nutrition > Food Safety'. On the left, there is a sidebar menu with 'Food Safety' selected, and 'Food Additives' is highlighted. The main content area is titled 'Food Additives' and contains several links: 'What is a food additive?', 'How are food additives regulated?', 'Food colour labelling', and 'Specific Topics on Food Additives'. Under the heading 'In this section', there is a list of links. The link 'Lists of Permitted Food Additives' is highlighted with a red box. Below it, there is a sub-link 'Transition Guide: Understanding and Using the Lists of Permitted Food Additives'. Other links in the list include 'Food Additive Submission Preparation - Abridged Guidance', 'Food Additive Dictionary', 'Policy for Differentiating Food Additives and Processing Aids', 'August 2016 - Results of the Consultation on the Food Directorate's Proposed Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods', '(2016) The Food Directorate's Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods', and 'Priority Scheduling and Expedited Handling of Submissions that have the Capacity to'.

○ 해당 목록 클릭

The screenshot shows a page titled 'Lists'. It contains a numbered list of 15 links. The 13th link, 'List of Permitted Starch Modifying Agents', is highlighted with a red box. Below the list is a link for 'Archived Lists'.

1. [List of Permitted Anticaking Agents](#)
2. [List of Permitted Bleaching, Maturing or Dough Conditioning Agents](#)
3. [List of Permitted Colouring Agents](#)
4. [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#)
5. [List of Permitted Food Enzymes](#)
6. [List of Permitted Firming Agents](#)
7. [List of Permitted Glazing or Polishing Agents](#)
8. [List of Permitted Food Additives with Other Accepted Uses](#)
9. [List of Permitted Sweeteners](#)
10. [List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents](#)
11. [List of Permitted Preservatives](#)
12. [List of Permitted Sequestering Agents](#)
13. [List of Permitted Starch Modifying Agents](#)
14. [List of Permitted Yeast Foods](#)
15. [List of Permitted Carrier or Extraction Solvents](#)

[Archived Lists](#)

● 정보 제공 범위

- 허용된 식품첨가물 목록, 첨가 허용 식품, 최대허용기준 및 조건



예시 | 전분개질제 목록

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
A.1	Acetic Anhydride	Starch	Good Manufacturing Practice
A.2	Adipic Acid	Starch	Good Manufacturing Practice
A.3	Aluminum Sulphate	Starch	Good Manufacturing Practice
C.1	Calcium Hypochlorite	Starch	Good Manufacturing Practice
E.1	Epichlorohydrin	[Removed, 2016-06-29. (See NOM/ADM-0074)]	
H.1	Hydrochloric Acid	Starch	Good Manufacturing Practice
H.2	Hydrogen Peroxide	Starch	Good Manufacturing Practice
M.1	Magnesium Sulphate	Starch	0.4%
N.1	Nitric Acid	Starch	Good Manufacturing Practice
O.1	Octenyl Succinic Anhydride (OSA)	Starch	Good Manufacturing Practice
P.1	Peracetic Acid	Starch	Good Manufacturing Practice
P.2	Phosphorus Oxychloride	Starch	Good Manufacturing Practice
P.3	Potassium Permanganate	Starch	50 p.p.m. of Manganese Sulphate calculated as Manganese
P.3A	Potassium Tripolyphosphate	Starch	Total residual phosphate not to exceed 0.4%, calculated as Phosphorus
P.4	Propylene Oxide	Starch	25%
S.1	Sodium Acetate	Starch	Good Manufacturing Practice
S.2	Sodium Bicarbonate	Starch	Good Manufacturing Practice
S.3	Sodium Carbonate	Starch	Good Manufacturing Practice
S.4	Sodium Chlorite	Starch	Good Manufacturing Practice
S.5	Sodium Hydroxide	Starch	Good Manufacturing Practice
S.6	Sodium Hypochlorite	Starch	Good Manufacturing Practice
S.6A	Sodium Potassium Tripolyphosphate	Starch	Total residual phosphate not to exceed 0.4%, calculated as Phosphorus
S.7	Sodium Trimetaphosphate	Starch	400 p.p.m. calculated as Phosphorus
S.7A	Sodium Tripolyphosphate	Starch	Total residual phosphate not to exceed 0.4%, calculated as Phosphorus
S.8	Succinic Anhydride	Starch	Good Manufacturing Practice
S.9	Sulphuric Acid	Starch	Good Manufacturing Practice

항목 번호	식품첨가물	첨가 허용 식품 또는 물질	최대허용기준 및 조건
A.1	아세트산 무수물	전분	GMP 기준
A.2	아디프산	전분	GMP 기준
A.3	알루미늄 황산염	전분	GMP 기준
C.1	차아염소산 칼슘	전분	GMP 기준
H.1	염산	전분	GMP 기준
H.2	과산화수소	전분	GMP 기준
M.1	황산 마그네슘	전분	0.4%
N.1	질산	전분	GMP 기준
O.1	옥테닐숙신산무수물	전분	GMP 기준
P.1	과초산	전분	GMP 기준
P.2	인산옥시클로라이드	전분	GMP 기준
P.3	과망간산 칼륨	전분	망간 기준으로 50 ppm
P.3A	삼중인산칼륨	전분	잔류 인산염이 0.4%를 초과하지 않음
P.4	프로필렌 옥사이드	전분	25%
S.1	초산 나트륨	전분	GMP 기준
S.2	탄산수소 나트륨	전분	GMP 기준
S.3	탄산 나트륨	전분	GMP 기준
S.4	아염소산 나트륨	전분	GMP 기준
S.5	수산화 나트륨	전분	GMP 기준
S.6	차아염소산 나트륨	전분	GMP 기준
S.6A	나트륨칼륨삼중인산염	전분	잔류 인산염이 0.4%를 초과하지 않음
S.7	나트륨트리메타인산염	전분	인 기준으로 400 ppm
S.7A	삼중인산나트륨	전분	잔류 인산염이 0.4%를 초과하지 않음
S.8	숙신산무수물	전분	GMP 기준
S.9	황산	전분	GMP 기준

\* E.1 항목은 삭제됨

## [ 허용된 식품첨가물(효모식품) 목록 ]

### ● 개요

<b>DB명</b>	허용 식품첨가물 목록 - 허용된 효모식품 목록
<b>관리기관</b>	캐나다 보건부(HC)
<b>DB 내용</b>	허용된 식품첨가물 목록, 첨가 허용 식품, 허용기준 및 조건
<b>접속 주소</b>	https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/14-year-foods.html
<b>정보 제공 건수</b>	20건('24.11. 기준)

### ● DB 접속 방법

#### ○ 캐나다 보건부 'Health Canada' 접속

The screenshot shows the official website of the Government of Canada. At the top, there are logos for the Government of Canada in English and French, a search bar, and a 'Sign In' button. Below the header is a 'MENU' dropdown. The main content area features a large banner with the text 'Canada.ca The official website of the Government of Canada'. Underneath, there is a 'Most requested' section with links to 'Sign in to an account', 'Employment Insurance and leave', 'Public pensions (CPP and OAS)', 'Get a passport', 'Find a job', 'Visit Canada', and 'Get a work permit'. The bottom section is organized into a grid of service categories: 'Jobs', 'Business and industry', 'Health', 'Immigration and citizenship', 'Benefits', 'Environment and natural resources', 'Travel and tourism', 'Taxes', and 'Money and finances', each with a brief description of the services provided.

○ 우측 상단란에 'Food Additives' 검색

Government of Canada / Gouvernement du Canada

Francis

food additives

MENU

Canada.ca

The official website of the Government of Canada

Sign in to an account | Employment Insurance and leave | Public pensions (CPP and OAS) | Get a passport

Find a job | Visit Canada | Get a work permit

**Jobs**  
Find a job, training, hiring programs, work permits, Social Insurance Number (SIN)

**Immigration and citizenship**  
Visit, work, study, immigrate, refugees, permanent residents, apply, check status

**Travel and tourism**  
In Canada or abroad, advice, advisories, passports, visit Canada, events, attractions

**Business and industry**  
Starting a business, permits, copyright, business support, selling to government

**Benefits**  
EI, family and sickness leave, pensions, housing, student aid, disabilities

**Taxes**  
Income tax, payroll, GST/HST, contribution limits, tax credits, charities

**Health**  
Food, nutrition, diseases, vaccines, drugs, product safety and recalls

**Environment and natural resources**  
Weather, climate, agriculture, wildlife, pollution, conservation, fisheries

**Money and finances**  
Personal finance, credit reports, fraud protection, paying for education

○ 'Food Additives' 클릭

Search results

food additives

Don't include personal information (telephone, email, SIN, financial, medical, or work details).

55,888 search results for "food additives"

**Food Additives**

Health Canada

<https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives.html>

Dec 14, 2016 - ... and their regulation in Canada. What is a **food additive**? How are **food additives** regulated? **Food** colour labelling Specific Topics on **Food Additives** In this section ... **food** ingredients such as salt, sugar, starch; ... **Food additives** must be of suitable quality, must be effective for their intended purpose, and, when used according to the ...

○ ‘Lists of Permitted Food Additives’ 클릭

Government of Canada / Gouvernement du Canada

Search Canada.ca

Franglais

MENU

Canada.ca > Departments and agencies > Health Canada > Food and nutrition > Food Safety

**Food Safety**

- Chemical Contaminants
- Food Additives**
- Caffeine in Foods
- ARCHIVED - Food Additive Dictionary
- Lists of Permitted Food Additives
- Sugar Substitutes
- ARCHIVED - Health Canada Requests Information from Industry on the Use of Aluminum-Containing Food Additives
- ARCHIVED - Health Canada Review of Dietary Exposure to Aluminum
- Questions and Answers

## Food Additives

This section provides information on food additives and their regulation in Canada.

[What is a food additive?](#)  
[How are food additives regulated?](#)  
[Food colour labelling](#)  
[Specific Topics on Food Additives](#)

**In this section**

- [Food Additive Submission Preparation - Abridged Guidance](#)
- **[Lists of Permitted Food Additives](#)**
  - [Transition Guide: Understanding and Using the Lists of Permitted Food Additives](#)
- [Food Additive Dictionary](#)
- [Policy for Differentiating Food Additives and Processing Aids](#)
- [August 2016 - Results of the Consultation on the Food Directorate's Proposed Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods](#)
- [\(2016\) The Food Directorate's Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods](#)
- [Priority Scheduling and Expedited Handling of Submissions that have the Capacity to](#)

○ 해당 목록 클릭

## Lists

1. [List of Permitted Anticaking Agents](#)
2. [List of Permitted Bleaching, Maturing or Dough Conditioning Agents](#)
3. [List of Permitted Colouring Agents](#)
4. [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#)
5. [List of Permitted Food Enzymes](#)
6. [List of Permitted Firming Agents](#)
7. [List of Permitted Glazing or Polishing Agents](#)
8. [List of Permitted Food Additives with Other Accepted Uses](#)
9. [List of Permitted Sweeteners](#)
10. [List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents](#)
11. [List of Permitted Preservatives](#)
12. [List of Permitted Sequestering Agents](#)
13. [List of Permitted Starch Modifying Agents](#)
14. **[List of Permitted Yeast Foods](#)**
15. [List of Permitted Carrier or Extraction Solvents](#)

[Archived Lists](#)

Part 1  
4. 원 가 문

● 정보 제공 범위

- 허용된 식품첨가물 목록, 첨가 허용 식품, 최대허용기준 및 조건



예시 | 원료명: 염화암모늄

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
A.1	Ammonium Chloride	(1) Flour; Whole wheat flour	(1) 2,000 p.p.m. of the flour
		(2) Bread	(2) 2,500 p.p.m. of the flour. For combinations see paragraph B.13.021(m)
		(3) Unstandardized foods	(3) Good Manufacturing Practice

항목 번호	식품첨가물	첨가 허용 식품 또는 물질	최대허용기준 및 조건
A.1	염화암모늄	(1) 밀가루, 통밀가루	(1) 밀가루 기준 2,000 ppm
		(2) 빵	(2) 밀가루 기준 2,500 ppm 조합에 대한 자세한 내용은 B.13.021(m) 참조
		(3) 비표준 식품	(3) GMP 기준

## [ 허용된 식품첨가물(용매) 목록 ]

### ● 개요

<b>DB명</b>	허용 식품첨가물 목록 - 허용된 용매 목록
<b>관리기관</b>	캐나다 보건부(HC)
<b>DB 내용</b>	허용된 식품첨가물 목록, 첨가 허용 식품, 허용기준 및 조건
<b>접속 주소</b>	<a href="https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/15-carrier-extraction-solvents.html">https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/15-carrier-extraction-solvents.html</a>
<b>정보 제공 건수</b>	24건('24.11. 기준)

### ● DB 접속 방법

#### ○ 캐나다 보건부 'Health Canada' 접속

The screenshot shows the official website of the Government of Canada. At the top, there are logos for the Government of Canada in English and French, a search bar, and a 'Sign In' button. Below the header is a 'MENU' dropdown. The main content area features a banner with the text 'Canada.ca The official website of the Government of Canada' over a background of autumn leaves. Underneath, there is a 'Most requested' section with links to 'Sign in to an account', 'Employment Insurance and leave', 'Public pensions (CPP and OAS)', 'Get a passport', 'Find a job', 'Visit Canada', and 'Get a work permit'. The bottom section is organized into a grid of service categories: 'Jobs', 'Business and industry', 'Health', 'Immigration and citizenship', 'Benefits', 'Environment and natural resources', 'Travel and tourism', 'Taxes', and 'Money and finances', each with a brief description of the services provided.

○ 우측 상단란에 'Food Additives' 검색

Government of Canada / Gouvernement du Canada

francais

food additives

MENU

Sign in

Canada.ca

The official website of the Government of Canada

Most requested

- Sign in to an account
- Employment Insurance and leave
- Public pensions (CPP and OAS)
- Get a passport
- Find a job
- Visit Canada
- Get a work permit

**Jobs**  
Find a job, training, hiring programs, work permits, Social Insurance Number (SIN)

**Immigration and citizenship**  
Visit, work, study, immigrate, refugees, permanent residents, apply, check status

**Travel and tourism**  
In Canada or abroad, advice, advisories, passports, visit Canada, events, attractions

**Business and industry**  
Starting a business, permits, copyright, business support, selling to government

**Benefits**  
EI, family and sickness leave, pensions, housing, student aid, disabilities

**Taxes**  
Income tax, payroll, GST/HST, contribution limits, tax credits, charities

**Health**  
Food, nutrition, diseases, vaccines, drugs, product safety and recalls

**Environment and natural resources**  
Weather, climate, agriculture, wildlife, pollution, conservation, fisheries

**Money and finances**  
Personal finance, credit reports, fraud protection, paying for education

○ 'Food Additives' 클릭

Search results

food additives

Don't include personal information (telephone, email, SIN, financial, medical, or work details).

55,888 search results for "food additives"

**Food Additives**

Health Canada

<https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives.html>

Dec 14, 2016 - ... and their regulation in Canada. What is a **food additive**? How are **food additives** regulated? **Food** colour labelling Specific Topics on **Food Additives** In this section ... **food** ingredients such as salt, sugar, starch; ... **Food additives** must be of suitable quality, must be effective for their intended purpose, and, when used according to the ...

○ ‘Lists of Permitted Food Additives’ 클릭

Government of Canada / Gouvernement du Canada

Search Canada.ca

Franglais

MENU

Canada.ca > Departments and agencies > Health Canada > Food and nutrition > Food Safety

**Food Safety**

- Chemical Contaminants
- Food Additives**
- Caffeine in Foods
- ARCHIVED - Food Additive Dictionary
- Lists of Permitted Food Additives
- Sugar Substitutes
- ARCHIVED - Health Canada Requests Information from Industry on the Use of Aluminum-Containing Food Additives
- ARCHIVED - Health Canada Review of Dietary Exposure to Aluminum
- Questions and Answers

## Food Additives

This section provides information on food additives and their regulation in Canada.

[What is a food additive?](#)  
[How are food additives regulated?](#)  
[Food colour labelling](#)  
[Specific Topics on Food Additives](#)

**In this section**

- [Food Additive Submission Preparation - Abridged Guidance](#)
- **[Lists of Permitted Food Additives](#)**
  - [Transition Guide: Understanding and Using the Lists of Permitted Food Additives](#)
- [Food Additive Dictionary](#)
- [Policy for Differentiating Food Additives and Processing Aids](#)
- [August 2016 - Results of the Consultation on the Food Directorate's Proposed Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods](#)
- (2016) [The Food Directorate's Pre-Market Submission Management Process for Food Additives, Infant Formulas and Novel Foods](#)
- [Priority Scheduling and Expedited Handling of Submissions that have the Capacity to](#)

○ 해당 목록 클릭

## Lists

1. [List of Permitted Anticaking Agents](#)
2. [List of Permitted Bleaching, Maturing or Dough Conditioning Agents](#)
3. [List of Permitted Colouring Agents](#)
4. [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#)
5. [List of Permitted Food Enzymes](#)
6. [List of Permitted Firming Agents](#)
7. [List of Permitted Glazing or Polishing Agents](#)
8. [List of Permitted Food Additives with Other Accepted Uses](#)
9. [List of Permitted Sweeteners](#)
10. [List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents](#)
11. [List of Permitted Preservatives](#)
12. [List of Permitted Sequestering Agents](#)
13. [List of Permitted Starch Modifying Agents](#)
14. [List of Permitted Yeast Foods](#)
15. **[List of Permitted Carrier or Extraction Solvents](#)**

[Archived Lists](#)

Part 1  
4. 원 가 문

● 정보 제공 범위

- 허용된 식품첨가물 목록, 첨가 허용 식품, 최대허용기준 및 조건



예시 | 원료명: 아세톤

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Residue	Column 4 Maximum Level of Use and Other Conditions
1.	Acetone	(1) Spice extracts; Natural extractives	(1) 30 p.p.m.	
		(2) Meat and Egg Marking Inks		(2) Good Manufacturing Practice

항목 번호	식품첨가물	첨가 허용 식품 또는 물질	최대 잔류량	최대허용기준 및 조건
1	아세톤	(1) 향신료 추출물, 천연 추출물	(1) 30 ppm	
		(2) 육류 및 계란 표기용 잉크		(2) GMP 기준

## ■ 유럽연합

### [ 식품, 사료 정보 포털 데이터베이스(식품첨가물) ]

#### ● 개요

<b>DB명</b>	식품, 사료 정보 포털 데이터베이스(식품첨가물)
<b>관리기관</b>	유럽위원회(EC)/유럽식품안전청(EFSA)
<b>DB 내용</b>	식품첨가물 특성, 사용조건, 관련 규정 등에 대한 정보 제공
<b>접속 주소</b>	https://ec.europa.eu/food/food-feed-portal/screen/food-additives/search
<b>정보 제공 건수</b>	사용 승인된 원료 총 410건('24.11. 기준)

#### ● DB 접속 방법

- 유럽위원회의 'Food and Feed Information Portal Database' 접속

The screenshot shows the 'Food and Feed Information Portal Database' website. At the top, there is a search bar and the European Commission logo. Below the header, there is a navigation menu with 'European Commission', 'Food', and 'Food and Feed Information Portal'. The main content area is divided into several sections:

- Decontamination Substances:** The Commission has established a European Union data base of substances, other than potable water, authorized to remove surface contamination from products of animal origin in accordance with Article 3(2) of Regulation (EC) No 853/2004.
  - Search for Decontamination Substances
- Feed Additives:** The Commission has established the European Union Register of Feed Additives, which is regularly updated, and it makes reference/links to the relevant authorisation Regulations. Those Regulations include the specific requirements for placing the additives on the EU and EEA market.
  - Search Feed Additives
  - Search Feed Additives authorisations
  - Download Register in Excel format
  - Latest updates to the Register
  - Archived expired authorisations (PDF)
  - APIs
  - Disclaimer
- Food Additives:** This database is a searchable tool informing about the food additives approved for use in food in the EU and their conditions of use. It is based on the Union list of approved food additives laid down in Annex II to Regulation (EC) No 1333/2008.
  - Search for Additives
  - Browse by categories
  - European Legislation on Food Additives
  - Information documents
  - APIs
  - Disclaimer
- Food Allergens:** This database is a searchable tool informing on substances or products causing allergies or intolerances as listed in Annex II to Regulation
- Food Contact Materials:** This database is a searchable tool informing about Food Contact Materials Union Register of recycling installations, facilities, companies,
- Food Flavouring:** This database is a searchable tool informing about the flavouring substances approved for use in food in the EU and their conditions of

○ 오른쪽 'Food Additives'의 'Search Food additives' 클릭

European Commission | English | Search

## Food and Feed Information Portal Database

European Commission > Food > Food and Feed Information Portal

Search | Search all domains

### Decontamination Substances

The Commission has established a European Union data base of substances, other than potable water, authorized to remove surface contamination from products of animal origin in accordance with Article 3(2) of Regulation (EC) No 853/2004.

- Search for Decontamination Substances

### Feed Additives

The Commission has established the European Union Register of Feed Additives, which is regularly updated, and it makes reference/links to the relevant authorisation Regulations. Those Regulations include the specific requirements for placing the additives on the EU and EEA market.

- Search Feed Additives
- Search Feed Additives authorisations
- Download Register in Excel format
- Latest updates to the Register
- Archived expired authorisations (PDF)
- APIs
- Disclaimer

### Food Additives

This database is a searchable tool informing about the food additives approved for use in food in the EU and their conditions of use. It is based on the Union list of approved food additives laid down in Annex II to Regulation (EC) No 1333/2008.

- Search for Additives**
- Browse by categories
- European Legislation on Food Additives
- Information documents
- APIs
- Disclaimer

### Food Allergens

This database is a searchable tool informing on substances or products causing allergies or intolerances as listed in Annex II to Regulation (EC) No 1831/2003.

### Food Contact Materials

This database is a searchable tool informing about Food Contact Materials Union Register of recycling installations, facilities, companies, and products.

### Food Flavouring

This database is a searchable tool informing about the flavouring substances approved for use in food in the EU and their conditions of use.

○ 'Additive/group name'에 검색하고자 하는 원료명 입력

European Commission | English | Search

## Food and Feed Information Portal Database

European Commission > Food > Food and Feed Information Portal > Food Additives > Search Food additives

### Food additives (1 matching records)

⚙ E no.	⚙ Is a group?	⚙ Additive/group name
<input type="text"/>	<input type="text"/>	<input type="text" value="calcium silicate"/>
E 552	No	Calcium silicate

○ 해당 원료 클릭

The screenshot shows the search results for 'calcium silicate' in the Food and Feed Information Portal Database. The search bar at the top contains 'calcium silicate' and the search button is labeled 'Search'. Below the search bar, the breadcrumb trail reads: 'European Commission > Food > Food and Feed Information Portal > Food Additives > Search Food additives'. The main heading is 'Food additives (1 matching records)'. Below this, there is a table with three columns: 'E no.', 'Is a group?', and 'Additive/group name'. The table contains one row with the following data: 'E 552', 'No', and 'Calcium silicate'. The text 'Calcium silicate' in the third column is highlighted with a red rectangular box.

○ 해당 원료의 상세 정보 확인

The screenshot displays the detailed information page for Calcium silicate. The page is organized into several sections:
 

- Characteristics:** A table with fields for Additive Name (Calcium silicate), Synonym Name(s), E No. (E 552), INS No., Notes, Group (No), and Member of (Silicon dioxide - silicates (E 551 - 553)).
- Messages:** A text block stating 'Substance is included in E 551 - 559, see also authorisation for Group E 551 - 559'.
- Conditions of use:** A section titled 'The additive is authorised to be used in the following category(ies):' followed by a reference to Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation EC No 1333/2008. Below this, it lists 'Individual restriction(s) / exception(s)' as 'quantum satis, surface treatment only'.
- Legislations:** A section listing 'Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation EC No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food Additives . TEXT with EEA relevance . applicable from 02/12/2011'.

## ● 정보 제공 범위

- 해당 원료의 특성, 안내, 사용조건, 관련 규정 등에 대한 정보 제공



예시 | 원료명: 규산칼슘

<b>① Characteristics</b>	
Additive Name	Calcium silicate
Synonym Name(s)	
E No.	E 552
INS No.	
Notes	
Group	No
Member of	Silicon dioxide - silicates (E 551 - 553)
<b>② Messages</b>	
Substance is included in E 551 - 559, see also authorisation for Group E 551 - 559	
<b>③ Conditions of use</b>	
The additive is authorised to be used in the following category(ies):	
5.3 <b>Chewing gum</b> (Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation EC No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food Additives - TEXT with EEA relevance. , applicable from 02/12/2011)	
Individual restriction(s) / exception(s)	quantum satis, surface treatment only
<b>④ Legislations</b>	
Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation EC No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food Additives - TEXT with EEA relevance. , applicable from 02/12/2011	

### ① 특성

- 첨가물명: 규산칼슘
- 동의어: -
- E 번호: E 552
- INS 번호: -
- 비교: -
- 그룹: 해당사항 없음
- 소속군: 이산화규소 - 실리케이트(E551-553)

② 안내(messages): 해당 원료는 E 551-559 그룹에 포함되며, 그룹 E 551-559의 승인 요건 참조 바람

③ 사용조건: 해당 첨가물은 다음 식품군에서 사용이 허가됨  
5.3 껌  
(이하 생략)

④ 관련 규정: (생략)

## [ 식품, 사료 정보 포털 데이터베이스(향미증진제) ]

### ● 개요

<b>DB명</b>	식품, 사료 정보 포털 데이터베이스(향미증진제)
<b>관리기관</b>	유럽위원회(EC)/유럽식품안전청(EFSA)
<b>DB 내용</b>	유럽연합에서 사용 승인된 향미증진제에 대한 정보 제공
<b>접속 주소</b>	https://ec.europa.eu/food/food-feed-portal/screen/food-flavourings/search
<b>정보 제공 건수</b>	2,549건('24.11. 기준) - 식품 및 식품첨가물로 사용되는 향료 및 특정 향미증진제에 관한 규정 (Regulation (EC) No 1334/2008)의 부속서 I에 명시된 승인된 물질 및 원료의 통합 목록(Union list)을 기반으로 한 데이터베이스

### ● DB 접속 방법

#### ○ 유럽위원회의 'Food and Feed Information Portal Database' 접속

The screenshot shows the official website of the European Commission's Food and Feed Information Portal Database. The page is in English and includes a search bar and navigation menu. The main content is organized into six columns, each representing a different category of substances:

- Decontamination Substances:** Describes the EU data base for substances other than potable water, authorized for surface decontamination from animal products.
- Feed Additives:** Describes the EU Register of Feed Additives, which is regularly updated and provides reference links to relevant regulations.
- Food Additives:** Describes a searchable tool for food additives approved for use in the EU, based on the Union list in Annex II to Regulation (EC) No 1333/2008.
- Food Allergens:** Describes a searchable tool for substances or products causing allergies or intolerances listed in Annex II to Regulation (EC) No 1831/2003.
- Food Contact Materials:** Describes a searchable tool for the Union Register of recycling installations, facilities, and companies.
- Food Flavouring:** Describes a searchable tool for flavouring substances approved for use in food in the EU.

○ 화면 하단의 ‘Food Flavouring’의 ‘Search for food flavouring’ 클릭

European Commission | English | Search

## Food and Feed Information Portal Database

European Commission > Food > Food and Feed Information Portal

Search | Search all domains

### Decontamination Substances

The Commission has established a European Union data base of substances, other than potable water, authorized to remove surface contamination from products of animal origin in accordance with Article 3(2) of Regulation (EC) No 853/2004.

- Search for Decontamination Substances

### Feed Additives

The Commission has established the European Union Register of Feed Additives, which is regularly updated, and it makes reference/links to the relevant authorisation Regulations. Those Regulations include the specific requirements for placing the additives on the EU and EEA market.

- Search Feed Additives
- Search Feed Additives authorisations
- Download Register in Excel format
- Latest updates to the Register
- Archived expired authorisations (PDF)
- APIs
- Disclaimer

### Food Additives

This database is a searchable tool informing about the food additives approved for use in food in the EU and their conditions of use. It is based on the Union list of approved food additives laid down in Annex II to Regulation (EC) No 1333/2008.

- Search for Additives
- Browse by categories
- European Legislation on Food Additives
- Information documents
- APIs
- Disclaimer

### Food Allergens

This database is a searchable tool informing on substances or products causing allergies or intolerances as listed in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers.

- Search for Allergens

### Food Contact Materials

This database is a searchable tool informing about Food Contact Materials Union Register of recycling installations, facilities, companies, schemes, authorisations and novel recycling technologies as described in Reg 2022/1615 under Art 24. Search the EU register of:

- Recycling Companies

### Food Flavouring

This database is a searchable tool informing about the flavouring substances approved for use in food in the EU and their conditions of use. It is based on the Union list of approved flavourings and source materials laid down in Annex I to Regulation (EC) No 1334/2008.

- Search for food flavouring

○ ‘Chemical name’에 검색하고자 하는 원료명 입력

## Food and Feed Information Portal Database

European Commission > Food > Food and Feed Information Portal > Food flavourings > Search Food flavourings

### Food flavourings (8 matching records)

CAS No.	FL No.	CoE No.	JECFA No.	Chemical name
				Vanillin
0188417-26-7	09.933		953	Ethyl vanillin isobutyrate
0020665-85-4	09.811		891	Vanillin isobutyrate
0122397-96-0	16.075		892	Ethyl vanillin beta-D-glucopyranoside
0180964-47-0	02.248		1879	Vanillin 3-(l-menthoxy)propane-1,2-diol acetal
0000121-33-5	05.018	107	889	Vanillin
0000121-32-4	05.019	108	893	Ethyl vanillin
0068527-74-2	06.104		1882	Vanillin propylene glycol acetal
0063253-24-7	06.132		960	Vanillin butan-2,3-diol acetal (mixture of stereo isomers)

○ 해당 원료 클릭

Food and Feed Information Portal Database

European Commission > Food > Food and Feed Information Portal > Food flavourings > Search Food flavourings

Food flavourings (8 matching records)

CAS No.	FL No.	CoE No.	JECFA No.	Chemical name
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text" value="Vanillin"/>
0188417-26-7	09.933		953	Ethyl vanillin isobutyrate
0020665-85-4	09.811		891	Vanillin isobutyrate
0122397-96-0	16.075		892	Ethyl vanillin beta-D-glucopyranoside
0180964-47-0	02.248		1879	Vanillin 3-(1-menthoxy)propane-1,2-diol acetal
0000121-33-5	05.018	107	889	Vanillin
0000121-32-4	05.019	108	893	Ethyl vanillin
0068527-74-2	06.104		1882	Vanillin propylene glycol acetal
0063253-24-7	06.132		960	Vanillin butan-2,3-diol acetal (mixture of stereo isomers)

○ 해당 원료 상세 정보 확인

Characteristics			
Chemical name	Vanillin		
Purity of the named substance at least 95% unless otherwise specified			
Cas No.	0000121-33-5		
FI No.	05.018	CoE No.	107
JECFA No.	889	Flavouring Type	substances
Mixture	No		
Notes			
Reference body			
Messages			
-			
Conditions of use			
All categories of flavoured foods (Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC, applicable from 22/10/2012)			
Individual restriction(s) / exception(s)	-		
Legislations			
Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC, applicable from 22/10/2012			

## ● 정보 제공 범위

- 해당 원료의 특성, 안내, 사용조건, 관련 규정 관한 정보 제공



예시 | 원료명: 바닐린(Vanillin)

<b>① Characteristics</b>			
Chemical name	Vanillin		
Purity of the named substance at least 95% unless otherwise specified			
Cas No.	0000121-33-5		
FI No.	05.018	CoE No.	107
JECFA No.	889	Flavouring Type	substances
Mixture	No		
Notes			
Reference body			
<b>② Messages</b>			
-			
<b>③ Conditions of use</b>			
All categories of flavoured foods (Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC, applicable from 22/10/2012)			
Individual restriction(s) / exception(s) -			
<b>④ Legislations</b>			
Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC, applicable from 22/10/2012			

### ① 특성

- 화학명: 바닐린
- 순도: 특별히 명시되지 않은 한 최소 95%
- CAS 번호: 0000121-33-5
- FL 번호: 05.018
- CoE 번호: 107
- JECFA 번호: 889
- 향미 유형: 물질
- 혼합 여부: 해당 없음
- 비고: -
- 참조 기관: -

### ② 안내(messages): -

### ③ 사용조건: 모든 카테고리의 향미 첨가 식품에서 사용 가능 (이하 생략)

### ④ 관련 규정: (생략)

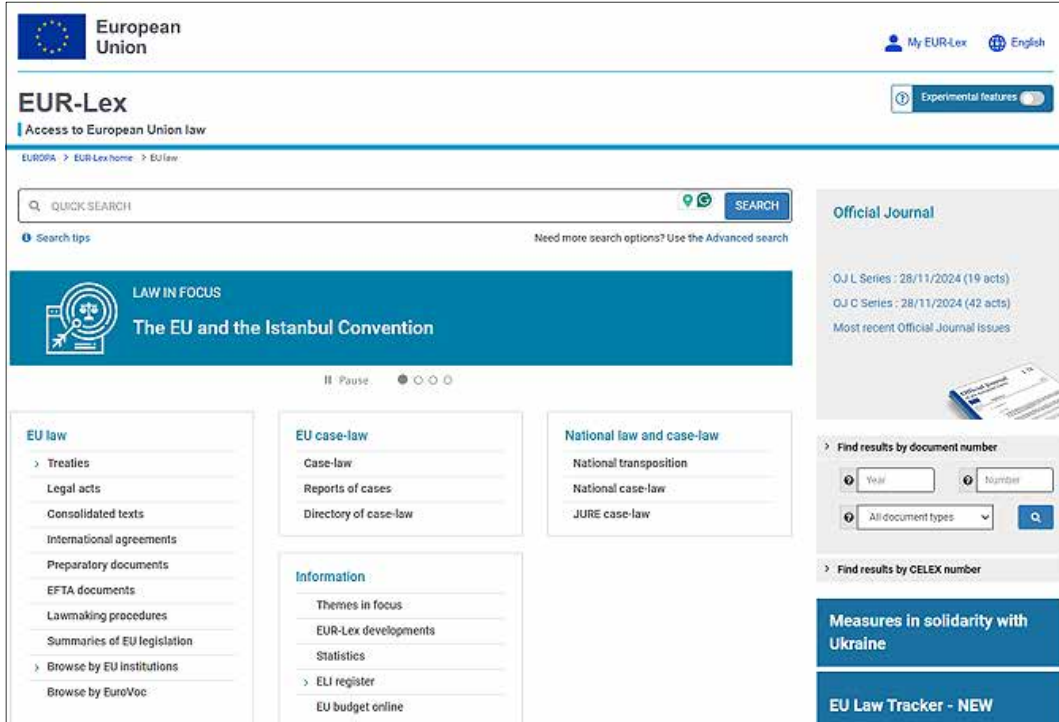
## [비타민, 미네랄 및 특정 기타 물질의 식품 첨가에 관한 규정]

### ● 개요

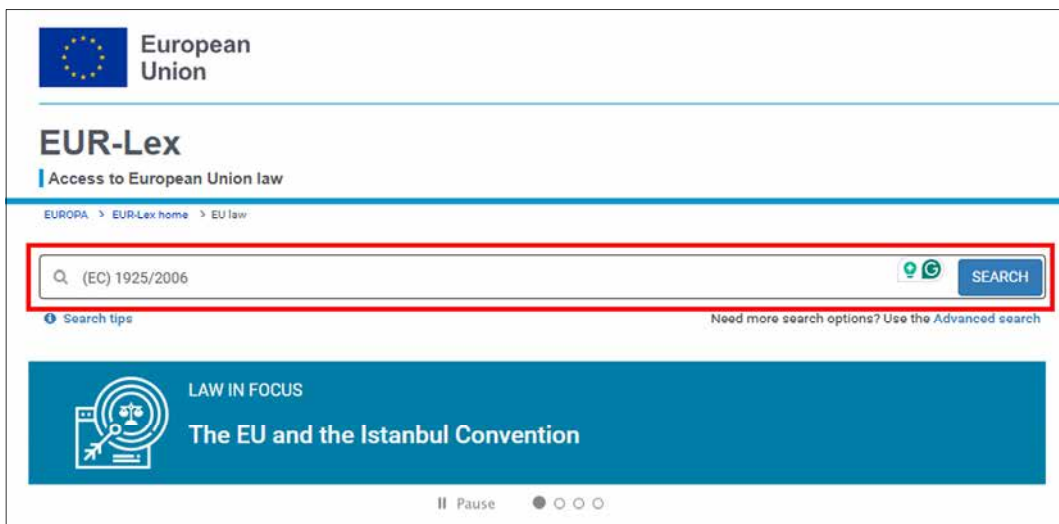
DB명	비타민, 미네랄 및 특정 기타 물질의 식품 첨가에 관한 규정 [(EC) No 1925/2006]
관리기관	유럽위원회(EC)/유럽식품안전청(EFSA)
DB 내용	부속서 I·II에서 식품보충제에 첨가 가능한 비타민 및 미네랄 목록 제공
접속 주소	<a href="https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R1925&amp;qid=1731237974212">https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R1925&amp;qid=1731237974212</a>
정보 제공 건수	총 141건('24.11. 기준) - 부속서 I 28건, 부속서 II 113건

● DB 접속 방법

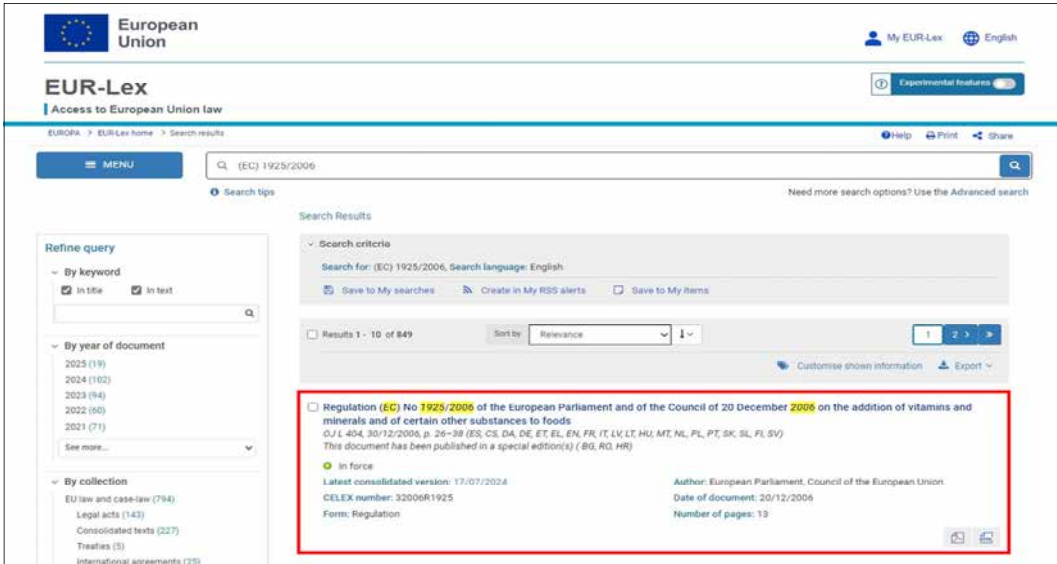
○ 유럽위원회의 'EUR-Lex' 접속



○ 검색란에 '(EC) 1925/2006' 입력 후 클릭



○ 해당 규정 클릭



○ 해당 규정 화면 아래로 이동하여 부속서 I·II의 식품에 첨가 가능한 원료 확인

ANNEX I VITAMINS AND MINERALS WHICH MAY BE ADDED TO FOODS	ANNEX II VITAMIN FORMULATIONS AND MINERAL SUBSTANCES WHICH MAY BE ADDED TO FOODS
<b>1. Vitamins</b> Vitamin A Vitamin D Vitamin E Vitamin K Vitamin B1 Vitamin B2 Niacin Pantothenic acid Vitamin B6 Folic acid Vitamin B12 Biotin Vitamin C <b>2. Minerals</b> Calcium Magnesium Iron Copper Iodine Zinc Manganese Sodium Potassium Selenium Chromium Molybdenum Fluoride Chloride Phosphorus	<b>1. Vitamin formulations</b> <b>VITAMIN A</b> retinol retinyl acetate retinyl palmitate beta-carotene <b>VITAMIN D</b> cholecalciferol ergocalciferol <b>VITAMIN E</b> D.alpha-tocopherol DL.alpha-tocopherol D.alpha-tocopheryl acetate DL.alpha-tocopheryl acetate D.alpha-tocopheryl acid succinate <b>VITAMIN K</b> phytyloquinone (phytomenadione) <b>VITAMIN B1</b> thiamin hydrochloride thiamin mononitrate <b>VITAMIN B2</b> riboflavin riboflavin 5'-phosphate, sodium <b>NIACIN</b> nicotinic acid nicotinamide <b>PANTOTHENIC ACID</b> D-pantothenate, calcium D-pantothenate, sodium dexpantethol

Part 1.  
4.원 가 명

● 정보 제공 범위

- 식품에 첨가될 수 있는 비타민 및 미네랄



예시 | 부속서 I

ANNEX I VITAMINS AND MINERALS WHICH MAY BE ADDED TO FOODS
<b>I. Vitamins</b>
Vitamin A
Vitamin D
Vitamin E
Vitamin K
Vitamin B1
Vitamin B2
Niacin
Pantothenic acid
Vitamin B6
Folic acid
Vitamin B12
Biotin
Vitamin C
<b>2. Minerals</b>
Calcium
Magnesium
Iron
Copper
Iodine
Zinc
Manganese
Sodium
Potassium
Selenium
Chromium
Molybdenum
Fluoride
Chloride
Phosphorus

부속서 I 식품에 첨가될 수 있는 비타민 및 미네랄
1.비타민
비타민 A
비타민 D
비타민 E
비타민 K
비타민 B1
비타민 B2
니아신
판토텐산
비타민 B6
2.미네랄
칼슘
마그네슘
철분
구리
요오드
아연
망간
나트륨
칼륨
셀레늄
크롬
몰리브데넘
플루오린
염화물
인

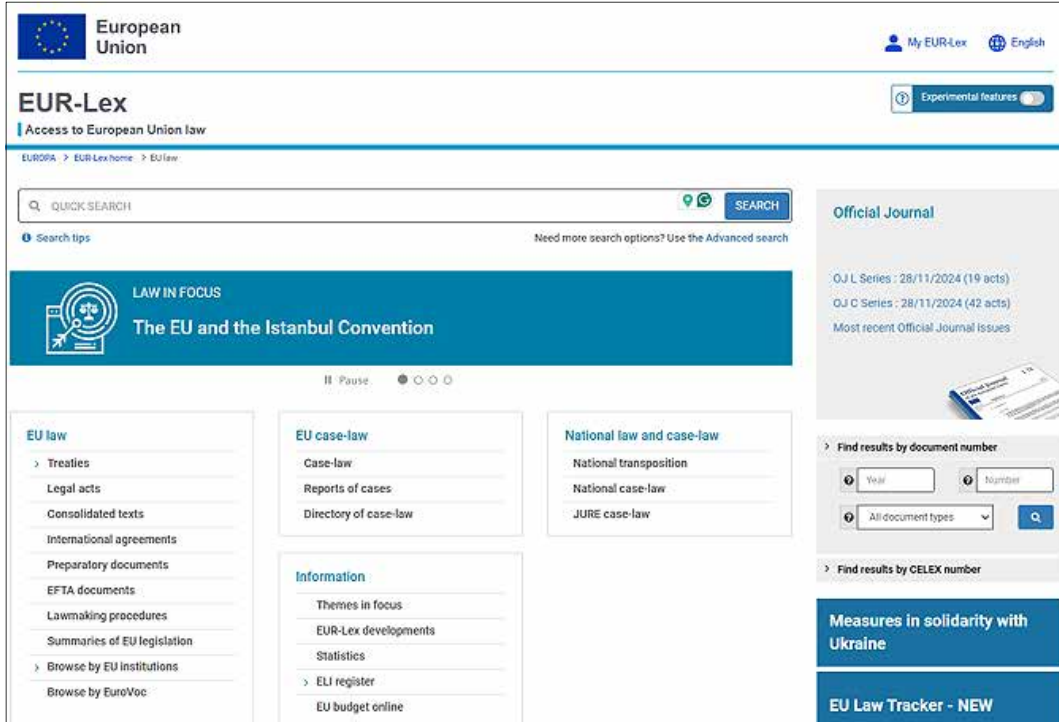
## [ 식품에 사용되거나 사용될 목적으로 제조된 혼제 향료에 관한 규정 ]

### ● 개요

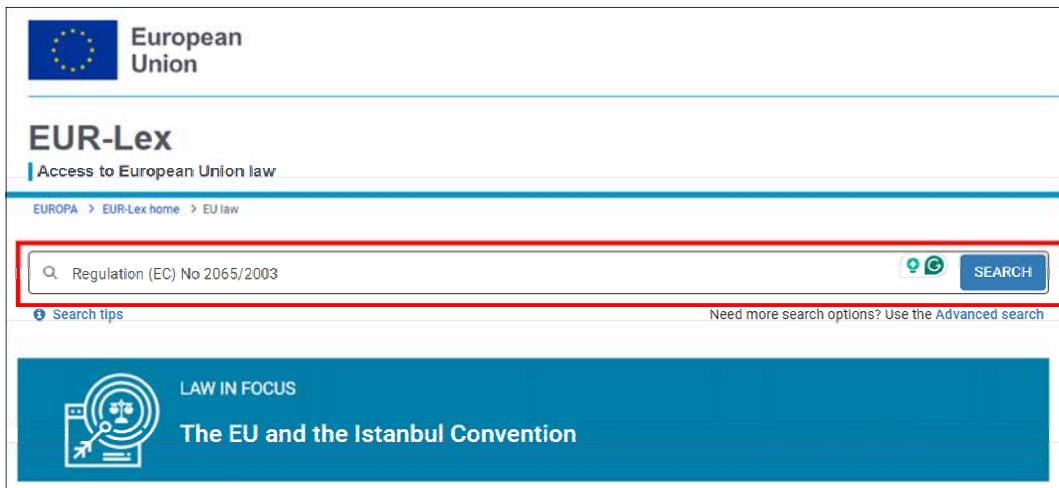
DB명	식품에 사용되거나 사용할 목적으로 제조된 혼제 향료에 관한 규정 [Regulation (EC) No 2065/2003]
관리기관	유럽위원회(EC)/유럽식품안전청(EFSA)
DB 내용	식품에 사용되었거나 사용될 목적으로 제조된 혼제 향료, 혼제 향료 생산에 사용되는 원료, 혼제 향료의 제조 조건, 혼제 향료가 포함되었거나 사용된 식품에 관한 규정 제공
접속 주소	<a href="http://data.europa.eu/eli/reg/2003/2065/oj">http://data.europa.eu/eli/reg/2003/2065/oj</a>
정보 제공 건수	-

● DB 접속 방법

○ 유럽위원회의 'EUR-Lex' 접속



○ 검색란에 'Regulation (EC) No 2065/2003' 입력 후 클릭



## ○ 해당 규정 클릭

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**Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods**

OJ L 309, 26/11/2003, p. 1–8 (ES, DA, DE, EL, EN, FR, IT, NL, PT, FI, SV)

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CELEX number: 32003R2065 Date of document: 10/11/2003

Form: Regulation Number of pages: 8

## ○ 상세 정보 확인

I

(Acts whose publication is obligatory)

**REGULATION (EC) No 2065/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
of 10 November 2003  
on smoke flavourings used or intended for use in or on foods

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 93 thereof,

Having regard to the proposal from the Commission <sup>(1)</sup>,

Having regard to the opinion of the European Economic and Social Committee <sup>(2)</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty <sup>(3)</sup>,

Whereas:

(1) Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production <sup>(4)</sup>, and in particular Article 5(1), seventh indent thereof, provides for the adoption of appropriate provisions concerning source materials used for the production of smoke flavourings and reaction conditions under which they are prepared.

(2) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(3) A high level of protection of human life and health should be assured in the pursuit of Community policies.

(4) In order to protect human health, smoke flavourings should undergo a safety assessment through a Community procedure before being placed on the market or used in or on foods within the Community.

(5) Differences between national laws, regulations and administrative provisions concerning the assessment and authorisation of smoke flavourings may hinder their free movement, creating conditions of unequal and unfair competition. An authorisation procedure should therefore be established at Community level.


(6) The chemical composition of smoke is complex and depends among other things on the types of wood used, the method used for developing smoke, the water content of the wood and the temperature and oxygen concentration during smoke generation. Smoked foods in general give rise to health concerns, especially with respect to the possible presence of polycyclic aromatic hydrocarbons. Because smoke flavourings are produced from smoke which is subjected to fractionation and purification processes, the use of smoke flavourings is generally considered to be of less health concern than the traditional smoking process. However, the possibility of wider applications of smoke flavourings in comparison to conventional smoking has to be taken into account in safety assessments.

(7) This Regulation covers smoke flavourings as defined in Directive 88/388/EEC. The production of these smoke flavourings starts with the condensation of smoke. The condensed smoke is normally separated by physical processes into a water-based primary smoke condensate, a water-insoluble high-density tar phase and a water-insoluble oily phase. The water-insoluble oily phase is a by-product and unsuitable for the production of smoke flavourings. The primary smoke condensates and fractions of the water-insoluble high-density tar phase, the 'primary tar fractions', are purified to remove components of smoke which are most harmful to human health. They may then be suitable for use as such in or on foods or for the production of derived smoke flavourings made by further appropriate physical processing such as extraction procedures, distillation, concentration by evaporation, absorption or membrane separation and the addition of food ingredients, other flavourings, food additives or solvents, without prejudice to more specific Community legislation.

<sup>(1)</sup> OJ C 262 E, 29.10.2002, p. 523.  
<sup>(2)</sup> OJ C 85, 8.4.2003, p. 32.  
<sup>(3)</sup> Opinion of the European Parliament of 5 June 2003 (not yet published in the Official Journal) and the Council Decision of 9 December 2003.  
<sup>(4)</sup> OJ L 184, 15.7.1988, p. 61; Directive as amended by Commission Directive 91/71/EEC (OJ L 42, 15.2.1991, p. 25).

● 정보 제공 범위

- 훈제 향료와 관련한 ▲ 일반 사용 및 안전 요건(제4조), ▲ 생산 조건(제5조), ▲ 허가 신청 등에 관한 규정을 제공
- 부속서 1·II에서는 1차 제품 생산 조건 및 과학적 평가에 필요한 정보를 제공하고 있음

 예시 | 제4조 일반 사용 및 안전 요건

Article 4

**General use and safety requirements**

1. The use of smoke flavourings in or on foods shall only be authorised if it is sufficiently demonstrated that

- it does not present risks to human health,
- it does not mislead consumers.

Each authorisation may be subject to specific conditions of use.

2. No person shall place on the market a smoke flavouring or any food in or on which such a smoke flavouring is present if the smoke flavouring is not a primary product authorised in accordance with Article 6, or if is not derived therefrom, and if the conditions of use laid down in the authorisation in accordance with this Regulation are not adhered to.

조 항	내 용
제4조 일반 사용 및 안전 요건	1. 식품 내 또는 식품 위에 훈제 향료를 사용하는 것은 다음 사항이 충분히 입증된 경우에만 허가된다: <ul style="list-style-type: none"> <li>- 인체 건강에 위험을 초래하지 않을 것</li> <li>- 소비자를 오도하지 않을 것</li> </ul> 각 허가는 특정 사용 조건에 따라 부여될 수 있다 2. 제6조에 따라 승인된 1차 제품이 아니거나, 해당 제품에서 유래하지 않았거나, 본 규정에 따른 허가에 명시된 사용 조건을 준수하지 않는 경우, 누구도 훈제 향료 또는 이를 포함한 식품을 시장에 출시해서는 안 된다.



예시 | 제5조 생산 조건

*Article 5*

**Conditions of production**

1. The wood used for the production of primary products shall not have been treated, whether intentionally or unintentionally, with chemical substances during the six months immediately preceding felling or subsequent thereto, unless it can be demonstrated that the substance used for the treatment does not give rise to potentially toxic substances during combustion.

The person who places on the market primary products must be able to demonstrate by appropriate certification or documentation that the requirements laid down in the first subparagraph have been met.

2. The conditions for the production of primary products are laid down in Annex I. The water-insoluble oily phase which is a by-product of the process shall not be used for the production of smoke flavourings.

3. Without prejudice to other Community legislation, primary products may be further processed by appropriate physical processes for the production of derived smoke flavourings. Where opinions differ as to whether a particular physical process is appropriate, a decision may be reached in accordance with the procedure referred to in Article 19(2).

조 항	내 용
제5조 생산 조건	<p>1. 1차 제품 생산에 사용되는 목재는 벌채 전후 6개월 동안 고의적이든 비의도적이든 화학 물질로 처리되지 않아야 한다. 다만, 해당 처리 물질이 훈제 과정에서 잠재적으로 유독한 물질을 생성하지 않음을 입증할 수 있는 경우는 예외로 한다. 1차 제품을 시장에 출시하는 자는 적절한 인증서나 문서를 통해 첫 번째 문단에 규정된 요건이 충족되었음을 입증할 수 있어야 한다.</p> <p>2. 1차 제품 생산 조건은 부속서 I에 명시되어 있다. 생산 공정의 부산물인 불수용성 유상성분은 훈제 향료 생산에 사용될 수 없다.</p> <p>3. 기타 공동체 법률을 침해하지 않는 범위에서, 1차 제품은 적절한 물리적 공정을 통해 파생 훈제 향료로 추가 가공될 수 있다. 특정 물리적 공정의 적합성에 대한 의견이 다를 경우, 제19조 제2항에 따른 절차에 따라 결정을 내릴 수 있다.</p>



*Article 7*

**Application for authorisation**

1. To obtain the inclusion of a primary product in the list referred to in Article 6(1), an application shall be submitted in accordance with the following provisions.
2. (a) The application shall be sent to the competent authority of a Member State.  
(b) The competent authority:
  - (i) shall acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;
  - (ii) shall inform without delay the European Food Safety Authority (hereinafter referred to as the 'Authority'); and
  - (iii) shall make the application and any supplementary information supplied by the applicant available to the Authority.(c) The Authority shall inform without delay the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them.
3. The application shall be accompanied by the following:
  - (a) the name and address of the applicant;
  - (b) the information listed in Annex II;
  - (c) a reasoned statement affirming that the product complies with Article 4(1), first indent;
  - (d) a summary of the dossier.
4. The Authority shall publish detailed guidance concerning the preparation and the submission of the application <sup>(1)</sup>.

조 항	내 용
제7조 허가 신청	<ol style="list-style-type: none"> <li>1. 제6조 제1항에 언급된 목록에 1차 제품을 등재하기 위해서는 다음 규정에 따라 신청서를 제출해야 한다.</li> <li>2.               <ol style="list-style-type: none"> <li>(a) 신청서는 회원국의 관할 기관에 제출한다.</li> <li>(b) 관할 기관은 다음을 수행한다:                   <ol style="list-style-type: none"> <li>(i) 신청서를 접수한 날로부터 14일 이내에 신청자에게 서면으로 접수 사실 통보 및 접수 날짜 명시 할 것</li> <li>(ii) 유럽식품안전청에 지체없이 이를 통보할 것</li> <li>(iii) 신청자가 제출한 신청서와 추가 정보를 당국에 제공할 것</li> </ol> </li> <li>(c) 유럽식품안전청은 지체없이 다른 회원국 및 집행위원회에 신청 사실을 통보하고, 신청서와 신청자가 제출한 추가 정보를 제공해야 한다.</li> </ol> </li> <li>3. 신청서에는 다음 항목을 첨부한다:               <ol style="list-style-type: none"> <li>(a) 신청자의 성명과 주소</li> <li>(b) 부속서 II에 명시된 정보</li> <li>(c) 제품이 제4조 제1항 첫 번째 항목을 준수함을 입증에 포함하는 진술서</li> <li>(d) 신청서 요약본</li> </ol> </li> <li>4. 유럽식품안전청은 신청서 준비 및 제출 관련 세부 지침을 공표해야 한다.</li> </ol>



## ANNEX I

## Conditions for the production of primary products

1. Smoke is generated from the wood referred to in Article 5(1). Herbs, spices, twigs of juniper and twigs, needles and cones of *pinus* may be added if they are free of residues of intentional or unintentional chemical treatment or if they comply with more specific Community legislation. The source material is subjected to controlled burning, dry distillation or treatment with superheated steam in a controlled oxygen environment with a maximum temperature of 600 °C.
2. The smoke is condensed. Water and/or, without prejudice to other Community legislation, solvents may be added to achieve phase separation. Physical processes may be used for isolation, fractionation and/or purification to obtain the following phases:
  - (a) a water-based 'primary smoke condensate' mainly containing carboxylic acids, carbonylic and phenolic compounds, having a maximum content of:

benzo[a]pyrene	10 µg/kg
benz[a]anthracene	20 µg/kg
  - (b) a water-insoluble high-density tar phase which during the phase separation will precipitate, and which cannot be used as such for the production of smoke flavourings but only after appropriate physical processing to obtain fractions from this water-insoluble tar phase which are low in polycyclic aromatic hydrocarbons, already defined as 'primary tar fractions', having a maximum content of:

benzo[a]pyrene	10 µg/kg
benz[a]anthracene	20 µg/kg
  - (c) a 'water-insoluble oily phase'.If no phase separation has occurred during or after the condensation, the smoke condensate obtained must be regarded as a water-insoluble high-density tar phase, and must be processed by appropriate physical processing to obtain primary tar fractions which stay within the specified limits.

## ANNEX II

## Information necessary for the scientific evaluation of primary products

The information should be compiled in accordance with the guidelines referred to in Article 7(4) and should be submitted as described therein. Without prejudice to Article 8(2), the following information should be included in the application for authorisation referred to in Article 7:

1. the type of wood used for the production of the primary product;
2. detailed information on the production methods of the primary products and the further processing in the production of derived smoke flavourings;
3. the qualitative and quantitative chemical composition of the primary product and the characterisation of the portion which has not been identified. Of major importance are the chemical specifications of the primary product and information on the stability and the degree of variability of the chemical composition. The portions which have not been identified, i.e. the amount of substances whose chemical structure is not known, should be as small as possible and should be characterised by appropriate analytical methods, e.g. chromatographic or spectrometric methods;
4. a validated analytical method for sampling, identification and characterisation of the primary product;
5. information on the intended use levels in or on specific foods or food categories;
6. toxicological data following the advice of the Scientific Committee on Food given in its report on smoke flavourings of 25 June 1993 or its latest update.

조 항	내 용
부속서 I 1차 제품 생산 조건	<p>1. 연기는 제5조 제1항에 언급된 목재에서 생성된다. 허브, 향신료, 노간주나무 가지 및 가문비나무 가지, 바늘, 솔방울은 고의적이거나 비의도적인 화학적 처리 잔류물이 없거나, 보다 구체적인 공동체 법률을 준수하는 경우 추가할 수 있다. 원료는 최대 600°C의 제어된 산소 환경에서 제어된 연소, 건류 또는 과열 증기로 처리된다.</p> <p>2. 연기는 응축된다. 상(phase) 분리를 위해 물 및/또는 공동체 법률을 침해하지 않는 범위 내에서 용매가 추가될 수 있다. 물리적 공정을 사용하여 분리, 분획 및/또는 정제를 수행하여 다음과 같은 상을 얻는다:</p> <p>(a) 물 기반 1차 연기 응축물(a water-based primary smoke condensate): 주로 카복실산, 카르보닐 및 페놀 화합물을 포함하며, 최대 함량은 다음과 같다:</p> <ul style="list-style-type: none"> <li>- 벤조[a]피렌: 10 µg/kg</li> <li>- 벤조[a]안트라센: 20 µg/kg</li> </ul> <p>(b) 불용성 고밀도 타르 상(a water-insoluble high-density tar phase): 상 분리 시 침전되며, 연기 향료 생산에는 그대로 사용할 수 없으며, 다환 방향족 탄화수소 함량이 낮은 '1차 타르 분획'을 연기 위해 적절한 물리적 공정을 거쳐야 한다. 최대 함량은 다음과 같다:</p> <ul style="list-style-type: none"> <li>- 벤조[a]피렌: 10 µg/kg</li> <li>- 벤조[a]안트라센: 20 µg/kg</li> </ul> <p>(c) 불용성 유상성분(a water insoluble oily phase): 응축 중 또는 응축 후 상 분리가 발생하지 않으면, 생성된 연기 응축물은 물에 불용성 고밀도 타르 상으로 간주되며, 지정된 한계 내의 1차 타르 분획을 연기 위해 적절한 물리적 처리가 필요하다.</p>
부속서 II 1차 제품의 과학적 평가에 필요한 정보	<p>제7조 제4항에 언급된 지침에 따라 정보를 수집하고, 해당 지침에 설명된 대로 제출해야 한다. 제8조 제2항을 침해하지 않는 한, 제7조에 언급된 승인을 위한 신청서에는 다음 정보가 포함되어야 한다:</p> <ol style="list-style-type: none"> <li>1. 1차 제품 생산에 사용된 목재의 종류</li> <li>2. 1차 제품의 생산 공정과 파생된 연기 향료 생산을 위한 추가 처리에 대한 상세 정보</li> <li>3. 1차 제품의 정성적 및 정량적 화학 조성과 식별되지 않은 부분의 특성화: <ul style="list-style-type: none"> <li>- 주요 화학적 명세 및 화학적 조성의 안정성과 변동성에 대한 정보</li> <li>- 확인되지 않은 부분, 즉 화학 구조가 알려지지 않은 물질의 양은 가능한 적어야 하며, 크로마토그래피 또는 분광법과 같은 적절한 분석 방법으로 특성화해야 한다.</li> </ul> </li> <li>4. 1차 제품의 샘플링, 식별 및 특성화를 위한 검증된 분석 방법</li> <li>5. 특정 식품 또는 식품 범주에서의 의도된 사용 수준에 대한 정보</li> <li>6. 1993년 6월 25일 또는 최신 업데이트된 식품 과학 위원회의 연기 향료 관련 보고서에서 제시된 권고에 따른 독성학적 데이터</li> </ol>

## [ 식품첨가물에 관한 규정 ]

### ● 개요

DB명	식품첨가물에 관한 규정[Regulation (EC) No 1333/2008]
관리기관	유럽위원회(EC)/유럽식품안전청(EFSA)
DB 내용	식품첨가물에 관한 규정 정보
접속 주소	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R1333&qid=1731242495915
정보 제공 건수	-

### ● DB 접속 방법

#### ○ 유럽위원회의 'EUR-Lex' 접속

The screenshot displays the EUR-Lex website interface. At the top, there is the European Union logo and the text 'European Union'. Below this, the 'EUR-Lex' logo is prominent, with the tagline 'Access to European Union law'. A search bar is located in the center, with a 'QUICK SEARCH' button and a 'SEARCH' button. To the right, there are links for 'My EUR-Lex' and 'English', along with an 'Experimental features' toggle. The main content area is divided into several sections: 'LAW IN FOCUS' with a banner for 'The EU and the Istanbul Convention', 'EU law' with a list of categories like 'Treaties' and 'Legal acts', 'EU case-law' with 'Case-law' and 'Reports of cases', and 'National law and case-law' with 'National transposition' and 'National case-law'. On the right side, there is an 'Official Journal' section with links to 'OJ L Series' and 'OJ C Series', and search filters for 'Find results by document number' and 'Find results by CELEX number'. At the bottom right, there are buttons for 'Measures in solidarity with Ukraine' and 'EU Law Tracker - NEW'.

- 검색란에 '1333/2008' 입력 후 클릭

European Union

## EUR-Lex

Access to European Union law

EUROPA > EUR-Lex home > EU law

Q 1333/2008 SEARCH

Search tips Need more search options? Use the Advanced search

**LAW IN FOCUS**  
The EU and the Istanbul Convention

- 해당 규정 클릭

**Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (Text with EEA relevance)**

OJ L 354, 31/12/2008, p. 16–33 (BG, ES, CS, DA, DE, ET, EL, EN, FR, GA, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV)  
This document has been published in a special edition(s) ( HR)

**In force**

Latest consolidated version: 28/10/2024 Author: European Parliament, Council of the European Union

CELEX number: 32008R1333 Date of document: 16/12/2008

Form: Regulation Number of pages: 18

Part 1.  
4. 원 가 문

- 해당 규정 화면 아래로 이동하여 부속서 II 의 Part 2 식품첨가물에 대한 상세한 요건 확인 가능

<i>ANNEX II</i>	
<b>Union list of food additives approved for use in foods and conditions of use</b>	
<i>PART A</i>	
<b>1. Introduction</b>	
This Union list includes:	
▼M53 ↓	— the name of the food additive and its E-number; as an alternative more specific E-numbers and names listed in Commission Regulation (EU) No 231/2012 ( <sup>6</sup> ) may be used, excluding synonyms, if the named food additives have indeed been added to a certain food,
▼M2 ↓	— the foods to which the food additive may be added, — the conditions under which the food additive may be used, — restrictions on the sale of the food additive directly to the final consumer.
<b>2. General provisions on listed food additives and conditions of use</b>	
▼M53 ↓	1. Only the substances listed in Part B, as specified by Regulation (EU) No 231/2012, may be used as additives in foods, unless more specifically provided for in Part E.
▼M2 ↓	2. Additives may only be used in the foods and under the conditions set out in Part E of this Annex.
	3. In Part E of this Annex, foods are listed on the basis of food categories set out in Part D of this Annex and additives are grouped on the basis of definitions set out in Part C of this Annex.
▼M7 ↓	4. Aluminium lakes prepared from all colours listed in Table 1 of Part B are authorised until 31 July 2014. From 1 August 2014 only aluminium lakes prepared from the colours listed in Table 3 of this Part A are authorised and only in those food categories where provisions on maximum limits on aluminium coming from lakes are explicitly stated in Part E.
▼M98 ↓	5. The colours E 123, E 127, E 160b(i), E 160b(ii), E 161g, E 171, E 173 and E 180 and mixtures thereof may not be sold directly to the consumer.
▼M2 ↓	6. The substances listed under numbers E 407, E 407a and E 440 may be standardised with sugars, on condition that this is stated in addition to the number and designation.

- 정보 제공 범위

- 자료가 방대하여 식품첨가제 목록은 식품, 사료 정보 포털 데이터베이스에서 확인하는 것이 신속함

## [ 식품 및 식품첨가물로 사용되는 향료 및 특정 향미증진제에 관한 규정 ]

### ● 개요

DB명	식품 및 식품 첨가물로 사용되는 향료 및 특정 향미증진제에 관한 규정 [Regulation (EC) No 1334/2008]
관리기관	유럽위원회(EC)/유럽식품안전청(EFSA)
DB 내용	식품 및 식품첨가물로 사용되는 향료 및 특정 향미증진제에 관한 규정
접속 주소	http://data.europa.eu/eli/reg/2008/1334/oj
정보 제공 건수	-

### ● DB 접속 방법

#### ○ 유럽위원회의 'EUR-Lex' 접속

The screenshot displays the EUR-Lex website, which provides access to European Union law. The interface includes a search bar with a 'QUICK SEARCH' option and a 'SEARCH' button. Below the search bar, there are several navigation menus and sections:

- EU law:** Includes links for Treaties, Legal acts, Consolidated texts, International agreements, Preparatory documents, EFTA documents, Lawmaking procedures, Summaries of EU legislation, Browse by EU institutions, and Browse by EuroVoc.
- EU case-law:** Includes links for Case-law, Reports of cases, and Directory of case-law.
- Information:** Includes links for Themes in focus, EUR-Lex developments, Statistics, and the EU register.
- National law and case-law:** Includes links for National transposition, National case-law, and JURE case-law.
- Official Journal:** Displays information about the Official Journal, including OJ L Series and OJ C Series.
- Find results by document number:** Includes a search form with fields for Year and Number, and a dropdown menu for All document types.
- Find results by CELEX number:** A section for searching by CELEX number.
- Measures in solidarity with Ukraine:** A prominent blue button.
- EU Law Tracker - NEW:** A blue button at the bottom right.

- 검색란에 '1334/2008' 입력 후 클릭

**EUR-Lex**  
Access to European Union law

EUROPA > EUR-Lex home > EU law

1334/2008 SEARCH

Search tips Need more search options? Use the Advanced search

**REDISCOVER EUR-LEX**  
Word of the week: Equality between women and men

Pause

- 해당 규정 클릭

Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (Text with EEA relevance)

OJ L 354, 31/12/2008, p. 34-50 (BG, ES, CS, DA, DE, ET, EL, EN, FR, GA, IT, LV, LI, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV)  
This document has been published in a special edition(s) ( HR)

**In force**

**Latest consolidated version:** 05/02/2024 **Author:** European Parliament, Council of the European Union

**CELEX number:** 32008R1334 **Date of document:** 16/12/2008

**Form:** Regulation **Number of pages:** 17

- 해당 규정 화면 아래로 이동하여 부속서 III~V에서 향미증진제 요건 확인

**ANNEX III**  
**Presence of certain substances**

**Part A: Substances which shall not be added as such to food**

Agaric acid  
Aloin  
Capsaicin  
1,2-Benzopyrone, coumarin  
Hypericin  
Beta-asarone  
1-Allyl-4-methoxybenzene, estragole  
Hydrocyanic acid  
Menthofuran  
4-Allyl-1,2-dimethoxybenzene, methyleugenol  
Pulegone  
Quassin  
1-Allyl-3,4-methylene dioxy benzene, safrole  
Teucriin A  
Thujene (alpha and beta)

**Part B: Maximum levels of certain substances, naturally present in flavourings and food ingredients with flavouring properties, in certain compound food as consumed to which flavourings and/or food ingredients with flavouring properties have been added**

Name of the substance	Compound food in which the presence of the substance is restricted	Maximum level mg/kg
Beta-asarone	Alcoholic beverages	1,0
1-Allyl-4-methoxybenzene, Estragol (*)	Dairy products	50
	Processed fruits, vegetables (incl. mushrooms, fungi, roots, tubers, pulses and legumes), nuts and seeds	50

● 정보 제공 범위

- 부속서 III: 특정 물질의 존재
  - Part A: 식품에 직접 첨가해서는 안 되는 물질
  - Part B: 향료 및 향미 성분이 포함된 식품첨가물이 추가된 특정 복합 식품 내에서, 향료 및 향미 성분에 자연적으로 함유된 특정 물질의 최대 허용 수준
- 부속서 IV: 향료 및 향미 성분을 생산 시 사용이 제한되는 물질
  - Part A: 향료 및 향미 성분을 생산 시 사용이 금지되는 물질
  - Part B: 특정 물질에서 생산된 향료 및 향미 성분의 사용조건
- 부속서 V: 열처리 향료의 생산 조건 및 열처리 향료 내 특정 물질의 최대 허용 기준
  - Part A: 생산 조건
  - Part B: 특정 물질의 최대 허용 기준

## 호주

### [ 호주뉴질랜드 식품기준 코드 - 별표 15 - 식품첨가물로 사용될 수 있는 물질 ]

#### 개요

DB명	호주뉴질랜드 식품기준 코드 - 별표 15 - 식품첨가물로 사용될 수 있는 물질 (Australia New Zealand Food Standards Code - Schedule 15 - Substances that may be used as food additives)
관리기관	호주뉴질랜드 식품기준청(FSANZ)
DB내용	허용된 식품 첨가물 목록
접속 주소	<a href="https://www.legislation.gov.au/F2015L00439/latest/text">https://www.legislation.gov.au/F2015L00439/latest/text</a>
정보 제공 건수	-

#### DB 접속 방법

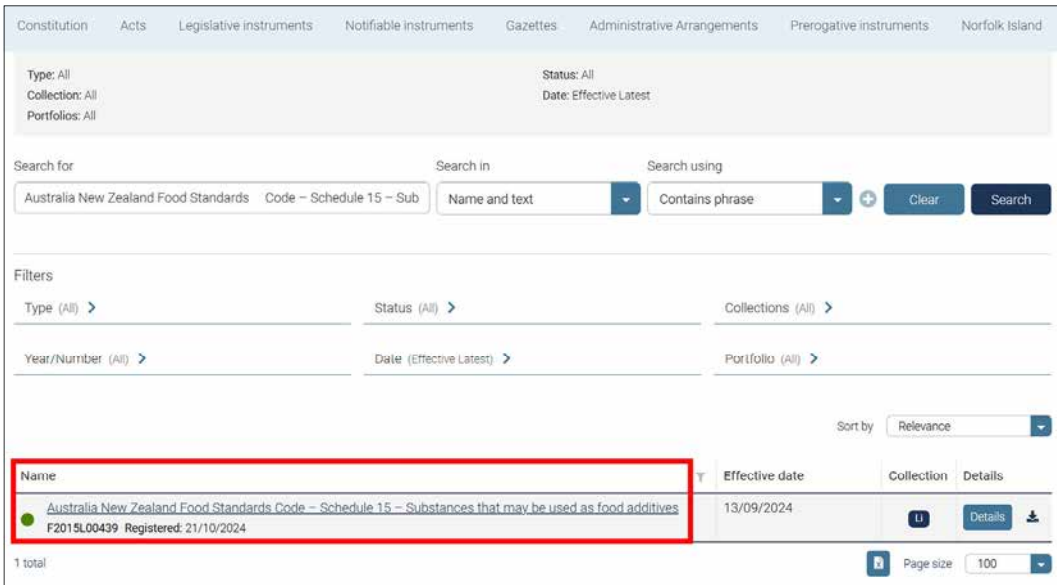
##### Federal Register of Legislation 접속

The screenshot shows the Australian Government Federal Register of Legislation website. At the top, there are links for 'Help and resources', 'Register for My Account', and 'Sign in to My Account'. The main header includes the Australian Government logo and the title 'Federal Register of Legislation'. Below the header, there are navigation tabs for 'Constitution', 'Acts', 'Legislative instruments', 'Notifiable instruments', 'Gazettes', 'Administrative Arrangements', 'Prerogative instruments', and 'Norfolk Island'. The main content area is titled 'Explore the Federal Register of Legislation' and features a search interface. The search interface has a 'Search' tab and a 'Browse' tab. There are three buttons for filtering by status: 'All', 'In force', and 'No longer in force'. The search input field contains the text 'example: Legislation Act 2003'. There are two dropdown menus for 'Search in' (set to 'Name and text') and 'Search using' (set to 'Contains phrase'). Below the search input, there are checkboxes for 'Filter by collection' with options for 'Act', 'Gazette', 'Legislative instrument', and 'Notifiable instrument'. At the bottom of the search interface, there are 'Search' and 'Advanced search' buttons.

- ‘검색란(Search for)’에 ‘Australia New Zealand Food Standards Code – Schedule 15 – Substances that may be used as food additives’ 입력 후 ‘Search’ 클릭



- 화면 아래쪽으로 이동하여 해당 문서 클릭



Part 1.  
4.원 가.문

- ‘돋보기’ 아이콘 클릭 후 검색하고자 하는 원료의 영문 명칭 입력 후 클릭

Constitution Acts Legislative instruments Notifiable instruments Gazettes Administrative Arrangements Prerogative instruments Norfolk Island

Food Standards Australia New Zealand Act 1991

View document Legislative instrument

Table of contents

Search within

Calcium silicate

Previous Next

**Schedule 15** Substances that may be used as food additives

Note 1 This instrument is a standard under the Food Standards Code. See also section 1.1.1—3.

Substances used as food additives are required to:

- identify substances for substances used as food additives
- contain permissions to use substances used as food additives
- contain associated restrictions for paragraph 1.3.1—3(1)(b); and
- set out maximum permitted levels for section 1.3.1—4.

Note 2 The provisions of the Code that apply in New Zealand are incorporated in, or adapted under, the Food Act 2014 (NZ). See also section 1.1.1—3.

**S15—1 Name**

This Standard is *Australia New Zealand Food Standards Code – Schedule 15 – Substances that may be used as food additives*.

Note Commencement  
This Standard commences on 1 March 2016, being the date specified as the commencement date in notices in the Gazette and the New Zealand Gazette under section 92 of the Food Standards Australia New Zealand Act 1991 (Cth). See also section 93 of that Act.

**S15—2 Permissions to use substances as food additives**

Unless the table to section S15—5 expressly provides otherwise, for each class of food identified by a numbered heading in the table to section S15—5, the substances that may be used as a food additive in any food within that class are the following:

(a) any of the substances listed directly under the heading;

(b) any of the substances listed directly under a higher-level heading.

Example For the heading numbered 4.3.4, higher-level headings are those numbered 4.3 and 4. However, headings such as those numbered 4.3.4.1, 4.3.4.2 and 3 are not higher-level headings.

Note In many cases, there is more than 1 substance listed directly under a heading.

**S15—3 Preparations of food additives**

If a substance may be used as a food additive under the table to section S15—5:

(a) the substance may be added in the form of a preparation of the substance; and

- 해당 원료의 요건 확인

Constitution Acts Legislative instruments Notifiable instruments Gazettes Administrative Arrangements Prerogative instruments Norfolk Island

Food Standards Australia New Zealand Act 1991

View document Legislative instrument

Table of contents

Search within


calcium silicate

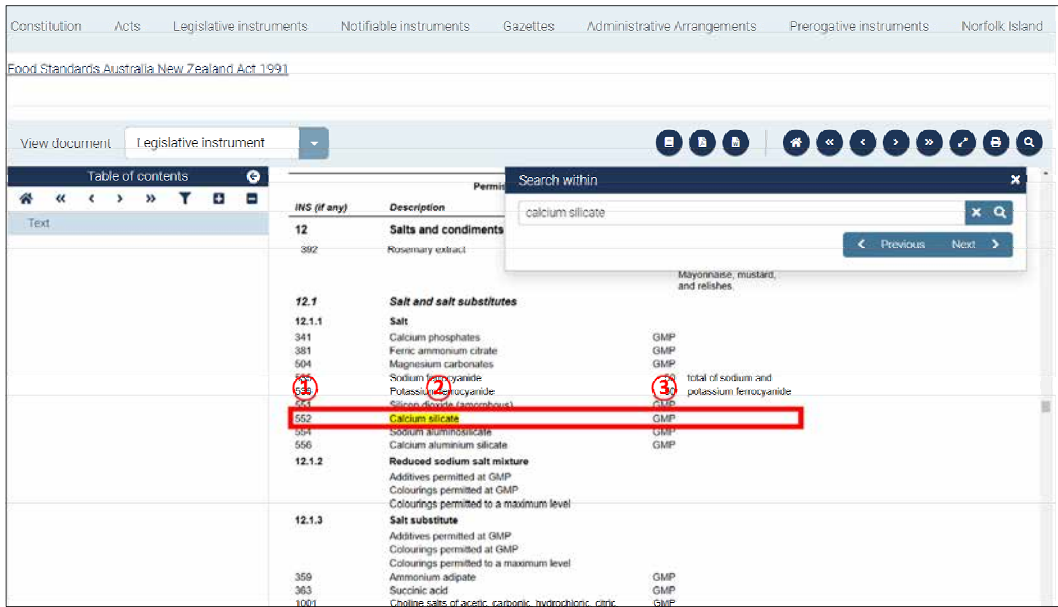
Previous Next

INS (if any)	Description	Permitted
12	<b>Salts and condiments</b>	
392	Rosemary extract	
	Mayonnaise, mustard, and relishes.	
12.1	<b>Salt and salt substitutes</b>	
12.1.1	<b>Salt</b>	
341	Calcium phosphates	GMP
381	Ferrous ammonium citrate	GMP
404	Magnesium carbonates	GMP
535	Sodium ferrocyanide	50 total of sodium and potassium ferrocyanide
536	Potassium ferrocyanide	50 potassium ferrocyanide
551	Silicon dioxide (amorphous)	GMP
552	<b>Calcium silicate</b>	GMP
554	Sodium aluminosilicate	GMP
556	Calcium aluminium silicate	GMP
12.1.2	<b>Reduced sodium salt mixture</b>	
	Additives permitted at GMP	
	Colourings permitted at GMP	
	Colourings permitted to a maximum level	
12.1.3	<b>Salt substitute</b>	
	Additives permitted at GMP	
	Colourings permitted at GMP	
	Colourings permitted to a maximum level	
359	Ammonium adipate	GMP
363	Succinic acid	GMP
1001	Choline salts of acetic, carbonic, hydrochloric, citric	GMP

● 정보 제공 범위

- INS번호, 식품첨가물 제제, 최대허용기준(MRL), 조건 등의 정보를 제공하고 있으며 PDF, Word 형식으로 다운로드 가능

 예시 | 원료명: 규산칼슘(Calcium silicate)



INS (if any)	Description	Permitted
12	<b>Salts and condiments</b>	
392	Rosemary extract	
	Mayonnaise, mustard, and relishes.	
12.1	<b>Salt and salt substitutes</b>	
12.1.1	<b>Salt</b>	
341	Calcium phosphates	GMP
381	Ferrous ammonium citrate	GMP
504	Magnesium carbonates	GMP
595	Sodium ferrocyanide	total of sodium and potassium ferrocyanide
596	Potassium ferrocyanide	
721	Silicon dioxide (amorphous)	GMP
552	<b>Calcium silicate</b>	GMP
554	Sodium aluminosilicate	GMP
556	Calcium aluminium silicate	GMP
12.1.2	<b>Reduced sodium salt mixture</b>	
	Additives permitted at GMP	
	Colourings permitted at GMP	
	Colourings permitted to a maximum level	
12.1.3	<b>Salt substitute</b>	
	Additives permitted at GMP	
	Colourings permitted at GMP	
	Colourings permitted to a maximum level	
359	Ammonium adipate	GMP
363	Succinic acid	GMP
1001	Choline salts of acetic, carbonic, hydrochloric, citric	GMP

- ① INS: 552
- ② 식품첨가물 제제: 규산칼슘
- ③ 최대허용기준: GMP

## 인도

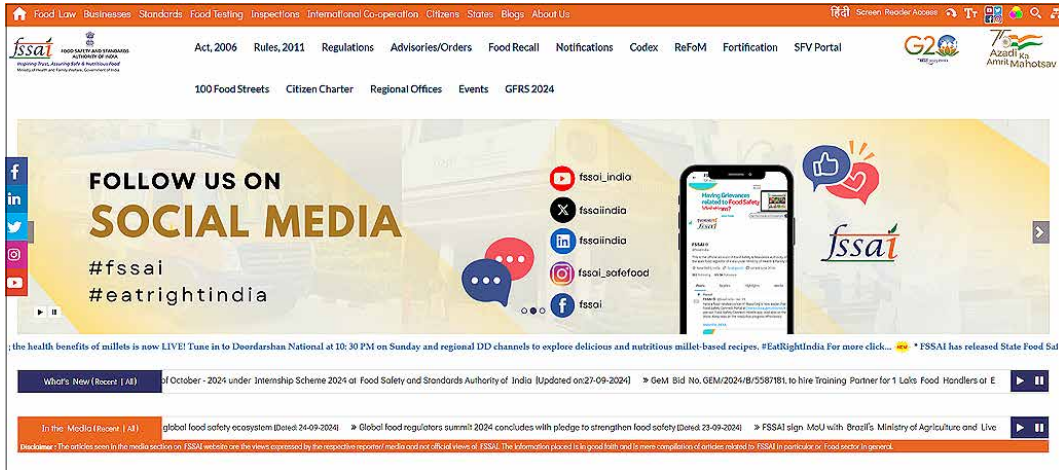
### [ 식품 안전 및 기준(식품 기준 및 식품첨가물) 규정 ]

#### ● 개요

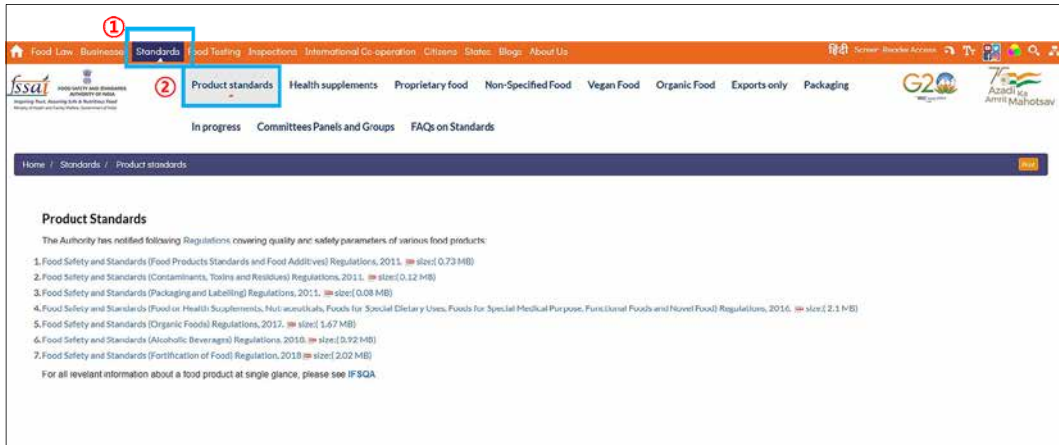
DB명	식품 기준 및 식품첨가물 규정
관리기관	식품안전기준청(FSSAI)
DB 내용	품목별 식품첨가물 목록 제공
접속 주소	<a href="https://fssai.gov.in/cms/product-standards.php">https://fssai.gov.in/cms/product-standards.php</a>
정보 제공 건수	- - 정확한 정보 건수 확인은 어려움이 있으나 다음 품목에 대한 식품첨가물 기준을 부속서 I에서 제공하고 있음: ▲ 빵 및 비스킷류 ▲ 식품류 ▲ 비지정 식품류 ▲ 식용유 및 지방 ▲ 생선 및 생선류 ▲ 열처리된 과일류 ▲ 열처리된 채소류 ▲ 설탕 및 염분류 ▲ 코코아 파우더, 초콜릿류, 당절임과자류, 추잉검·버블검 ▲ 유제품류 ▲ 치즈류 - 부속서 II에서는 해산물, 향료, 유제품류, 특정식품류에 대한 미생물 요건을 제공하고 있음

● DB 접속 방법

○ Food Safety and Standards Authority of India 접속

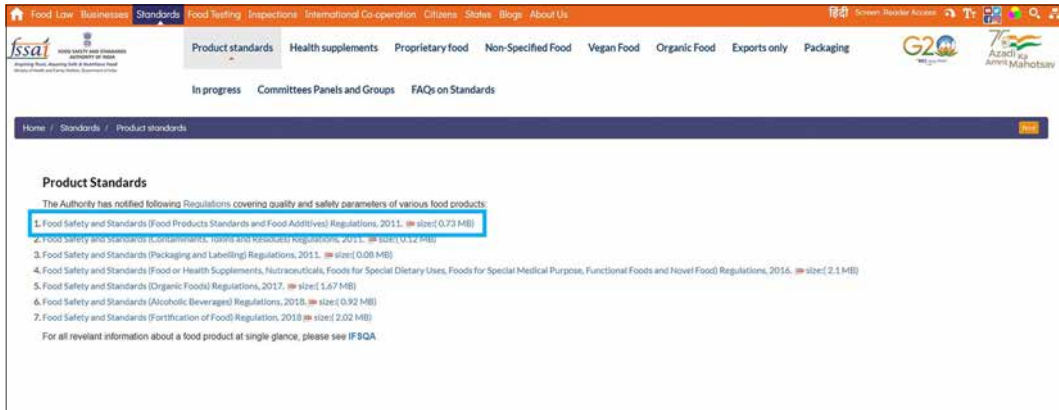


○ 상단의 'Standards' 클릭 후 'Product standards' 클릭

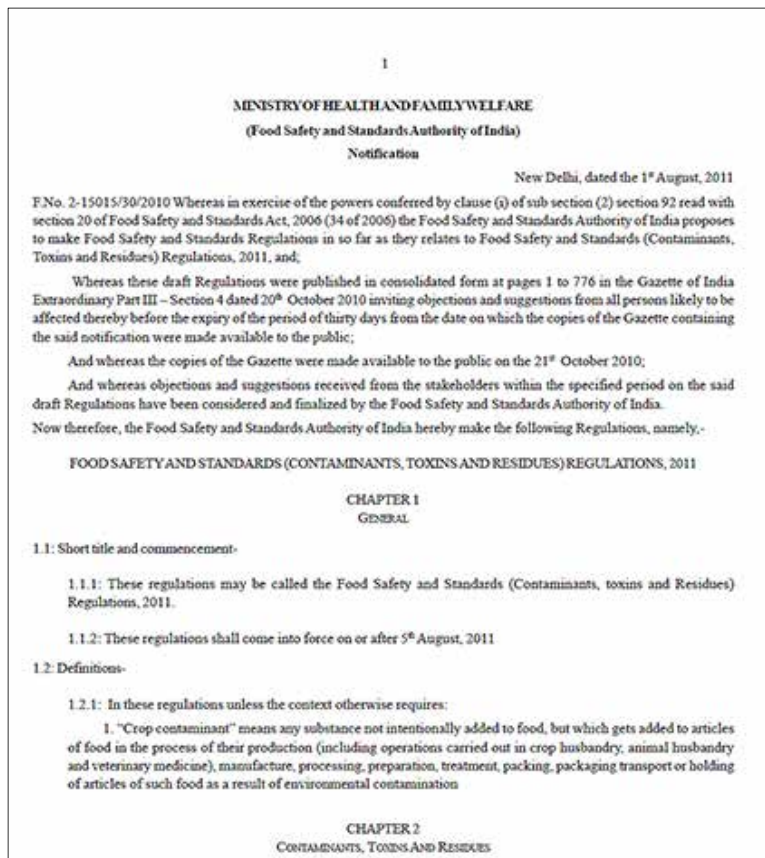


Part 1.  
4.원 가 명

- 목록 중 ‘Food Safety and Standards(Food Products and Food Additives) Regulations, 2011’ 클릭



- 해당 규정 확인(웹사이트 오류가 빈번하여 해당 파일 다운로드 권장)





● 정보 제공 범위

○ 품목별 식품첨가물 기준 제공



예시 | 원료명: 모든 유형의 요거트(all types of yoghurts)

Table 14  
List of food additives for use in Milk products

Sl. No.	Name of additives	Cheese/ Sliced/ Cur/Shredded cheese	Processed cheese	Processed cheese spread	All types of yoghurts	Evaporated milk	Sweetened condensed milk	Butter	Milk fat/butter oil and Anhydrous milk fat/ Anhydrous butter oil	Milk powder and Cream powder	Ice cream, Kulfis, Filled icecream mix, Frozen desserts, Milk Ice, Milk lollies, Ice candy	Casein products	Whey powder	Chhana/ Paneer
A Stabilisers and emulsifiers singly or in combination expressed as anhydrous substance														
1	Sodium, Potassium and calcium chloride	-	-	-	-	-	-	-	-	-	-	-	-	-
	Sodium, Potassium and calcium carbonate	-	-	-	-	-	-	-	-	-	-	-	-	-
	Sodium, Potassium and calcium Citrate	-	-	-	-	-	-	-	-	-	-	-	-	-
	Calcium salt of orthophosphoric acid	-	-	-	-	-	-	-	-	-	-	-	-	-
	Calcium salt of polyphosphoric acid	-	-	-	-	-	-	-	-	-	-	-	-	-
	Potassium salt of orthophosphoric acid	-	-	-	-	-	-	-	-	-	-	-	-	-
	Potassium salt of polyphosphoric acid	-	-	-	-	-	-	-	-	-	-	-	-	-
	Sodium salt of orthophosphoric acid	-	-	-	-	-	-	-	-	-	-	-	-	-
	Sodium salt of polyphosphoric acid	-	-	-	-	-	-	-	-	-	-	-	-	-
2	Carrageenan	-	-	-	-	5 g/kg max	150 mg/kg max	-	-	-	-	-	-	-
3	Sodium, Potassium, Calcium and Ammonium Alginate	-	-	-	-	-	-	-	-	-	-	-	-	-
4	Gelatin	-	-	-	-	10 g/kg max	-	-	-	-	-	-	-	-
5	Lecithin	-	-	-	-	-	-	-	-	-	-	-	-	-
6	Pectins	-	-	-	-	10 g/kg max	-	-	-	-	-	-	-	-
7	Sodium carboxymethyl cellulose	-	-	-	-	5 g/kg max	-	-	-	-	-	-	-	-

- ①
- ②
- ③
- ④
- ⑤
- ⑥

- ① 카라기난: 최대 5 g/kg 허용(Max. 5 g/kg)
- ② 나트륨, 칼륨, 칼슘, 암모늄 알지네이트: GMP 기준에 따름
- ③ 젤라틴: 최대 10 g/kg 허용(Max. 10 g/kg)
- ④ 레시틴: 최대 10 g/kg 허용(Max. 10 g/kg)
- ⑤ 펙틴: 최대 10 g/kg 허용(Max. 10 g/kg)
- ⑥ 나트륨 카르복시메틸셀룰로스: 최대 5 g/kg 허용(Max. 5 g/kg)

## 중국

# [ GB 2760-2024 식품첨가물 사용표준 ]

### ● 개요

<b>DB명</b>	GB 2760-2024 식품첨가물 사용표준(食品添加剂使用标准)
<b>관리기관</b>	식품화반넷
<b>DB 내용</b>	식품첨가물(가공보조제, 효소제, 에센스향료 포함)
<b>접속 주소</b>	<a href="https://gb2760.cfsa.net.cn/">https://gb2760.cfsa.net.cn/</a>
<b>정보 제공 건수</b>	2,513건('24.11. 기준)
<b>기타</b>	동 DB에서 제공하고 있는 내용은 24년 개정본으로 시행일자는 2025년 2월부터임

### ● 식품첨가물 DB 접속 방법

- 'GB 2760-2024 식품첨가물 사용표준 검색플랫폼(<https://gb2760.cfsa.net.cn/>)' 접속

The screenshot displays the official website for the GB 2760-2024 Food Additive Use Standard. At the top, there is a search bar and navigation tabs. The main content area is divided into a left sidebar with a table of contents and a right section with the standard's title and introductory text in Chinese. The table of contents lists various categories of food additives, and the main text provides a detailed overview of the standard's scope and purpose.

- ① 검색어[예: 중문(维生素) 또는 영문(vitamin)] 입력 후 ② 검색(搜索) 버튼 클릭

GB 2760-2024 食品添加剂使用标准

搜索: 维生素 [1] 搜索 [2]

中文名称	英文名称	CI号	INS	功能
抗坏血酸 (L-抗坏血酸)	ascorbic acid (Vitamin C)	04.114	300	抗氧化剂, 还原剂
维生素E (D-α-生育酚, d-α-生育酚, 混合生育酚(油溶性))	vitamin E [D-α-tocopherol, d-α-tocopherol, mixed tocopherol (oil soluble)]	04.116	307	抗氧化剂

- 검색 결과에서 다음 ‘아스코르브산(抗坏血酸)’ 클릭

GB 2760-2024 食品添加剂使用标准

搜索: 维生素

中文名称	英文名称	CI号	INS	功能
抗坏血酸 (L-抗坏血酸)	ascorbic acid (Vitamin C)	04.114	300	抗氧化剂, 还原剂
维生素E (D-α-生育酚, d-α-生育酚, 混合生育酚(油溶性))	vitamin E [D-α-tocopherol, d-α-tocopherol, mixed tocopherol (oil soluble)]	04.116	307	抗氧化剂

○ ‘아스코르브산’ 상세 제공 정보

Table 2: 抗坏血酸 (又名维生素C)			
中文名称	抗坏血酸 (又名维生素C)		
英文名称	ascorbic acid (vitamin C)		
CAS	50-014		
INS	300		
功能	面粉处理剂、抗氧化剂		
抗坏血酸 (又名维生素C) 允许使用品种、使用范围 以及最大使用量或残留量			
食品分类号	食品名称	最大使用量(g/kg)	备注
04.01.01.03	非发酵型肉罐头(熏制)	5.0	
04.02.01.03	去皮、切块或切丝的蔬菜	5.0	
06.03.01	小麦粉	0.2	
06.03.01.01	通用小麦粉	0.2	
06.03.01.02	专用小麦粉 (包括发酵、饺子粉等)	0.2	
14.02.01	维生素C (C)	1.5	以还原态计, 相应的国际食品标准规格确定使用量
—	食品添加剂 (按A.2中编号为1-5, 10-62, 66的食品类别除外)	按生产需要适量使用	
抗坏血酸 (又名维生素C) 对附录A.2中, 可在如下的食品分类中按生产需要适量使用			
食品分类号	食品名称	最大使用量(g/kg)	备注
01.01.03	调制乳	按生产需要适量使用	
01.02.02	风味发酵乳	按生产需要适量使用	

Part 1.  
4. 원 가 물

● 정보 제공 범위

- 해당 원료의 중문 및 영문 명칭, CNS, INS, 기능 등의 정보 제공

**예시** | 원료명: 아스코르브산(비타민 C)

食品分类号	食品名称	最大使用量(g/kg)	备注
04.02.01.03	淀粉、淀粉或改性淀粉类	5.0	
06.03.01	小麦粉	0.2	
06.03.01.01	通用小麦粉	0.2	
06.03.01.02	专用小麦粉(后面发酵、饺子粉等)	0.2	
14.02.01	果汁(类)	1.5	以原果汁计, 橙汁和橙味饮料按原果汁使用量
-	亚洲食品(除A.2中编号为1-5、11-12、60的食品类别外)	按生产需要适量使用	

- ① 중문명: 抗坏血酸(又名维生素C)
- ② 영문명: ascorbic acid(Vitamin C)
- ③ CNS: 04.014
- ④ INS: 300
- ⑤ 기능: 밀가루처리제, 항산화제
- ⑥ 아스코르브산(비타민 C): 사용허가 품목, 사용범위 및 최대 사용량 또는 잔류량
- ⑦ 식품분류번호;식품명칭;최대 사용량(g/kg);비고
- ⑧ 아스코르브산(비타민 C): 대조A.2표, 다음 식품유형에서 생산 필요에 따라 적당량 사용 가능
- ⑨ 식품분류번호;식품명칭;최대 사용량(g/kg);비고

# [ GB 14880-2012 식품영양강화제 사용표준 ]

## ● 개요

DB명	GB 14880-2012 식품영양강화제 사용표준(食品营养强化剂使用标准)
관리기관	식품화반넷
DB 내용	식품영양강화제
접속 주소	http://14880.foodvip.net/
정보 제공 건수	94건('24.11. 기준)
기타	'영양강화제' 명칭 또는 '식품분류'에 따라 영문, 중문 모두 검색 가능

## ● 식품영양강화제 DB 접속 방법

- 'GB 14880-2012 식품영양강화제 사용표준 검색플랫폼(<http://14880.foodvip.net/>)' 접속

The screenshot shows the website interface for GB 14880-2012. It features a search bar at the top right and a main content area with a table of contents. The table of contents lists various categories of food products and their corresponding standards, such as 'Food Nutrient Fortifier Usage Standard' and 'Food Nutrient Fortifier Usage Standard for Various Food Products'.

Part 1.  
4. 원 가 메



○ ‘비타민B12’ 상세 제공 정보

維生素 B12				
营养成分	維生素 B12			
化合物来源	微生物, 动物源性, 植物性			
备注	此成分于普通食品, 食品营养强化剂均有添加			
維生素 B12 在各食品类别(名称)中的限量要求				
食品名称	化合物来源	使用量要求	来源	备注
婴儿奶粉 (在婴儿配方奶粉)	微生物, 动物源性, 植物性	10-30 µg/kg	GB 14880-2012 食品营养强化剂使用标准	仅限儿童配方奶粉
婴儿奶粉 (在特殊配方奶粉)	微生物, 动物源性, 植物性	10-66 µg/kg	GB 14880-2012 食品营养强化剂使用标准	仅限特殊配方奶粉
即食食品, 包括罐装食品 (非)	微生物, 动物源性, 植物性	5-10 µg/kg	GB 14880-2012 食品营养强化剂使用标准	
其他罐装食品	微生物, 动物源性, 植物性	10-70 µg/kg	GB 14880-2012 食品营养强化剂使用标准	
饮料类 (1421, 1426 类及特殊类)	微生物, 动物源性, 植物性	0.8-1.6 µg/kg	GB 14880-2012 食品营养强化剂使用标准	1421, 1426 类及特殊类
固体饮料类	微生物, 动物源性, 植物性	10-66 µg/kg	GB 14880-2012 食品营养强化剂使用标准	
果冻	微生物, 动物源性, 植物性	2-4 µg/kg	GB 14880-2012 食品营养强化剂使用标准	
调味料 (在特殊配方奶粉)	微生物, 动物源性, 植物性	10-66 µg/kg	GB 14880-2012 食品营养强化剂使用标准	依据 GB 14880-2012 附录 A 中, 食品单位可在“特殊配方奶粉”中使用“调味料(在特殊配方奶粉)”中规定的营养强化剂, 其使用量应符合特殊配方奶粉。
调味料 (在婴儿配方奶粉)	微生物, 动物源性, 植物性	10-30 µg/kg	GB 14880-2012 食品营养强化剂使用标准	依据 GB 14880-2012 附录 A 中, 食品单位可在“婴儿配方奶粉”中使用“调味料(在婴儿配方奶粉)”中规定的营养强化剂, 其使用量应符合特殊配方奶粉。

● 정보 제공 범위

- 해당 원료의 명칭, 화합물 출처, 사용량 등 정보 제공

 예시 | 원료명: 비타민B12

维生素B12					
①	营养强化剂	维生素B12			
②	化合物来源	糖化糖、淀粉糖、糖醇糖			
③	备注	仅用于食品添加剂(食品添加剂使用标准)			
④	维生素B12 在各食品类别(名称)中的限量要求				
⑤	食品名称	化合物来源	使用量要求	来源	备注
	调味剂粉 (仅指工业用剂粉)	糖化糖、淀粉糖、糖醇糖	10-30 µg/kg	GB 14880-2012 食品添加剂使用标准	仅指工业用剂粉
	调味剂粉 (仅指食品用剂粉)	糖化糖、淀粉糖、糖醇糖	10-66 µg/kg	GB 14880-2012 食品添加剂使用标准	仅指食品用剂粉
	即食食品, 包括罐装食品 (片)	糖化糖、淀粉糖、糖醇糖	5-10 µg/kg	GB 14880-2012 食品添加剂使用标准	
	其他罐装食品	糖化糖、淀粉糖、糖醇糖	10-70 µg/kg	GB 14880-2012 食品添加剂使用标准	
	饮料类 (14.01, 14.06 涉及品种除外)	糖化糖、淀粉糖、糖醇糖	0.6-1.8 µg/kg	GB 14880-2012 食品添加剂使用标准	14.01, 14.06 涉及品种除外
	固体饮料类	糖化糖、淀粉糖、糖醇糖	10-66 µg/kg	GB 14880-2012 食品添加剂使用标准	
	果冻	糖化糖、淀粉糖、糖醇糖	2-6 µg/kg	GB 14880-2012 食品添加剂使用标准	
	调味剂 (仅指食品用)	糖化糖、淀粉糖、糖醇糖	10-66 µg/kg	GB 14880-2012 食品添加剂使用标准	依据GB 14880-2012第五十条, 生产单位可在“食品用调味剂”中使用“调味剂(仅指食品用剂粉)”中规定的食品添加剂, 其使用量应符合相应食品添加剂标准。
	调味剂 (仅指工业用)	糖化糖、淀粉糖、糖醇糖	10-30 µg/kg	GB 14880-2012 食品添加剂使用标准	依据GB 14880-2012第五十条, 生产单位可在“工业用调味剂”中使用“调味剂(仅指工业用剂粉)”中规定的食品添加剂, 其使用量应符合相应食品添加剂标准。

- ① 영양강화제 명칭: 维生素B12
- ② 화합물 출처: ascorbic acid(Vitamin C)
- ③ 비교: 일반식품에 사용 허가
- ④ 비타민B12 식품유형(명칭)에서의 제한량 요구
- ⑤ 식품명칭;화합물출처;사용량요구;출처;비교

## ■ 일본

### [ 식품첨가물 리스트 ]

#### ● 개요

DB명	식품첨가물 리스트
관리기관	후생노동성
DB 내용	지정된 식품첨가물 리스트(보존료, 감미료, 착색료, 향료 등), 기존 식품첨가물, 일반식품 첨가물, 첨가물 관련 규정 등
접속 주소	<a href="https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/shokuhin/syokuten/index.html">https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/shokuhin/syokuten/index.html</a>
정보 제공 건수	3,284건 외('24.11. 기준)

● DB 접속 방법

- ‘후생노동성’ 접속 후 ‘정책에 대하여(製作について)’에서 ‘분야별 정책 일람(分野別の製作一覧)’ 클릭



- ‘건강·의료(健康·医療)’ 탭의 ‘식품(食品)’ 클릭



○ ‘식품(食品)’ 탭에서 아래로 스크롤



○ 아래의 ‘식품첨가물(食品添加物)’ 탭 클릭



Part 1.  
4. 원가 명

- ‘식품첨가물 리스트 등(食品添加物のリスト等)’ 아래의 PDF, xlsx 파일 및 웹사이트 링크로 이어지는 링크 확인 가능

[どこを掲載しているか](#)

## 添加物のリスト等

原則として、食品衛生法第12条に基づいて、厚生労働大臣の指定を受けた添植物（指定添植物）だけを使用することができます。  
指定添植物以外で添加物として使用できるのは、既存添植物、天然香料、一般飲食物添加物のみです。

### 指定添加物

食品衛生法第12条に基づき、厚生労働大臣が使用してよいと定めた食品添加物です。食品衛生法施行規則別表1に収載されています。この指定の対象には、化学的合成品だけでなく、天然物も含まれます。  
なお、指定添加物のうち、「エステル類」等の一括名称で指定した香料（18類香料）については、各分類に該当すると判断したものを通知で示しています。

- ▶ [指定添加物リスト（規則別表第1）](#)
- ▶ 18類香料リスト
  - ▶ [リスト \[2.3MB\]](#)
  - ▶ [X | リスト \[230KB\]](#)
- （参考）改正前の旧18類香料リスト ※令和4年12月31日以前
  - ▶ [旧リスト \[2.9MB\]](#)
  - ▶ [X | 旧リスト \[249KB\]](#)
- ▶ 照会様式はこちら
  - ▶ [X | 香料化合物の類に係わる照会様式 \[35KB\]](#)
- ▶ [添加物使用基準リスト（※既存添植物も含む）](#)

\* 일본식품화학연구원진흥재단으로 이어지는 웹사이트 링크 제공

● 정보 제공 범위

- 식품 첨가물에 대한 영문명, 일문명, 분류, CAS 번호 등 제공



예시 | 원료명: 안젤산(angelic acid/안желиック 아시드)

171	alpha-amylocinnamyl acetate	α-아밀신나미르 아세테이트	에스테르類	4	7493-78-9
172	alpha-amylocinnamyl alcohol	α-아밀신나미르 알코올	芳香族알코올類	16	101-85-9
173	alpha-amylocinnamyl isovalerate	α-아밀신나미르 이소발레레이트	에스테르類	4	7493-80-3
174	(5or6)-decenoic acid	(5or6)-데세노익 아시드	지방산類	6	72881-27-7 85382-03-6 85382-04-7
175	trans-anethole	trans-아네토ール	페놀어테르類	13	4180-23-8
177	angelic acid	안желиック 아시드	지방산類	6	565-63-9
178	alpha-angelicalactone	α-안жели리카락톤	락톤類	18	591-12-8
179	2-methoxybenzaldehyde	2-메톡시벤즈알데히드	芳香族알데히드類	17	135-02-4
181	anisaldehyde diethyl acetal	아니스알데히드 디에틸 아세타ール	어테르類	3	2403-58-9
182	anisaldehyde dimethyl acetal	아니스알데히드 디메틸 아세타ール	어테르類	3	2186-92-7
183	anisaldehyde hexyleneglycol acetal	아니스알데히드 헥시렌글리콜 아세타ール	어테르類	3	
184	anisaldehyde propyleneglycol acetal	아니스알데히드 프로피렌글리콜 아세타ール	어테르類	3	6414-32-0
185	anisic acid	아니시크 아시드	페놀어테르類	13	100-09-4

- ① 영문명: angelic acid
- ② 일문명: 안желиック 아시드
- ③ 분류: 지방산류
- ④ 분류 번호: 6번
- ⑤ CAS 번호: 565-63-9

Part 1.  
4. 원 가 명

## [ 식품첨가물공정서 ]

### ● 개요

DB명	식품첨가물공정서
관리기관	소비자청
DB 내용	식품 첨가물 성분 규격 및 보관 기준
접속 주소	https://www.caa.go.jp/policies/policy/standards_evaluation/food_additives/official_documents_002
정보 제공 건수	-

### ● DB 접속 방법

- ‘소비자청’ 접속 후 ‘정책(製作)’ 탭의 ‘식품위생기준심사(食品衛生基準審査)’ 클릭

The screenshot shows the homepage of the Japanese Consumer Affairs Agency (CAA). The navigation menu includes 'Policy' (政策), which is highlighted with a red box. Under the 'Policy' menu, the 'Food Safety Standard Review' (食品衛生基準審査) option is also highlighted with a red box. The page content is in Japanese, and the interface is clean and professional.

○ ‘식품첨가물(食品添加物)’ 란의 ‘제10판 식품첨가물 공정서(第10版食品添加物公定書)’ 클릭



○ 공정서의 항목 D의 아행부터 원재료 목록 확인 가능. E, F, G행에는 규정에 대한 상세 내용 확인 가능



Part 1.  
4. 원가 명



● 정보 제공 범위

- 명칭, 함량, 성상, 확인시험, 비선광도, 순도시험, 건조감량 등

**예시 | 원료명: 비오틴**

- ① 명칭: 비오틴(Biotin)
- ② 함량: 본 제품을 건조시킨 것은 비오틴(C<sub>10</sub>H<sub>16</sub>N<sub>2</sub>O<sub>3</sub>S) 98.0% 이상을 포함한다.
- ③ 성상: 백색의 결정 또는 결정성 분말로서 냄새 및 맛은 없다.
- ④ 확인시험: 건조하고 적외선 흡수 스펙트럼 측정법 중 정제법으로 측정 (이하 생략)
- ⑤ 비선광도:  $[\alpha]_{20D} = +89 \sim +93^\circ$  (0.4 g, 수산화나트륨 시액(0.1 mol/L), 20 mL, 건조물환산)
- ⑥ 순도시험
- ⑦ 건조감량: 0.5% 이하(105°C, 4시간)
- ⑧ 강열잔분: 0.1% 이하
- ⑨ 정량법

Part 1.  
4. 원 가 명

## [ 기존첨가물 명부 ]

### ● 개요

DB명	기존첨가물 명부
관리기관	일본식품화학연구진흥재단
DB 내용	기존 첨가물 목록
접속 주소	https://www.ffcr.or.jp/tenka/list/post-12.html?OpenDocument
정보 제공 건수	357건('24.11. 기준)

### ● DB 접속 방법

- 홈페이지 접속 후 상단의 '식품첨가물(食品添加物)' 탭 클릭

The screenshot shows the homepage of the Japanese Food Chemical Research Foundation (FFCR). The navigation menu at the top includes 'Home', 'About Us', 'Support Projects', 'Food Additives', 'Residue Management', 'Equipment & Packaging', and 'Chemical Substances'. The 'Food Additives' tab is highlighted with a red box. Below the navigation, there are sections for 'Topics' and 'New Information'. The 'Topics' section lists recent news items with dates and brief descriptions. The 'New Information' section has a sub-menu with 'Food Additives' selected, showing a list of recent updates with dates and titles in Japanese.

- ‘식품첨가물 리스트(食品添加物のリスト)’란의 ‘기존첨가물 명부(既存添加物名簿)’ 클릭



- 원재료 웹사이트 고시 정보 및 PDF 파일 다운로드 가능



Part 1.  
4. 원 가 명

● 정보 제공 범위

- 품명(명칭/다른 명칭), 간략명, 기원, 용도, 비교

예시 | 원료명: 메나퀴논(비타민K/メナキノ/メナquinone)

abutsu\_2020\_pdf 13 / 14 149% +

既存添加物名簿収載品目リスト 公益財団法人 日本食品化学研究振興財団 最終改正 令和2年2月16日

番号	品名	別名	別称名又は別号名	基原・製法・本質	用途	備考
316	ムラサキトウモロコシ色素 (トウモロコシの種子から得られた、シアニジン-β-グルコシドを主成分とするものをいう。)	ムラサキコーン色素	アントシアニン	※	着色料	Purple Corn Color
317	ムラサキヤマイモ色素 (ヤマイモの塊根から得られた、シアニジンアルグルコシドを主成分とするものをいう。)		アントシアニン アントシアニン色素	ヤマイモ科ヤマイモ ( <i>Dioscorea alata</i> LINE) の塊根の塊根より、室温水又は希酸性水溶液で抽出して得られたものである。主色素はシアニジンアルグルコシドである。紫青色を呈する。	着色料	Purple yam colour
318	ムラサギーザ メナキノ (抽出物) (アルトバクターの培養液から得られた、メナキノ-四を主成分とするものをいう。)	ビタミク <sub>2</sub> (抽出物)	ビタミク <sub>2</sub> ビタミク V.K <sub>2</sub> V.K メナキノ	※	解凍 強化剤	Murasage Menaquinone (Extract) Vitamin K2 (Extract)
320	メバロン酸			酵母 ( <i>Saccharomyces fibuligera</i> ) による コースチーフリカー又はカゼイン由来のペプトンを主原料とする発酵培養液より、有機溶剤で抽出して得られたものである。成分はメバロン酸である。	製造用剤	Mevatonic acid
321	メラロイカ精油 (メラロイカの葉から得られた、精油を主成分とするものをいう。)			フトモモ科メラロイカ ( <i>Melaleuca alternifolia</i> DEHL) の葉より、水蒸気蒸留により得られたものである。成分は精油 (α-テルピネン及びγ-テルピネン等) である。	酸化防止剤	Melaleuca oil
322	モウソウチク乾留物 (モウソウチクの茎を乾留して得られたものをいう。)		竹乾留物	イネ科モウソウチク ( <i>Phyllostachys heteroscylla</i> MiF.) の茎をチップ状にしたものを、減圧加熱下で乾留したもより得られたものである。	製造用剤	Mousouchiku dry distilla
323	モウソウチク抽出物 (モウソウチクの茎の表皮から得られた、2,6-ジメチルシロ-4-ベンジキノンを主成分とするものをいう。)			イネ科モウソウチク ( <i>Phyllostachys heteroscylla</i> MiF.) の茎の表皮を、粉砕したもより、高温熱エタノールで抽出して得られたものである。成分として2,6-ジメチルシロ-4-ベンジキノンを含有。	製造用剤	Mousouchiku extract

- ① 품명(명칭/다른 명칭): 메나퀴논(추출물)/비타민K(추출물)
- ② 간략명: 비타민K<sub>2</sub>/비타민K/V.K<sub>2</sub>/V.K
- ③ 기원: -
- ④ 용도: 강화제
- ⑤ 비교: Menaquinone(Extract)/Vitamin K<sub>2</sub>(Extract)

## [ 지정첨가물 명부 ]

### ● 개요

DB명	지정첨가물 명부
관리기관	일본식품화학연구진흥재단
DB 내용	식품위생법 제12조에 따라 사용가능으로 지정된 식품첨가물
접속 주소	<a href="https://www.ffcr.or.jp/tenka/list/post-12.html?OpenDocument">https://www.ffcr.or.jp/tenka/list/post-12.html?OpenDocument</a>
정보 제공 건수	476건('24.11. 기준)

### ● DB 접속 방법

- 홈페이지 접속 후 상단의 '식품첨가물(食品添加物)' 탭 클릭

The screenshot shows the homepage of the Japanese Food Chemical Research Foundation. The top navigation bar includes a home icon, '財団紹介', '助成事業', '食品添加物' (highlighted with a red box), '残留農薬', '器具・容器包装', and '化学物質'. Below the navigation bar, there is a 'Topics' section with two news items: '令和7年度研究助成及び(前期)シンポジウム開催補助事業のお知らせ' (dated 2024.10.15) and '令和6年度研究等助成の選考結果' (dated 2024.09.20). A '新着情報' (New Information) section follows, with a sub-navigation bar for '最新情報', '助成事業', '食品添加物', '残留農薬', '化学物質', and '器具・容器包装'. Below this, there are several news items with dates and titles, such as '食品添加物' (2024.11.05) regarding the revision of standards, '残留農薬' (2024.09.18) regarding residue limits, and '食品添加物' (2024.09.05) regarding the publication of names.

○ ‘식품첨가물 리스트(食品添加物のリスト)’란의 ‘지정첨가물 리스트(指定添加物リスト)’ 클릭



○ 원재료 웹사이트 고시 정보 및 PDF 파일 다운로드 가능



● 정보 제공 범위

● 일문명칭, 영문명칭



예시 | 원료명: 베타카로틴( $\beta$ -カロテン/ $\beta$ -Carotene)

cc0f0ca1499e11362fe7539496cf001e3f483f28.pdf 4 / 16 122%

令和6年3月1日改正

・左欄の日本語名称は、食品衛生法施行規則別表第1の内容を掲載したものです。「食品添加物公定書」(厚生労働省)の表記を参考に、漢数字をアラビア数字に改める等の表記上の加工をしています。

・右欄の英語名称は、「食品添加物公定書」及び同書英訳(国立医薬品食品衛生研究所)等を参考に左欄を英訳したものです。

・必要に応じ前述の各原典をご参照していただくようお願いいたします。

96	オルトフェニルフェノール及びオルトフェニルフェノールナトリウム	$\sigma$ -Phenylphenol and Sodium $\sigma$ -Phenylphenolate
97	オレイン酸ナトリウム	Sodium Oleate
98	過酢酸	Peracetic Acid
99	過酸化水素	Hydrogen Peroxide
100	過酸化ベンゾイル	Benzoyl Peroxide
101	カゼインナトリウム	Sodium Caseinate
102	過硫酸アンモニウム	Ammonium Persulfate
103	カルボキシメチルセルロースカルシウム(別名繊維素グリコール酸カルシウム)	Calcium Carboxymethylcellulose (Calcium Cellulose Glycolate)
104	カルボキシメチルセルロースナトリウム(別名繊維素グリコール酸ナトリウム)	Sodium Carboxymethylcellulose (Sodium Cellulose Glycolate)
1	$\beta$ -カロテン(別名 $\beta$ -カロチン)	$\beta$ -Carotene
106	カンタキサンチン	Canthaxanthin
107	ギ酸イソアミル	Isaamylic Formate
108	ギ酸ゲラニル	Geranyl Formate
109	ギ酸シトロネリル	Citronellylic Formate
110	Xylitol	
111	キチングルカン	Chitin-Glucan
	5-デアニル酸ナトリウム(別名5-デアニル酸ナト	

① 일문명: 베타카로틴[ $\beta$ -カロテン(別名 $\beta$ -カロチン)]

② 영문명:  $\beta$ -Carotene

## [ 천연향료 기원 물질 리스트 ]

### ● 개요

DB명	천연향료 기원 물질 리스트
관리기관	일본식품화학연구진흥재단
DB 내용	천연향료 기원 물질 리스트
접속 주소	https://www.ffcr.or.jp/tenka/list/post-13.html
정보 제공 건수	2,538건('24.11. 기준)

### ● DB 접속 방법

- 홈페이지 접속 후 상단의 '식품첨가물(食品添加物)' 탭 클릭

The screenshot shows the homepage of the Japanese Food Chemical Research Foundation (日本食品化学研究振興財団). The navigation menu at the top includes: 財団紹介, 助成事業, **食品添加物** (highlighted with a red box), 残留農薬, 器具・容器包装, and 化学物質. Below the navigation, there are sections for 'Topics' and 'New Information' (新着情報) with various news items and dates. On the right side, there are links to 'Consumer Affairs / Ministry of Health, Labour and Welfare Food Chemistry Information', 'Food Safety Commission Information', 'Food Chemistry Related Materials', and 'Related Sites'.

- ‘식품첨가물 리스트(食品添加物のリスト)’란의 ‘천연향료 기원 물질 리스트(天然香料基原物質リスト)’ 클릭



- 원재료 웹사이트 고시 정보 및 PDF 파일 다운로드 가능



Part 1.  
4. 원재료

● 정보 제공 범위

- 기원물질명, 다른 명칭, 비고(영문명)



예시 | 원료명: 켈냘(개박하)[キャットニップ(イヌハッカ)/Catnip]

天然香料基原物質リスト 公益財団法人 日本食品化学研究振興財団

基原物質名	別名	備考
カラミント		Calaminth
カラムス		Calamus
カランガ		Galanga
カーラント		Currant
カリッサ		Carissa, Karanda
カリン		Chinese quince
カルダモン	ショウズク	Cardamon
カルパナム		Galbanum
カレー		Curry powder
カレーリーフ	カリリーフ	Curry leaf
カウミドリ		Kawamidori
カンゾウ	リコリス	Licorice
ガンビア		Gambir
カンラン		Chinese olive
キウイフルーツ		Kiwifruit
キカイガラタケ		Kikaigaratake
キキョウ		Kikyo, Baloon flower
キク		Chrysanthemum
キクラゲ		Kikurage, Jew s-ear
キササゲ		Kisasage
ギシギシ		Gishigishi, Dock
キダチアロエ		Kidachi aloe
キンナ		Cinchona
キハダ		Kihada
キバナオウギ		Kibanahagi
ギベシ		Gibeshi
ギムネマシルベスタ		Gynema sylvestre
① キャットニップ	② イヌハッカ	③ Catnip
キヤラウェイ	ヒメウイキョウ	Caraway
キヤロブ	イナゴマメ、カロブ	Carob, Locust bean
キュウリ	キューカンパー	Cucumber
キラヤ		Quillaja, Quillaja

- ① 기원물질명: 켈냘(キャットニップ)
- ② 다른 명칭: 개박하(イヌハッカ)
- ③ 비고(영문명): Catnip

## [ 일반첨가물 리스트 ]

### ● 개요

DB명	일반첨가물 리스트
관리기관	일본식품화학연구진흥재단
DB 내용	일반적으로 식품으로 음식에 제공되는 것으로 첨가물로 사용되는 품목 리스트
접속 주소	<a href="https://www.ffcr.or.jp/tenka/list/post-14.html">https://www.ffcr.or.jp/tenka/list/post-14.html</a>
정보 제공 건수	112건('24.11. 기준)

### ● DB 접속 방법

- 홈페이지 접속 후 상단의 '식품첨가물(食品添加物)' 탭 클릭

The screenshot shows the homepage of the Japanese Food Chemical Research Foundation (日本食品化学研究振興財団). The navigation menu at the top includes 'Home', 'Introduction', 'Support Projects', 'Food Additives' (食品添加物), 'Residue Management', 'Equipment & Packaging', and 'Chemical Substances'. The 'Food Additives' tab is highlighted with a red box. Below the navigation, there are sections for 'Topics' and 'New Information' (新着情報) with various news items and dates.

Part 1.  
4. 원 가 명

- ‘식품첨가물 리스트(食品添加物のリスト)’란의 ‘천연향료 기원 물질 리스트(天然香料基原物質リスト)’ 클릭



- 원재료 웹사이트 고시 정보 및 PDF 파일 다운로드 가능



● 정보 제공 범위

- 품명(명칭/다른 명칭), 간략명, 기원, 용도, 비교(영문명)

예시 | 원료명: 클로렐라(クロレラ末/Powdered chlorella)

enka.pdf 4 / 8 99% +

公益財団法人 日本食品化学研究振興財団

一般に食品として飲食に供させている物であって添加物として使用される品目リスト

品名	別名	略称又は類別名	基原・製法・本質	用途	備考
① クロレラ末		②	緑藻類クロレラ(Chlorella)を、乾燥し、粉末にしたものである。	着色料	Powdered chlorella
ココア	ココアパウダー			着色料	Cocoa
小麦粉				製造用剤	Wheat flour
コムギ抽出物			イネ科コムギ( <i>Triticum aestivum</i> LINNE)の種子(莖葉)を、はい煎後、経時水で抽出して得られたものである。	製造用剤	Wheat extract
コラーゲン				製造用剤	Collagen
コンニャクイモ抽出物	グルコマンナン		サトイモ科コンニャク( <i>Amorphophallus konjac</i> )の根茎を、乾燥、粉砕後、温水エタールで洗浄して得られたもの、又はこれを冷時~室温水で抽出して得られたもので、グルコースとマンノースで構成される多糖類からなる。	増粘安定剤 製造用剤	Konjac extract
サツマイモセルロース		セルロース	ヒルガオ科サツマイモ( <i>Ipomoea batatas</i> POIRE)の塊根より得られたものである。主成分はセルロースである。	製造用剤 増粘安定剤	Sweetpotato
サフラン				着色料	Saffron
サフラン色素		カロチノイド カロチノイド色素 カロチノイド カロチノイド色素 クロシン サフラン	アヤメ科サフラン( <i>Crocus sativus</i> LINNE)の塊根より、エタールで抽出して得られたものである。主色素は、カロチノイド系のクロシン、クロセチンである。黄色を呈する。	着色料	Saffron colour
サーモンベリー色素		アントシアニン アントシアニン色素 果実色素	バラ科サーモンベリー( <i>Rubus spectabilis</i> PURSH)の果実より、搾汁したもの、又は水で抽出して得られたものである。主色素はアントシアニンである。赤色の着色を呈する。	着色料	Salmonberry colour
シソ色素		アントシアニン アントシアニン色素 野菜色素	シソ科シソ( <i>Perilla frutescens</i> BRITT var. <i>acuta</i> KUDO)の葉より、室温水、弱酸性水溶液又は含水エタールで抽出して得られたものである。主色素は、シソニン、マロニルシソニンである。赤色の着色を呈する。	着色料	Beefsteak plant colour Perilla colour
ストロベリー色素		アントシアニン アントシアニン色素 果実色素	バラ科オランダイアゴ( <i>Fragaria ananassa</i> BOUGHESNE)の果実より、搾汁したもの、又は水で抽出して得られたものである。主色素は、シ	着色料	Strawberry colour

- ① 품명(명칭/다른 명칭): 클로렐라분말(クロレ라末)
- ② 간략명: -
- ③ 기원·제조법·본질: 녹조류 클로렐라(Chlorella)를 건조하고, 분말화한 것
- ④ 용도: 착색료
- ⑤ 비교(영문명): Powdered chlorella

Part 1.  
4. 원 가 명

## [ 유전자 재조합 첨가물 목록 ]

### ● 개요

DB명	유전자 재조합 첨가물 목록
관리기관	일본식품화학연구진흥재단
DB 내용	안전성 심사 절차를 거친 유전자 재조합 첨가물 목록
접속 주소	<a href="https://www.ffcr.or.jp/tenka/list/post-15.html">https://www.ffcr.or.jp/tenka/list/post-15.html</a>
정보 제공 건수	42건('24.11. 기준)

### ● DB 접속 방법

- 홈페이지 접속 후 상단의 '식품첨가물(食品添加物)' 탭 클릭

The screenshot shows the homepage of the Japanese Food Chemical Research Foundation (日本食品化学研究振興財団). The navigation menu at the top includes 'Home', 'Introduction', 'Support Projects', 'Food Additives' (食品添加物), 'Residue Management', 'Equipment & Packaging', and 'Chemical Substances'. The 'Food Additives' tab is highlighted with a red box. Below the navigation, there are sections for 'Topics' and 'New Information' (新着情報) with various news items and dates.

- ‘식품첨가물 리스트(食品添加物のリスト)’란의 ‘안전성 심사 절차를 거친 유전자 재조합 첨가물 목록(安全性審査の手續を経た遺伝子組換え添加物一覧)’ 클릭



- 원재료 웹사이트 고시 정보 확인 가능


The screenshot shows the detailed page for 'Safety Review of Genetically Modified Additives'. It includes a table with the following columns: 'Item Name', 'Name', 'Type', 'Applicant/Developer', and 'Approval Date (Year, Month, Day)'. The table lists several additives, including TS-25, BSG-아미라제, TMS-아미라제, S0961, LE399, and SPEZYME FRED™.

対象品目	名 称	性 質	申請者/開発者等	官 署 指 定 日 (年,月,日)
α-アミラーゼ	TS-25	生成性向上	ノボザイムズジャパン株式会社 Novozymes A/S (デンマーク)	2001.3.30
	BSG-アミラーゼ	生成性向上	ノボザイムズジャパン株式会社 Novozymes A/S (デンマーク)	2001.3.30
	TMS-アミラーゼ	生成性向上	ノボザイムズジャパン株式会社 Novozymes A/S (デンマーク)	2001.3.30
	S0961	生成性向上	ノボザイムズジャパン株式会社 Novozymes A/S (デンマーク)	2002.2.21
	LE399	生成性向上	ノボザイムズジャパン株式会社 Novozymes A/S (デンマーク)	2005.10.31
	SPEZYME FRED™	耐熱性向上	ジェネンコア植物株式会社 Genencor International, Inc.	2007.4.12

Part 1.  
4. 원 가 명

● 정보 제공 범위

- 대상품목, 명칭, 성질, 신청자/개발자 등, 관보 게시일

 예시 | 원료명: 카이맥스(カイマックス/CHY-MAX M)

公益財団法人 日本食品化学研究振興財団 The Japan Food Chemical Research Foundation		食と化学の豊かな未来を拓くために活動します		English		サイト内を検索	
財団紹介	助成事業	食品添加物	残留農薬	器具・容器包装	化学物質		
	α-アミラーゼ	上	ヤパン 株式会社	(デンマーク)			
	NZYM-AV株を利用して生産された α-アミラーゼ	耐熱性向上	ノボライムズジャパン 株式会社	Novozymes A/S (デンマーク)	2016.3.29		
	JSF-Q7-170-3株を利用して生産されたα-アミラーゼ	生産性向上 耐熱性向上	ダニスコジャパン株式会社	Danisco US, Inc. (米国)	2018.7.30.		
	マキシレン	生産性向上	株式会社ロビン	DSM (オランダ)	2001.3.30		
① キモシン	② カイマックス	③ キモシン 生産性	④ 株式会社野澤組	⑤ CHR. HANSEN A/S (デンマーク)	⑥ 2003.6.30		
	CIN株を利用して生産されたキモシン	凝乳活性の向上	DSM株式会社	DSM (オランダ)	2018.11.26		
	カイマックス M	生産性向上	株式会社野澤組	CHR. HANSEN A/S (デンマーク)	2019.3.26		

- ① 대상품목: 키모신(chymosin)
- ② 명칭: 카이맥스(カイマックス/CHY-MAX M)
- ③ 성질: 키모신의 생산성
- ④ 신청자/개발자: 주식회사 노사와(株式会社野澤組)/CHR. HANSEN A/S
- ⑤ 관보 게시일: 2003.6.30.

## ■ 베트남

### [ 식품첨가물 사용, 관리에 관한 규정 ]

#### ● 개요

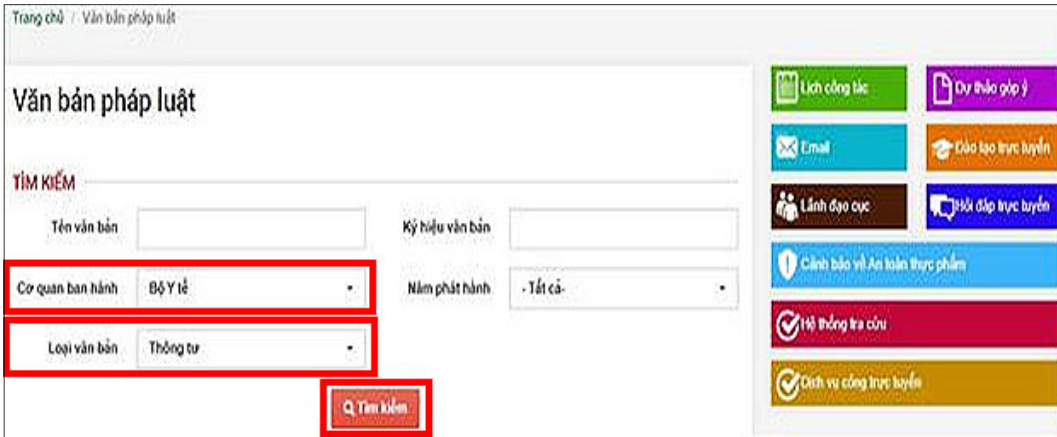
<b>DB명</b>	식품첨가물 사용, 관리에 관한 규정(No.09/VBHN-BYT)
<b>관리기관</b>	보건부 식품안전국(VFA)
<b>DB 내용</b>	식품에 사용이 허가된 식품첨가물 목록 정보를 제공함
<b>접속 주소</b>	<a href="https://vfa.gov.vn/van-ban.html">https://vfa.gov.vn/van-ban.html</a>
<b>정보 제공 건수</b>	식품첨가물 400종 외('24.11. 기준)

#### ● DB 접속 방법

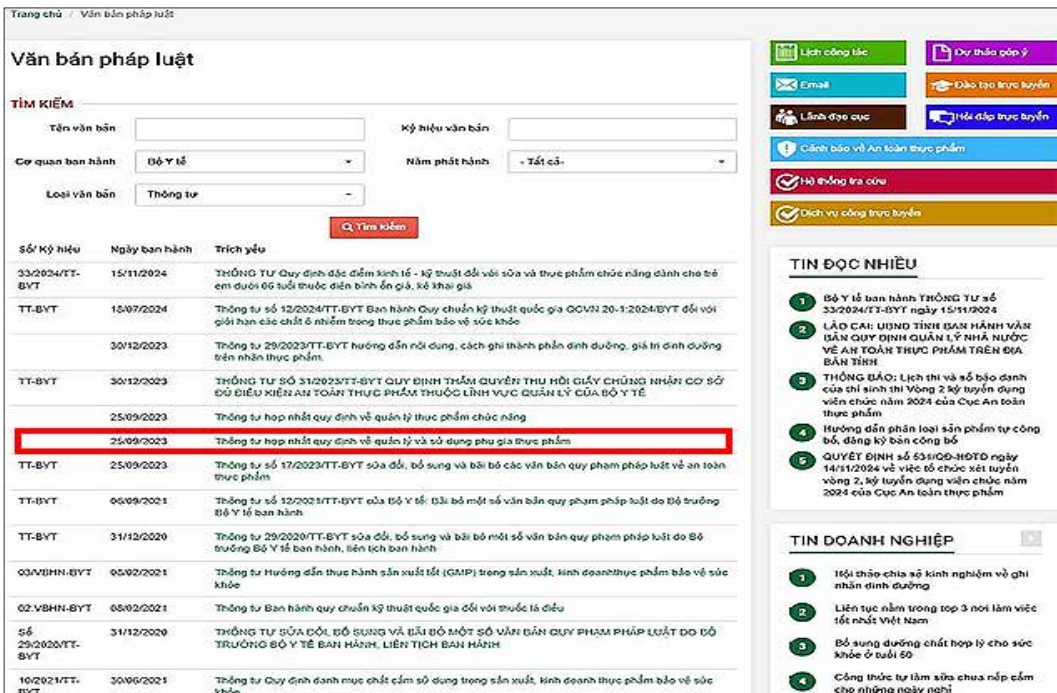
- ‘식품안전국 누리집’ 접속 후 ‘문서서비스(Văn bản)’ 클릭



- ‘법률문서(Văn bản pháp luật)’ 화면으로 이동 후 카테고리 설정: 발행기관(cơ quan ban hành)-보건부(Bộ Y tế), 문서종류(Loại văn bản)-시행규칙(Thông tư), ‘찾기(Tìm kiếm)’ 클릭



- 시행규칙 목록 중 ‘식품첨가물 사용, 관리에 관한 규정(No.09/VBHN-BYT)’ 클릭 ⇒ 접속 후 PDF 파일 다운로드



● 정보 제공 범위

- 식품 제조, 영업 간 사용이 허가된 가공보조제 목록(예)

**PHỤ LỤC 27**

**① DANH MỤC CHẤT HỖ TRỢ CHẾ BIẾN ĐƯỢC PHÉP SỬ DỤNG TRONG SẢN XUẤT, KINH DOANH THỰC PHẨM**

TT	② Tên chất tiếng Việt	③ Tên chất Tiếng Anh	Lĩnh vực sử dụng ④	MRL (mg/kg) ⑤
I	Các chất chống tạo bọt	Antifoam agents		
1	Methyl este của acid béo	Fatty acid methyl ester		
2	Este poly alkyl glycol của acid béo	Fatty acid polyalkylene glycol ester	Protein thực vật	
3	Alcohol béo C8-C30	Fatty alcohols (C8-C30)	Protein thực vật	
4	Dầu dừa hydro hóa	Hydrogenated coconut oil	Sản xuất bánh kẹo	5-15

- ① 식품 제조, 영업 간 사용이 허가된 가공보조제 목록
- ② 물질명(베트남어)
- ③ 물질명(영문)
- ④ 사용영역
- ⑤ 최대사용한도

Part 1.  
4. 원가 명

## ■ 대만

### [ 식품첨가물 사용범위 및 제한량, 규격표준 ]

#### ● 개요

DB명	식품첨가물 사용범위 및 제한량, 규격표준
관리기관	위생복지부 식품약품관리서
DB 내용	영양강화제 등 식품첨가물의 사용범위, 제한량, 규격표준 정보 제공
접속 주소	<a href="https://consumer.fda.gov.tw/Law/FoodAdditivesList.aspx?nodeID=521">https://consumer.fda.gov.tw/Law/FoodAdditivesList.aspx?nodeID=521</a>
정보 제공 건수	798건('24.11. 기준) - 영양강화제: 320건
기타	검색 결과에 영문명을 제공하고 있어 영문 검색이 가능하며 식품 형태에 따른 사용 제한량을 확인할 수 있음. 제·개정 상황에 따라 수시로 업데이트될 수 있음

● DB 접속 방법

- ‘식품약물 소비자 카테고리’ 접속 후 ‘통합 조회 서비스(整合查詢服務)’ 클릭



- ‘통합 조회 서비스’ 화면으로 이동 후 ‘1.식품(1.食品)’ 클릭



Part 1.  
4. 附件

- ‘식품(食品)’ 화면으로 이동 후 ‘4.식품법규 조회(食品法規查詢)’ 클릭

The screenshot shows the '食品' (Food) section of the FDA Integrated Query Service. The page features a navigation bar with categories like '食品', '西藥', and '檢驗方法查詢'. Below the navigation bar, there are several menu items, with '食品法規查詢' (Food Regulation Query) highlighted in a blue box.

項次	標題
1	核可資料查詢
2	食品原料整合查詢平臺
3	遷境檢驗不符合食品資訊查詢(另開新視窗)
4	食品法規查詢
5	HACCP 查詢
6	吃的健康
7	食品相關法規暨解釋彙編查詢(另開新視窗)

- ‘식품법규 조회’ 화면에서 ‘4.식품첨가물 사용범위 및 제한량, 규격표준(食品添加物使用範圍及限量暨規格標準)’ 클릭

The screenshot shows the '食品法規查詢' (Food Regulation Query) section of the FDA Integrated Query Service. The page features a navigation bar with categories like '食品', '西藥', and '檢驗方法查詢'. Below the navigation bar, there are several menu items, with '食品添加物使用範圍及限量暨規格標準' (Food Additive Use Range and Limitation and Specification Standards) highlighted in a blue box.

項次	標題
1	食品法規條文查詢
2	動物用藥殘留標準
3	農藥殘留容許量標準
4	食品添加物使用範圍及限量暨規格標準

○ ‘식품첨가물 사용범위 및 제한량, 규격표준’ 접속 완료

○ ‘키워드(關鍵字)’에 검색하고자 하는 식품첨가물의 중문 또는 영문 명칭 입력 후 ‘검색(搜尋)’ 버튼 클릭

Part 1.  
4. 원가 매

○ 검색 결과에서 해당 식품첨가물의 중문 명칭(하이퍼링크) 클릭

食品添加物 :  關鍵字 :

共有 6 筆搜尋結果

項次	類別	中文品名	英文品名	使用食品範圍及限量	使用限制	規格
1	(三) 抗氧化劑	L-抗壞血酸 (維生素C)	L-Ascorbic Acid (Vitamin C)	本品可使用於各類食品；用量以Ascorbic Acid 計為1.3g/kg 以下	限用為抗氧化劑。	<ul style="list-style-type: none"> <li>03003維生素C L-Ascorbic acid (Vitamin C).pdf</li> </ul>
2	(八) 營養添加劑	抗壞血酸 (維生素C)	Ascorbic Acid (Vitamin C)	1.形態膠囊狀、錠狀且標示有每日食用限量之食品，在每日食用量中，其維生素C之總含量不得高於1000mg。 2.其他一般食品，在每日食用量或每300g食品(未標示每日食用量者)中，其維生素C之總含量不得高於150mg。 3.嬰兒(輔助)食品，在每日食用量或每300g食品(未標示每日食用量者)中，其維生素C之總含量不得高於60mg。	限於補充食品中不足之營養素時使用。	<ul style="list-style-type: none"> <li>08012抗壞血酸L-Ascorbic acid (Vitamin C).pdf</li> </ul>
3	(八) 營養添加劑	抗壞血酸鈉 (維生素C)	Sodium Ascorbate (Vitamin C)	1.形態膠囊狀、錠狀且標示有每日食用限量之食品，在每日食用量中，其維生素C之總含量不得高於1000mg。 2.其他一般食品，在每日食用量或每300g食品(未標示每日食用量者)中，其維生素C之總含量不得高於150mg。 3.嬰兒(輔助)食品，在每日食用量或每300g食品(未標示每日食用量者)中，其維生素C之總含量不得高於60mg。	限於補充食品中不足之營養素時使用。	<ul style="list-style-type: none"> <li>08013抗壞血酸鈉 Sodium L-Ascorbate.pdf</li> </ul>

○ 해당 식품첨가물의 상세 정보 확인

衛生福利部食品藥物管理署  
Food and Drug Administration  
FDA 食品藥物消費者專區 **整合查詢服務**

食品 西藥 檢驗方法查詢 食品藥物管理署官網政策專區 食品藥物管理署官網法規專區 化粧品管理用成分管理規定

人體器官飲食界▼

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### 食品添加物使用範圍及限量暨規格標準

類別：(八) 營養添加劑 **抗壞血酸 (維生素C)**

類別	(八) 營養添加劑
中文名稱	抗壞血酸 (維生素C)
外文名稱	Ascorbic Acid (Vitamin C)
使用食品範圍及限量	1.形態膠囊狀、錠狀且標示有每日食用限量之食品，在每日食用量中，其維生素C之總含量不得高於1000mg。 2.其他一般食品，在每日食用量或每300g食品(未標示每日食用量者)中，其維生素C之總含量不得高於150mg。 3.嬰兒(輔助)食品，在每日食用量或每300g食品(未標示每日食用量者)中，其維生素C之總含量不得高於60mg。
使用限制	限於補充食品中不足之營養素時使用。
規格	<a href="#">08012抗壞血酸L-Ascorbic acid (Vitamin C).pdf</a>

● 정보 제공 범위

- 식품첨가물의 유형, 중문 및 영문 명칭, 식품 사용범위 및 제한량, 사용 제한, 규격 정보 제공

**예시** | 식품첨가물명: **비타민 C**

食品添加物使用範圍及限量暨規格標準	
類別：(八) 營養添加劑 <b>抗壞血酸 (維生素C)</b>	
詳細資料	類別說明
① 類別	(八) 營養添加劑
② 中文名稱	抗壞血酸 (維生素C)
③ 外文名稱	Ascorbic Acid (Vitamin C)
④ 使用食品範圍及限量	1. 形態屬膠囊狀、錠狀且標示有每日食用限量之食品，在每日食用量中，其維生素C之總含量不得高於1000mg。 2. 其他一般食品，在每日食用量或每300g食品(未標示每日食用量者)中，其維生素C之總含量不得高於150mg。 3. 嬰兒(輔助)食品，在每日食用量或每300g食品(未標示每日食用量者)中，其維生素C之總含量不得高於60mg。
⑤ 使用限制	限於補充食品中不足之營養素時使用。
⑥ 規格	<a href="#">08012抗壞血酸L-Ascorbic acid (Vitamin C).pdf</a>

- ① 유형: (8) 영양강화제
- ② 중문 명칭: 아스코르브산(비타민 C)
- ③ 외국어(영문) 명칭: Ascorbic Acid(Vitamin C)
- ④ 사용 식품범위 및 제한량:
  1. 형상이 캡슐, 정제형이며 일일섭취제한량이 표시된 식품으로 일일섭취량 중 비타민 C의 총합량이 1000 mg보다 높지 않아야 함
  2. 기타 일반식품으로 일일섭취량 중 또는 식품 300 g당(일일섭취량이 표시되지 않은 경우) 비타민 C의 총합량이 150 mg보다 높지 않아야 함
  3. 영아(보조)식품으로 일일섭취량 중 또는 식품 300 g 당(일일섭취량이 표시되지 않은 경우) 비타민 C의 총합량이 60 mg보다 높지 않아야 함
- ⑤ 사용 제한: 식품 중 부족한 영양소를 보충하는 경우에만 사용
- ⑥ 규격: pdf 파일 다운로드

Part 1  
4. 원가 명

## [ 천연식용색소 위생표준 ]

### ● 개요

DB명	천연식용색소 위생표준
관리기관	위생복지부 식품약물관리서
DB 내용	천연식용색소 정보 제공
접속 주소	<a href="https://consumer.fda.gov.tw/Law/Detail.aspx?nodeID=518&amp;lawid=139">https://consumer.fda.gov.tw/Law/Detail.aspx?nodeID=518 &amp;lawid=139</a>
정보 제공 건수	25건('24.11. 기준)
기타	대만은 천연식용색소(부형제나 기타 첨가물이 첨가된 경우 제외)를 「천연식용색소 위생표준」에 따라 식품첨가물과 별도로 관리하고 있음. 해당 규정 내 별표(pdf 파일)에서 천연식용색소 목록을 확인할 수 있으며 영문 번역본도 제공하고 있음

● DB 접속 방법

- ‘식품약품 소비자 카테고리’ 접속 후 ‘통합 조회 서비스(整合查詢服務)’ 클릭



- ‘통합 조회 서비스’ 화면으로 이동 후 ‘1.식품(1.食品)’ 클릭



Part 1.  
4.원가본

- ‘식품(食品)’ 화면으로 이동 후 ‘4.식품법규 조회(食品法規查詢)’ 클릭

The screenshot shows the 'Food' category page on the FDA website. The page title is '食品' (Food). Below the title is a table with 7 items. Item 4, '食品法規查詢' (Food Regulation Query), is highlighted with a blue box.

項次	標題
1	核可資料查詢
2	食品原料整合查詢平臺
3	邊境檢驗不符合食品資訊查詢(另開新視窗)
4	<b>食品法規查詢</b>
5	HACCP 查詢
6	吃的健康
7	食品相關法規暨解釋彙編查詢(另開新視窗)

- ‘식품법규 조회’ 화면에서 ‘1.식품법규조문 조회(食品法規條文查詢)’ 클릭

The screenshot shows the 'Food Regulation Query' page on the FDA website. The page title is '食品法規查詢' (Food Regulation Query). Below the title is a table with 4 items. Item 1, '食品法規條文查詢' (Food Regulation Article Query), is highlighted with a blue box.

項次	標題
1	<b>食品法規條文查詢</b>
2	動物用藥殘留標準
3	農藥殘留容許量標準
4	食品添加物使用範圍及限量暨規格標準

- ‘키워드(關鍵字)’에 ‘천연식용색소(天然食用色素)’ 중문 입력 후 ‘검색(搜尋)’ 버튼 클릭

食品法規條文查詢

類別: 所有類別      法規性質: 全部

標題:      關鍵字: 天然食用色素

搜尋 重置

所有類別(208)   食品衛生標準(25)   食品輸入及查驗登記(42)   食品標示及廣告(32)   食品製造及衛生安全管理(45)   其它(93)

項次	標題	法律性質	發佈日期
1	花生及其製品製造業者符合食品良好衛生規範準則之指引	行政指導	2024/09/06
2	食品原料珍珠及珍珠鈣之使用限制	法規命令	2024/07/11
3	食品原料貝殼及貝殼鈣之使用限制	法規命令	2024/07/11

- 검색 결과에서 ‘천연식용색소 위생표준(天然食用色素衛生標準)’ 하이퍼링크 클릭

食品法規條文查詢

類別: 所有類別      法規性質: 全部

標題:      關鍵字: 天然食用色素

搜尋 重置

所有類別(1)   食品衛生標準(1)   食品輸入及查驗登記(0)   食品標示及廣告(0)   食品製造及衛生安全管理(0)   其它(0)

項次	標題	法律性質	發佈日期
1	天然食用色素衛生標準 <b>EN</b>	法規命令	2023/03/29

※ 초록색 표시부분 클릭 시 영문 버전 확인 가능

● 이동한 화면에서 하단 ‘별표 배포(發布附表)’ pdf 파일 다운로드 클릭

### 食品法規條文查詢

天然食用色素衛生標準 2023/03/29

法規性質	法規命令
法規類別	食品衛生標準

**天然食用色素衛生標準**  
 中華民國100年4月21日署授食字第1001300978號令發布  
 中華民國102年8月20日部授食字第1021350146號令修正第1條  
 中華民國102年11月25日部授食字第1021351259號令修正5條  
 中華民國112年3月29日衛授食字第1121300442號令修正發布

**第一條** 本標準依食品安全衛生管理法第十七條規定訂定之。  
**第二條** 萃取天然食用色素之溶劑來源，包括：  
 一、水、乙醇、植物油或其他食品原料。  
 二、加工助劑衛生標準准用之溶劑。  
**第三條** 添加賦形劑或其他添加物之天然食用色素，其所添加者，限於食品添加物使用範圍及限量監視格標準所載品名別，或其他可供食用之食品原料。  
**第四條** 天然食用色素之來源、主成分及規格，應符合附表之規定。  
**第五條** 本標準自中華民國一百一十二年一月一日施行。

📄 檔案下載

- [發布附表.pdf](#)
- [\(113.1.1實施\)發布全文\(無沿革\)-天然食用色素衛生標準.pdf](#)
- [天然食用色素衛生標準1021125修正.pdf](#)

● ‘별표’ pdf 파일 다운로드 완료

第四條附表修正規定			
附 表			
英文名稱	中文名稱	來源/主成分	規格 Specifications Standard *
Algal carotenes	藻類胡蘿蔔素	來源：鹽生杜氏藻( <i>Dunaliella salina</i> )菌絲 主成分：類胡蘿蔔素(Carotenoids)	
Amaranthus Colors	紅莧菜色素	來源：莧(紅莧菜) 主成分：莧紅素(Amaranthin)	
Annatto	荳蔻多	來源：胭脂樹/紅木( <i>Bixa Orellana</i> L.)種子 主成分：水溶性荳蔻多：降紅木素(Norbixin)； 油溶性荳蔻多：紅木素(Bixin)	赤:1 mg/kg 以下 鈉:0.5 mg/kg 以下
Anthocyanin	花青素	來源：紅、藍、紫色等深色植物 效果實：如：藍莓、櫻桃、接骨木莓(Elderberry)、葡萄汁、葡萄果皮、洛神花、桑椹、紫蘇、李子、紅玉蜀黍、紫甘藍菜、草莓、茄子皮、紫甘藍、紅羅望子、蝶豆花等 主成分：花青素(Anthocyanin)	赤:1 mg/kg 以下 鈉:1 mg/kg 以下
Beet Red Color	紅甜菜色素	來源：甜菜( <i>Beta vulgaris</i> )根莖 主成分：甜菜苷(Betain)	赤:1 mg/kg 以下 鈉:1 mg/kg 以下
Carmine	胭脂紅	來源：雌性胭脂蟲( <i>Dactylopius coccus</i> Costa) 主成分：胭脂蟲酸(Carmine acid)	碎:1 mg/kg 以下 赤:0.5 mg/kg 以下 鈉:0.1 mg/kg 以下 沙門氏菌:陰性
Chlorophyll	葉綠素	來源：可食植物或綠藻中提取 主成分：葉綠素(Chlorophyll)	赤:1 mg/kg 以下 鈉:1 mg/kg 以下
Cocoa Color	可可色素	來源：可可( <i>Theobroma cacao</i> )種子 主成分：類黃酮(Flavonoids)	
Gardenia Blue	梔子藍	來源：梔子果實萃取物經酵素處理後所得 主成分：Gentiin	
Gardenia Red	梔子紅	來源：梔子果實萃取物經酵素處理後所得 主成分：Gentiin	
Gardenia Yellow	梔子黃	來源：梔子果實 主成分：黃梔苷(Crocin)	
Laver Color	紫菜色素	來源：紫菜 主成分：藻紅素(Phycocyanin)	
Monascus Color	紅麴色素	來源：紅麴菌( <i>Monascus</i>	
Onion Color	洋蔥色素	來源：洋蔥之鱗莖 主成分：類黃酮(Flavonoids)	
Persimmon Color	柿子色素	來源：柿之可食部分經發酵、分糖、加糖、糊化、過濾、濃縮、乾燥而得 主成分：多酚類(Polyphenol)	赤:1 mg/kg 以下 鈉:1 mg/kg 以下
Plant carbon	植物碳	來源：以木、纖維素、泥炭、椰子殼及果殼等原料，經高溫(800-1000°C)碳化而製成之黑色粉末	
Plant carotenes	植物胡蘿蔔素	來源：植物或植物油中提取，如：胡蘿蔔、紅椒、橘子果皮、黃玉蜀黍種子、甘薯等 主成分：類胡蘿蔔素(Carotenoids)	
Safflower Yellow	紅花黃	來源：紅花( <i>Carthamus tinctorius</i> L.)之花瓣 主成分：類黃酮(Flavonoids)	赤:1 mg/kg 以下 鈉:1 mg/kg 以下
Saffron	番紅花	來源：番紅花( <i>Crocus sativus</i> L.)之柱頭 主成分：黃梔苷(Crocin)及黃梔配質(Crocein)	
Sorghum Color	高粱色素	來源：高粱果實之殼 主成分：類黃酮(Flavonoids)	
Spirulina Color	螺旋藻/藍藻色素	來源：螺旋藻/藍藻( <i>Spirulina</i> ) 主成分：藻藍素(Phycocyanin)	赤:1 mg/kg 以下
Tamarind Color	酸豆/羅望子色素	來源：酸豆/羅望子( <i>Tamarindus indica</i> L.)種子 主成分：類黃酮(Flavonoids)	
Tomato Color	番茄色素	來源：番茄之果實 主成分：番茄紅素(Lycopene)	鈉:1 mg/kg 以下 鈉:1 mg/kg 以下
Turmeric Color	薑黃色素	來源：薑黃( <i>Curcuma longa</i> L.)之根莖 主成分：薑黃素(Curcumin)	
Xanthophylls	葉黃素類	來源：限於目前中萃取濃縮而得者 主成分：葉黃素類(Xanthophylls)	赤:1 mg/kg 以下 鈉:1 mg/kg 以下

備註：  
 一、天然食用色素中砷、鉛之限量，除本表另有規定者外，應符合以下規定：  
 (一)砷：3 mg/kg 以下。  
 (二)鉛：2 mg/kg 以下。  
 二、天然食用色素中總黃麴毒素及總胺基酸之限量，應符合食品中污染物質及毒素衛生標準之規定。

● 정보 제공 범위

- 천연식용색소의 영문 및 중문 명칭, 유래 및 주성분, 규격 정보 제공



예시 | 식품첨가물명: 안토시아닌

**第四條附表修正規定**

**附 表**

① 英文名稱	② 中文名稱	③ 來源/主成分	④ Specifications Standard *
Algal carotenes	藻類胡蘿蔔素	來源：鹽生杜氏藻( <i>Dunaliella salina</i> )菌株 主成分：類胡蘿蔔素(Carotenoids)	
Amaranthus Colors	紅莧菜色素	來源：由紅莧菜取得。 主成分：莧紅素(Amaranthin)。	
Annatto	荳蔻多	來源：胭脂樹/紅木( <i>Bixa Orellana</i> L.)種子。 主成分： 水溶性荳蔻多：降紅木素(Norbixin)； 油溶性荳蔻多：紅木素(Bixin)	乘:1 mg/kg 以下 鎊:0.5 mg/kg 以下
Anthocyanin	花青素	來源：紅、藍、紫色等深色植物及果實；如：藍莓、櫻桃、接骨木莓(Elderberry)、葡萄汁、葡萄果皮、洛神花、桑椹、紫蘇、李子、紅玉蜀黍、紫甘藍菜、草莓、茄子皮、紫甘藷、紅羅望子、蝶豆花等 主成分：花青素(Anthocyanin)	乘:1 mg/kg 以下 鎊:1 mg/kg 以下

- ① 영문 명칭: Anthocyanin
- ② 중문 명칭: 안토시아닌(花青素)
- ③ 유래/주성분
  - 유래: 적색, 남색, 자색 등 짙은 색 식물 및 과실
  - 예: 블루베리, 앵두, 엘더베리, 포도즙 (이하 생략)
  - 주성분: 안토시아닌
- ④ 규격 Specifications Standard
  - 수은: 1 mg/kg 이하
  - 카드뮴: 1 mg/kg 이하

Part 1.  
4. 원 가 명





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# 5. 기 타

5-1 표시 • 336

5-2 규정 • 354

5-3 기타 • 392

## 5-1. 표시

### ■ 미국

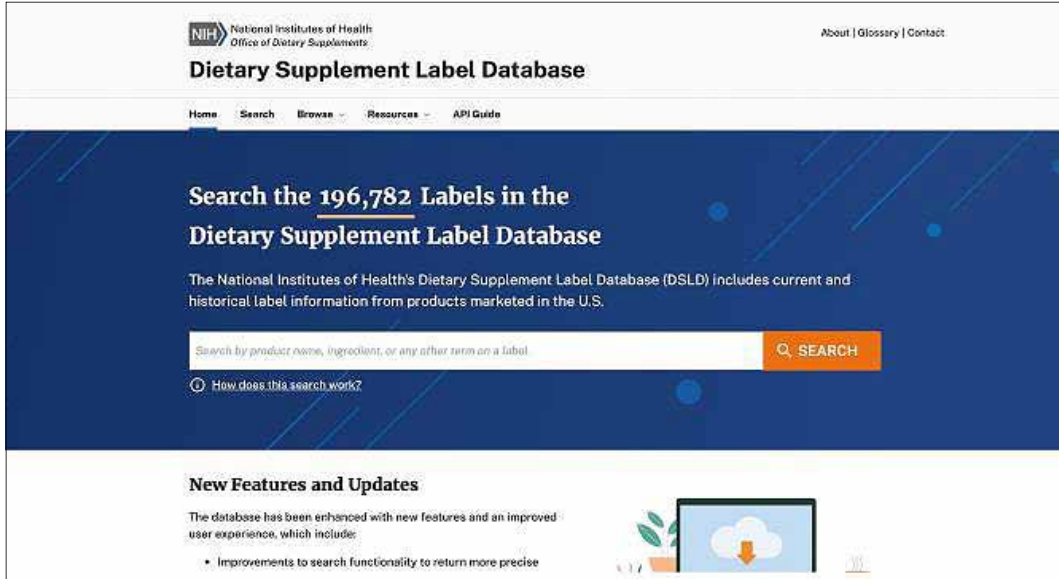
#### [ 식이보충제 라벨 정보 데이터베이스 ]

##### ● 개요

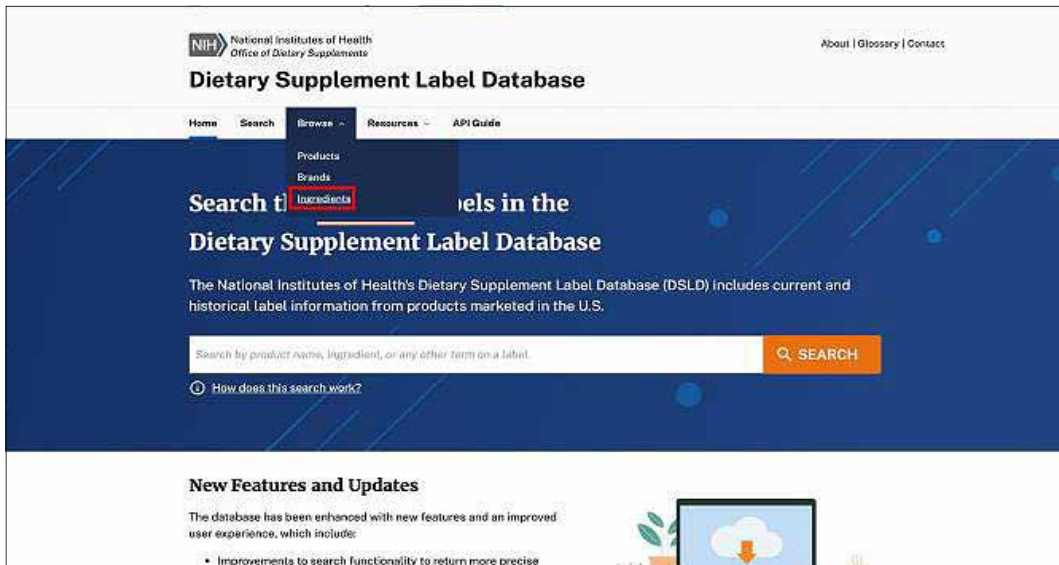
DB명	식이보충제 라벨 정보 데이터베이스 (Dietary Supplement Label Database)
관리기관	국립보건원(NIH)
DB 내용	미국에서 판매되는 식이보충제 라벨의 원료정보와 동의어 정보 (원료 동의어 사전에 더 가까움)
접속 주소	<a href="https://dslid.od.nih.gov/browse-ingredients/by_letter/A/0/20">https://dslid.od.nih.gov/browse-ingredients/by_letter/A/0/20</a>
정보 제공 건수	6,408건('24.11. 기준)

● DB 접속 방법

- 식이보충제 라벨 정보 데이터베이스(Dietary Supplement Label Database) 홈페이지 접속

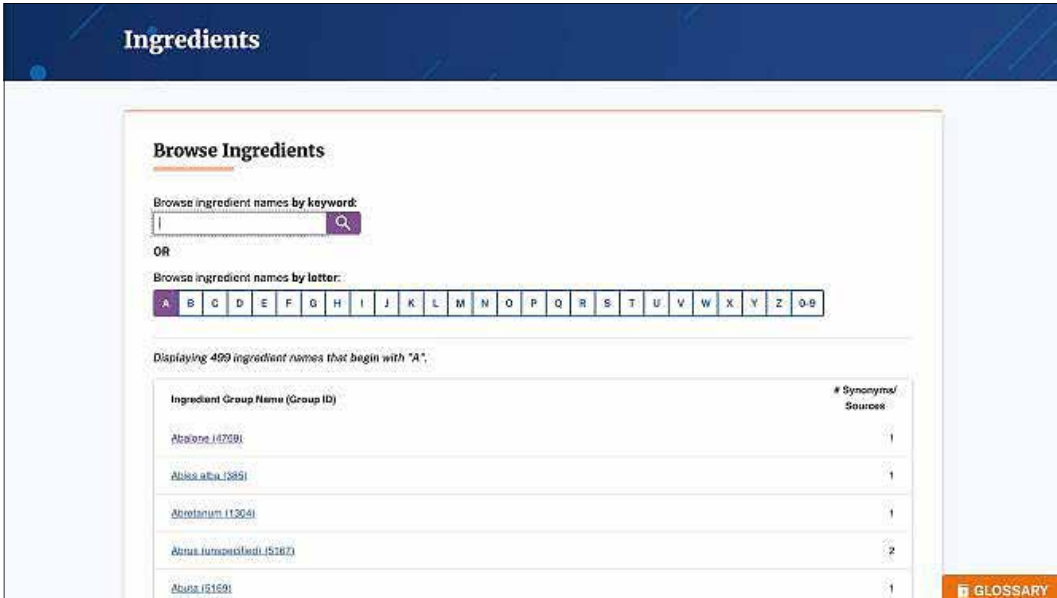


- 식이보충제 라벨 정보 데이터베이스(Dietary Supplement Label Database)에서 '검색(Browse)' → '성분(Ingredients)' 항목 클릭

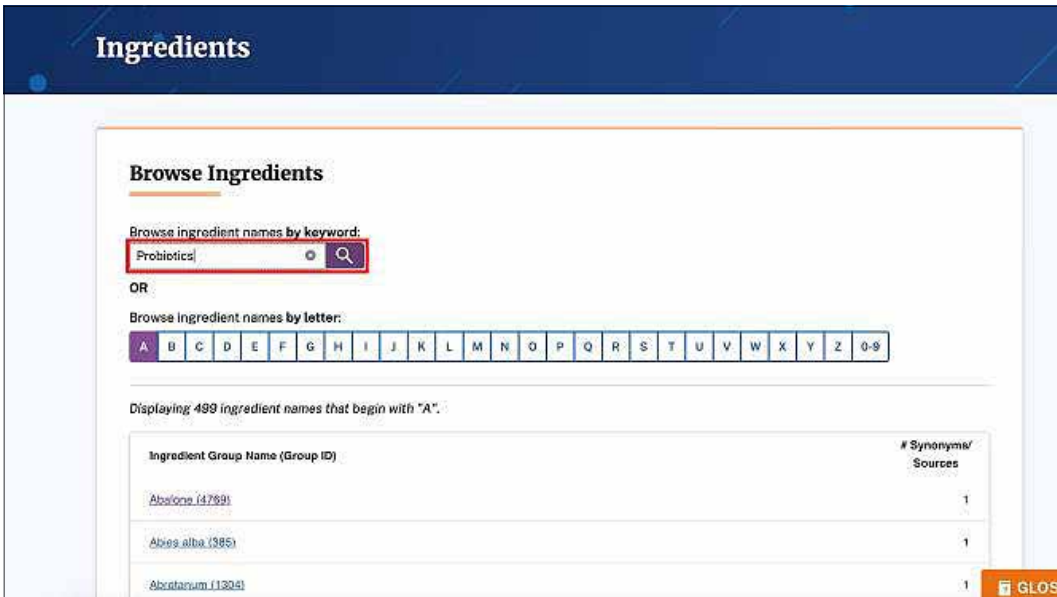


Part 1 .  
5.기 타

- 식이보충제 라벨 정보 데이터베이스(Dietary Supplement Label Database) 접속 완료



- 검색창에 검색하고자 하는 원료의 영문 명칭 입력 후 찾기버튼 클릭



- 정보 제공 범위
- 분류, 연구 자료, 동의어/출처 등 검색 가능

 예시 | 원료명: Probiotics



- ① 분류: 박테리아
- ② 연구 자료: (하이퍼링크) OralProbiotics:AnIntroduction(NCCAM)  
 Probiotics-Clinicaltrials(PubMed)  
 Probiotics-Doseandadministration(PubMed)  
 Probiotics-Adverseeffects(PubMed)  
 Probiotics-Contraindications(PubMed)  
 Probiotics-Mechanismofaction(PubMed)  
 Probiotics-Kinetics(PubMed)  
 Probiotics-Poisoning(PubMed)  
 Probiotics-Dietarysupplementuseinhuman(PubMed)
- ③ 동의어/출처: Cytofloraprobiotics lystate; Fermented probiotic media;  
 Probiotics

## ■ 유럽연합

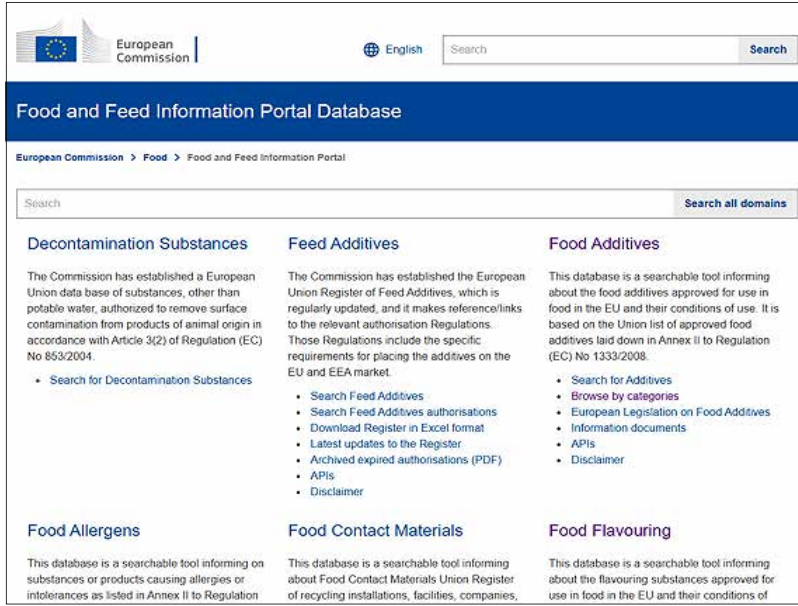
### [ 식품, 사료 정보 포털 데이터베이스(건강강조표시) ]

#### ● 개요

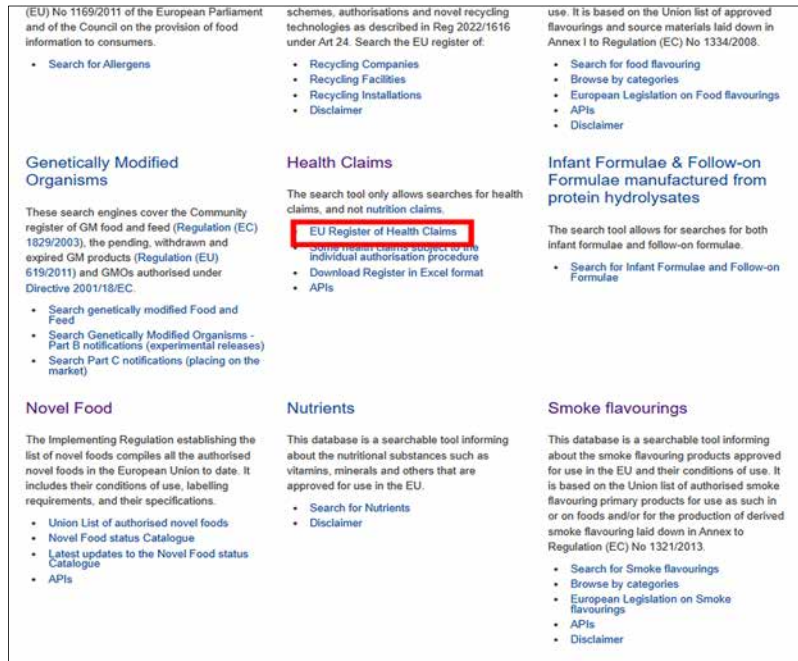
DB명	식품, 사료 정보 포털 데이터베이스(건강강조표시)
관리기관	유럽위원회(EC)/유럽식품안전청(EFSA)
DB 내용	허용 가능한 건강강조표시 정보
접속 주소	<a href="https://food.ec.europa.eu/food-safety/labelling-and-nutrition/nutrition-and-health-claims_en">https://food.ec.europa.eu/food-safety/labelling-and-nutrition/nutrition-and-health-claims_en</a>
정보 제공 건수	2,326건('24.11. 기준)

● DB 접속 방법

○ 유럽위원회의 ‘Food and Feed Information Portal Database’ 접속



○ 화면 하단의 ‘Health Claims’의 ‘EU Register of Health Claims’ 클릭



- 검색하고자 하는 원료명의 건강강조표시 정보 검색(필요 시 왼쪽의 'Search Option'을 사용하여 검색 설정을 할 수 있음)

**SEARCH OPTIONS**

**Claim Status**  
 ▼

**Type of Claim**  
 ▼

**EFSA opinion reference**  
 ▼

**Legislation**  
 ▼

**Protection of proprietary data granted**  
 ▼

**Health Claims (1 matching records)**

**Chitosan**  
 Chitosan contributes to the maintenance of normal blood cholesterol levels Authorised

*Health relationship:* maintenance of normal blood LDL-cholesterol concentrations

- 해당 원료의 상세 정보 확인

Characteristics	
Entry ID	4663
Nutrient substance food or food category	Chitosan
Claim type	Art.13(1)
Status	Authorised
Claim	
Chitosan contributes to the maintenance of normal blood cholesterol levels	
Conditions of use of the claim / Restriction of use / Reasons for non-authorisation	
The claim may be used only for food which provides a daily intake of 3 g of chitosan. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 3 g of chitosan.	
Health relationship	
maintenance of normal blood LDL-cholesterol concentrations	
EFSA Opinion reference	
2011.9(6) 2214	
Legislation	
Addition Commission Regulation (EU) 432/2012	
Health claim for which protection of proprietary data has been granted	
No	

● 정보 제공 범위

- 목록은 표1과 표2로 구분되어 있으며, 표1은 ▲ 승인된 신소재 식품, ▲ 신소재 식품의 사용조건(식품분류 및 최대허용수준), ▲ 표시 요건, ▲ 기타 요건을 명시하고 있으며 표2는 승인된 신소재 식품의 규격을 설명함



예시 | 원료명: 키토산(Chitosan)

<b>①</b>	<b>Characteristics</b>
	Entry ID 4663
	Nutrient substance food or food category Chitosan
	Claim type Art.13(1)
	Status Authorised
<b>②</b>	<b>Claim</b>
	Chitosan contributes to the maintenance of normal blood cholesterol levels
<b>③</b>	<b>Conditions of use of the claim / Restriction of use / Reasons for non- authorisation</b>
	The claim may be used only for food which provides a daily intake of 3 g of chitosan. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 3 g of chitosan.
<b>④</b>	<b>Health relationship</b>
	maintenance of normal blood LDL-cholesterol concentrations
<b>⑤</b>	<b>EFSA Opinion reference</b>
	2011.9(6)2214
<b>⑥</b>	<b>Legislation</b>
	Addition Commission Regulation (EU) 432/2012
<b>⑦</b>	<b>Health claim for which protection of proprietary data has been granted</b>
	No

① 특성

- 항목 ID: 4663
- 영양성분 또는 식품 분류: 키토산
- 강조표시 유형: Art.13(1)
- 상태: 승인됨

② 강조표시

키토산은 정상적인 혈중 콜레스테롤 수치 유지에 기여한다.

③ 강조표시 사용 조건·사용 제한·승인 불가 사유

이 강조표시는 하루 3g의 키토산을 섭취할 수 있는 식품에만 사용될 수 있다. 이 강조표시를 사용하기 위해서는 소비자에게 하루 3g의 키토산 섭취로 유익한 효과를 얻을 수 있다는 정보를 제공해야 한다.

④ 건강 연관성

정상적인 혈중 LDL-콜레스테롤 농도 유지

⑤ EFSA 의견 참조: 2011;9(6):2214

⑥ 관련법규(legislation)

Addition Commission Regulation (EU) 432/2012

⑦ 독점 데이터 보호 부여 건강강조표시 여부: 해당사항 없음

## [ 식품에 사용하는 영양 및 건강강조표시 관련 규정 ]

### ● 개요

DB명	식품에 사용하는 영양 및 건강강조표시 관련 규정 [Regulation (EC) No 1924/2006]
관리기관	유럽위원회(EC)/유럽식품안전청(EFSA)
DB 내용	식품에 사용하는 영양 및 건강강조표시 요건
접속 주소	http://data.europa.eu/eli/reg/2006/1924/2014-12-13
정보 제공 건수	24건('24.11. 기준)

### ● DB 접속 방법

#### ○ 유럽위원회의 'EUR-Lex' 접속

The screenshot displays the EUR-Lex website interface. At the top, there is the European Union logo and the text 'European Union'. Below this, the 'EUR-Lex' logo is prominent, followed by the tagline 'Access to European Union law'. A search bar with the placeholder 'QUICK SEARCH' and a 'SEARCH' button is visible. To the right, there are links for 'My EUR-Lex' and 'English', along with a toggle for 'Experimental features'. A 'LAW IN FOCUS' banner highlights 'The EU and the Istanbul Convention'. The main content area is divided into several sections: 'EU law' (with sub-sections like Treaties, Legal acts, Consolidated texts, etc.), 'EU case-law' (with sub-sections like Case-law, Reports of cases, Directory of case-law), and 'National law and case-law' (with sub-sections like National transposition, National case-law, JURE case-law). There is also an 'Information' section with links to Themes in focus, EUR-Lex developments, Statistics, and the ELI register. On the right side, there is a section for 'Official Journal' with links to OJ L Series and OJ C Series, and search options for 'Find results by document number' and 'Find results by CELEX number'. At the bottom right, there are buttons for 'Measures in solidarity with Ukraine' and 'EU Law Tracker - NEW'.

Part 1 .  
5.기 타

- 검색란에 '1924/2006' 입력 후 클릭

European Union

# EUR-Lex

Access to European Union law

EUROPA > EUR-Lex home > EU law

Q EC 1924/2006 SEARCH

Search tips Need more search options? Use the Advanced search

REDISCOVER EUR-LEX

Word of the week: Equality between women and men

- 해당 규정 클릭

European Union

My EUR-Lex English

# EUR-Lex

Access to European Union law

EUROPA > EUR-Lex home > Search results

MENU (EC) 1925/2006 SEARCH

Search tips Need more search options? Use the Advanced search

Search Results

Search criteria

Search for: (EC) 1925/2006, Search language: English

Save to My searches Create in My RSS alerts Save to My items

Results 1 - 10 of 849 Sort by Relevance

Customise shown information Export

Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods  
OJ L 404, 30/12/2006, p. 26-38 (ES, CS, DA, DE, ET, EL, EN, FR, IT, LV, LT, HU, MT, NL, PL, PT, SK, SL, FI, SV)  
This document has been published in a special edition(s) (BG, RO, HR)

In force

Latest consolidated version: 17/07/2024 Author: European Parliament, Council of the European Union

CELEX number: 32006R1925 Date of document: 20/12/2006

Form: Regulation Number of pages: 13

Refine query

By keyword

In title In text

By year of document

2025 (19)

2024 (162)

2023 (94)

2022 (66)

2021 (71)

See more...

By collection

EU law and case-law (794)

Legal acts (143)

Consolidated texts (227)

Treaties (5)

International agreements (25)

- 해당 규정 화면 아래로 이동하여 부속서의 허용된 영양강조표시 및 건강강조표시 상세조건 확인

ANNEX	
Nutrition claims and conditions applying to them	
<b>LOW ENERGY</b>	A claim that a food is low in energy, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain more than 40 kcal (170 kJ)/100 g for solids or more than 20 kcal (80 kJ)/100 ml for liquids. For table-top sweeteners the limit of 4 kcal (17 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately one teaspoon of sucrose), applies.
<b>ENERGY-REDUCED</b>	A claim that a food is energy-reduced, and any claim likely to have the same meaning for the consumer, may only be made where the energy value is reduced by at least 30 %, with an indication of the characteristic(s) which make(s) the food reduced in its total energy value.
<b>ENERGY-FREE</b>	A claim that a food is energy-free, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain more than 4 kcal (17 kJ)/100 ml. For table-top sweeteners the limit of 0,4 kcal (1,7 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately one teaspoon of sucrose), applies.
<b>LOW-FAT</b>	A claim that a food is low in fat, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 3 g of fat per 100 g for solids or 1,5 g of fat per 100ml for liquids (1,8 g of fat per 100 ml for semi-skimmed milk).
<b>FAT-FREE</b>	A claim that a food is fat-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,5 g of fat per 100 g or 100 ml. However, claims expressed as 'X % fat-free' shall be prohibited.
<b>LOW-SATURATED FAT</b>	A claim that a food is low in saturated fat, and any claim likely to have the same meaning for the consumer, may only be made if the sum of saturated fatty acids and trans-fatty acids in the product does not exceed 1,5 g per100 g for solids or 0,75 g/100 ml for liquids and in either case the sum of saturated fatty acids and trans-fatty acids must not provide more than 10 % of energy.

● 정보 제공 범위

- 영양강조표시 및 건강강조표시 조건에 대하여 명시하고 있으며, 부속서에 각 강조 표시에 대한 설명을 제공



예시 | 부속서 영양강조표시 및 건강강조표시 요건

ANNEX	
Nutrition claims and conditions applying to them	
<b>LOW ENERGY</b>	A claim that a food is low in energy, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain more than 40 kcal (170 kJ)/100 g for solids or more than 20 kcal (80 kJ)/100 ml for liquids. For table-top sweeteners the limit of 4 kcal (17 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately one teaspoon of sucrose), applies.
<b>ENERGY-REDUCED</b>	A claim that a food is energy-reduced, and any claim likely to have the same meaning for the consumer, may only be made where the energy value is reduced by at least 30 %, with an indication of the characteristic(s) which make(s) the food reduced in its total energy value.
<b>ENERGY-FREE</b>	A claim that a food is energy-free, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain more than 4 kcal (17 kJ)/100 ml. For table-top sweeteners the limit of 0,4 kcal (1,7 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately one teaspoon of sucrose), applies.
<b>LOW-FAT</b>	A claim that a food is low in fat, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 3 g of fat per 100 g for solids or 1,5 g of fat per 100ml for liquids (1,8 g of fat per 100 ml for semi-skimmed milk).
<b>FAT-FREE</b>	A claim that a food is fat-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0,5 g of fat per 100 g or 100 ml. However, claims expressed as 'X % fat-free' shall be prohibited.
<b>LOW-SATURATED FAT</b>	A claim that a food is low in saturated fat, and any claim likely to have the same meaning for the consumer, may only be made if the sum of saturated fatty acids and trans-fatty acids in the product does not exceed 1,5 g per100 g for solids or 0,75 g/100 ml for liquids and in either case the sum of saturated fatty acids and trans-fatty acids must not provide more than 10 % of energy.

\* 일부만 발취

원 문	번 역
<p><b>LOW ENERGY</b></p> <p>A claim that a food is low in energy, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain more than 40 kcal (170 kJ)/100 g for solids or more than 20 kcal (80 kJ)/100 ml for liquids. For table-top sweeteners the limit of 4 kcal (17 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately one teaspoon of sucrose), applies.</p>	<p><b>저열량</b></p> <p>식품이 저열량이라는 강조표시, 또는 소비자에게 동일한 의미를 전달할 가능성이 있는 모든 강조표시는 다음 조건을 충족하는 경우에만 허용:</p> <ul style="list-style-type: none"> <li>- 100 g당 40 kcal(170 kJ) 이하의 열량인 고형식품</li> <li>- 100 ml당 20 kcal(80 kJ) 이하의 열량인 액체식품</li> <li>- 테이블용 감미료의 경우, 6 g의 자당(약 1티스푼 자당)과 동일한 감미 효과를 가지는 1회 제공량당 4 kcal(17 kJ)의 제한이 적용됨</li> </ul>
<p><b>ENERGY-REDUCED</b></p> <p>A claim that a food is energy-reduced, and any claim likely to have the same meaning for the consumer, may only be made where the energy value is reduced by at least 30%, with an indication of the characteristic(s) which make(s) the food reduced in its total energy value.</p>	<p><b>열량이 감소된</b></p> <p>열량이 감소된 식품이라는 강조표시, 또는 소비자에게 동일한 의미를 전달할 가능성이 있는 모든 강조표시는 다음 조건을 충족하는 경우에만 허용:</p> <ul style="list-style-type: none"> <li>- 총열량 값이 최소 30% 이상 감소한 경우</li> <li>- 해당 식품의 열량 값 감소를 유발한 특성에 대해 명시해야 함</li> </ul>

## ■ 호주

### [ 의약품(허용 기능표시) 결정 ]

#### ● 개요

<b>DB명</b>	의약품(허용 기능표시) 결정[Therapeutic Goods (Permissible Indications) Determination (No.1)2021]* * 의약품(허용 기능표시) 결정, <a href="https://www.legislation.gov.au/F2021L00056/asmade/text">https://www.legislation.gov.au/F2021L00056/asmade/text</a>
<b>관리기관</b>	연방의료제품청(TGA)
<b>DB내용</b>	의약품에 사용할 수 있는 기능표시 목록을 제공
<b>접속 주소</b>	<a href="https://www.legislation.gov.au/F2021L00056/latest/text">https://www.legislation.gov.au/F2021L00056/latest/text</a>
<b>정보 제공 건수</b>	1,031건('24.11. 기준)

강조표시 유형	합계
일반 건강 또는 신체 부위 관련 효능	175개
뼈 관련 효능	31개
심혈관계 관련된 효능	48개
내분비계 관련 효능	8개
소화기계 관련 효능	142개
면역계 관련 효능	18개
근육 관련 효능	46개
신경계 관련 효능	77개
영양 관련 효능	15개
생식기계 관련 효능	80개
호흡기계 관련 효능	58개
피부 관련 효능	109개
비뇨기계 관련 효능	25개
전통 중국 의학 효능	131개
전통 아유르베다 의학 효능	68개
총 합계	1,031개

## ● DB 접속 방법

### ○ Federal Register of Legislation 접속

The screenshot shows the top of the Federal Register of Legislation website. At the top right, there are links for 'Help and resources', 'Register for My Account', and 'Sign in to My Account'. The main header includes the Australian Government logo and the title 'Federal Register of Legislation'. Below this is a navigation menu with categories: Constitution, Acts, Legislative instruments, Notifiable instruments, Gazettes, Administrative Arrangements, Prerogative instruments, and Norfolk Island. The main content area is titled 'Explore the Federal Register of Legislation' and features a search interface. The search interface includes a 'Search' tab and a 'Browse' tab. There are three buttons for filtering by status: 'All' (highlighted in blue), 'In force', and 'No longer in force'. Below these are three input fields: 'Search for' (with the example text 'example: Legislation Act 2003'), 'Search in' (with a dropdown menu set to 'Name and text'), and 'Search using' (with a dropdown menu set to 'Contains phrase'). There are also checkboxes for 'Filter by collection' with options for Act, Gazette, Legislative instrument, and Notifiable instrument. At the bottom of the search area are 'Search' and 'Advanced search' buttons.

### ○ '검색란(Search for)'에 'Therapeutic Goods(Permissible Indications) Determination (No.1) 2021' 입력 후 'Search' 클릭

This screenshot is identical to the one above but shows the search criteria entered. The 'Search for' field is highlighted with a red box and a circled '1', containing the text 'Therapeutic Goods (Permissible Indications) Determination (No.1)2021'. The 'Search' button is also highlighted with a red box and a circled '2'. The rest of the page layout remains the same.

○ 화면 아래쪽으로 이동하여 해당 문서 클릭

Constitution Acts Legislative instruments Notifiable instruments Gazettes Administrative Arrangements Prerogative instruments Norfolk Island

Home > Search results

Showing 4 results for: Name and text contains phrase "Therapeutic Goods (Permissible Indications) Determination (No.1)2021"

Type: All Status: All  
Collection: All Date: Effective Latest  
Portfolios: All

Search for: Therapeutic Goods (Permissible Indications) Determination (No.1)2021  
Search in: Name and text Search using: Contains phrase

Filters: Type (All) Status (All) Collections (All)  
Year/Number (All) Date (Effective Latest) Portfolio (All)

Sort by: Relevance

Name	Effective date	Collection	Details
Therapeutic Goods (Permissible Indications) Determination (No.1)2021 F2021L00056 Registered: 20/01/2021	20/01/2021		<a href="#">Details</a>

○ ‘돋보기’ 아이콘 클릭 후 검색하고자 하는 기능표시 키워드 입력 후 클릭

View document: Legislative instrument

Table of contents

7 Helps decrease/reduce/relieve symptoms of mild intolerance

8 Helps decrease/reduce/relieve symptoms of mild allergies

9 Helps decrease/reduce/relieve symptoms of seasonal allergies

10 Helps enhance/improve/promote immune system function

11 Helps reduce occurrence of symptoms of food

Search within: immune system

1 (Magnifying glass icon)


2 (Search within dialog box)

- 해당 기능표시 상세 정보 확인

Indications relating to the immune system			
Column 1	Column 2	Column 3	Column 4
10	Helps enhance/improve/promote immune system function	Scientific or Traditional	Product presentation must not imply or refer to serious immunological diseases.

● 정보 제공 범위

- 품목(번호), 기능표시 설명, 근거 유형, 기타요건 등의 정보를 제공하고 있으며 PDF, Word 형식으로 다운로드 가능
- 각 기능표시의 근거 유형은 ▲ 과학적 증거 ▲ 전통적 증거 ▲ 전통중국 의학에 기반한 증거 ▲ 전통 아유르베다 의학에 기반한 증거로 총 4가지 유형으로 분류되며 각 기능표시의 사용에 필요한 근거 유형을 명시하고 있음

 **예시** | 기능표시 문구: 면역체계를 강화/개선/촉진하는데 도움을 준다.

Indications relating to the immune system			
Column 1	Column 2	Column 3	Column 4
10 <b>①</b>	Helps enhance/improve/promote immune system function <b>②</b>	Scientific or Traditional <b>③</b>	Product presentation must not imply or refer to serious immunological diseases. <b>④</b>

- ① 품목: 10
- ② 기능표시: 면역체계를 강화/개선/촉진하는데 도움을 준다.
- ③ 근거유형: 과학적 또는 전통적
- ④ 기타요건: 제품 설명에서 심각한 면역학적 질환을 암시하거나 이를 언급해서는 안 됨

## 5-2. 규정

### ■ 유럽연합

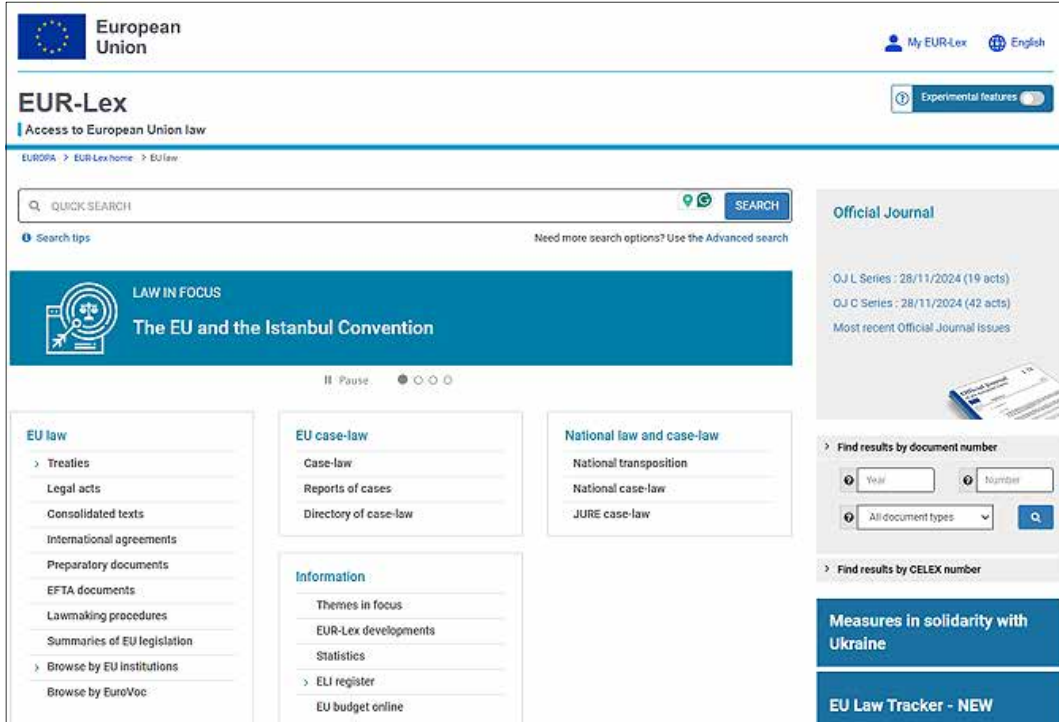
#### [ 식품보충제와 관련된 회원국 법률의 조화를 위한 지침 ]

##### ● 개요

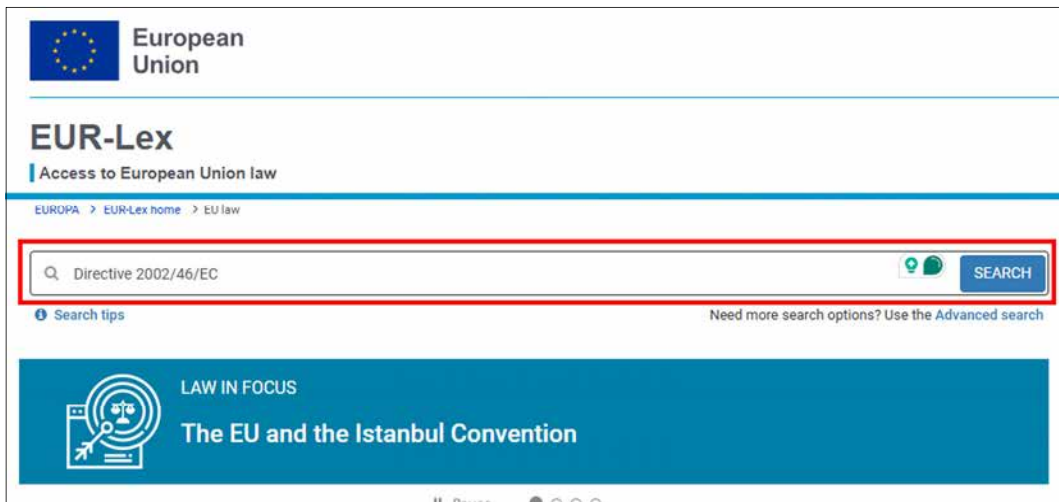
DB명	식품보충제와 관련된 회원국 법률의 조화를 위한 지침 (Directive 2002/46/EC)
관리기관	유럽위원회(EC)/유럽식품안전청(EFSA)
DB 내용	부속서 I·II에서 식품보충제에 첨가 가능한 비타민 및 미네랄 목록 제공
접속 주소	<a href="https://eur-lex.europa.eu/eli/dir/2002/46/oj">https://eur-lex.europa.eu/eli/dir/2002/46/oj</a>
정보 제공 건수	140건('24.11. 기준) - 부속서 I (28건) 부속서 II (112건)

● DB 접속 방법

○ 유럽위원회의 'EUR-Lex' 접속



○ 검색란에 'Directive 2002/46/EC' 입력 후 클릭



Part 1 .  
5.기 타

○ 해당 지침 클릭

Search Results

Search criteria

Search for: Directive 2002/46/EC, Search language: English

Save to My searches Create in My alerts (RSS feeds) Save to My items

Results 1 - 10 of 664 Sort by Relevance

Customise shown information Export

**Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (Text with EEA relevance)**

OJ L 183, 12/07/2002, p. 51-57 (ES, DA, DE, EL, EN, FR, IT, NL, PT, FI, SV)  
 This document has been published in a special edition(s) ( CS, ET, LV, LT, HU, MT, PL, SK, SL, BG, RO, HR)

In force

Latest consolidated version: 17/07/2024

Author: European Parliament, Council of the European Union

CELEX number: 32002L0046

Date of document: 10/06/2002

Form: Directive

Number of pages: 7

○ 해당 지침 화면 아래로 이동하여 부속서 I·II의 식품보충제 허용 원료 확인

(2) OJ C 14, 16.1.2001, p. 42.	Prophorol (mg)
(3) Opinion of the European Parliament of 14 February 2001 (OJ C 2/6, 1.10.2001, p. 126), Council Common Position of 3 December 2001 (OJ C 90 C, 16.4.2002, p. 1) and Decision of the European Parliament of 13 March 2002, Council Decision of 30 May 2002.	<b>ANNEX II</b>
(4) OJ L 109, 6.5.2000, p. 29.	Vitamin and mineral substances which may be used in the manufacture of food supplements
(5) OJ L 276, 6.10.1990, p. 40.	A. Vitamins
(6) OJ L 184, 17.7.1999, p. 23.	1. VITAMIN A
(7) OJ L 311, 28.11.2001, p. 67.	(a) retinol
(8) OJ L 31, 1.2.2002, p. 1.	(b) retinyl acetate
<b>ANNEX I</b>	(c) retinyl palmitate
Vitamins and minerals which may be used in the manufacture of food supplements	(d) beta-carotene
1. Vitamins	2. VITAMIN D
Vitamin A (µg RE)	(a) cholecalciferol
Vitamin D (µg)	(b) ergocalciferol
Vitamin E (mg α-TE)	3. VITAMIN E
Vitamin K (µg)	(a) D-alpha-tocopherol
Vitamin B1 (mg)	(b) DL-alpha-tocopherol
Vitamin B2 (mg)	(c) D-alpha-tocopheryl acetate
Niacin (mg NE)	(d) DL-alpha-tocopheryl acetate
Pantothenic acid (mg)	(e) D-alpha-tocopheryl acid succinate
Vitamin B6 (mg)	4. VITAMIN K
Folic acid (µg)	(a) phyloquinone (phytonadione)
Vitamin B12 (µg)	5. VITAMIN B1
	(a) thiamin hydrochloride
	(b) thiamin mononitrate
	6. VITAMIN B2
	(a) riboflavin
	(b) riboflavin 5'-phosphate, sodium

● 정보 제공 범위

- 식품보충제 제조에 사용될 수 있는 비타민 및 미네랄



예시 | 부속서 I

ANNEX I
Vitamins and minerals which may be used in the manufacture of food supplements
1. Vitamins
Vitamin A ( $\mu\text{g RE}$ )
Vitamin D ( $\mu\text{g}$ )
Vitamin E (mg $\alpha$ -TE)
Vitamin K ( $\mu\text{g}$ )
Vitamin B1 (mg)
Vitamin B2 (mg)
Niacin (mg NE)
Pantothenic acid (mg)
Vitamin B6 (mg)
Folic acid ( $\mu\text{g}$ )
Vitamin B12 ( $\mu\text{g}$ )
Biotin ( $\mu\text{g}$ )
Vitamin C (mg)
2. Minerals
Calcium (mg)
Magnesium (mg)
Iron (mg)
Copper ( $\mu\text{g}$ )
Iodine ( $\mu\text{g}$ )
Zinc (mg)
Manganese (mg)
Sodium (mg)
Potassium (mg)
Selenium ( $\mu\text{g}$ )
Chromium ( $\mu\text{g}$ )
Molybdenum ( $\mu\text{g}$ )
Fluoride (mg)
Chloride (mg)
Phosphorus (mg)

부속서 I  
식품보충제 제조에 사용될 수 있는  
비타민 및 미네랄

1.비타민
비타민 A ( $\mu\text{g RE}$ )
비타민 D ( $\mu\text{g}$ )
비타민 E (mg $\alpha$ -TE)
비타민 K ( $\mu\text{g}$ )
비타민 B <sub>1</sub> (mg)
비타민 B <sub>2</sub> (mg)
나이아신 (mg NE)
판토텐산 (mg)
비타민 B <sub>6</sub> (mg)
엽산 ( $\mu\text{g}$ )
비타민 B <sub>12</sub> ( $\mu\text{g}$ )
비오틴 ( $\mu\text{g}$ )
비타민 C (mg)
2.미네랄
칼슘 (mg)
마그네슘 (mg)
철분 (mg)
구리 ( $\mu\text{g}$ )
요오드 ( $\mu\text{g}$ )
아연 (mg)
망간 (mg)
나트륨 (mg)
칼륨 (mg)
셀레늄 ( $\mu\text{g}$ )
크롬 ( $\mu\text{g}$ )
몰리브덴 ( $\mu\text{g}$ )
플루오르화물 (mg)
염화물 (mg)
인 (mg)

## [ 신소재 식품에 관한 규정 ]

### ● 개요

DB명	신소재 식품에 관한 규정[Regulation (EU) No 2015/2283]
관리기관	유럽위원회(EC)/유럽식품안전청(EFSA)
DB 내용	신소재 식품의 정의 및 범위, 시장 진입 및 허가 절차 등에 관한 규정 제공
접속 주소	http://data.europa.eu/eli/reg/2015/2283/oj
정보 제공 건수	-

### ● DB 접속 방법

#### ○ 유럽위원회의 'EUR-Lex' 접속

The screenshot displays the EUR-Lex website interface. At the top, there is the European Union logo and the text 'European Union'. Below this, the 'EUR-Lex' logo is prominent, with the tagline 'Access to European Union law'. A search bar is located in the center, with a 'SEARCH' button. To the right, there are links for 'My EUR-Lex' and 'English', along with an 'Experimental features' toggle. A 'LAW IN FOCUS' banner highlights 'The EU and the Istanbul Convention'. The main content area is divided into three columns: 'EU law' (with sub-links like Treaties, Legal acts, Consolidated texts, etc.), 'EU case-law' (with sub-links like Case-law, Reports of cases, Directory of case-law), and 'National law and case-law' (with sub-links like National transposition, National case-law, JURE case-law). On the right side, there is an 'Official Journal' section with links to OJ L Series and OJ C Series, and a search box for 'Find results by document number'. At the bottom right, there are buttons for 'Measures in solidarity with Ukraine' and 'EU Law Tracker - NEW'.

- 검색란에 'Regulation (EU) No 2015/2283' 입력 후 클릭

European Union

## EUR-Lex

Access to European Union law

EUROPA > EUR-Lex home > EU law

Regulation (EU) No 2015/2283 SEARCH

Search tips Need more search options? Use the Advanced search

REDISCOVER EUR-LEX

Word of the week: Equality between women and men

Pause

- 해당 규정 클릭

Search Results

Search criteria

Search for: Regulation (EU) No 2015/2283, Search language: English

Save to My searches Create in My RSS alerts Save to My Items

Results 1 - 10 of 520 Sort by Relevance

Customise shown information Export

Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (Text with EEA relevance)

OJ L 327, 11/12/2015, p. 1–22 (BG, ES, CS, DA, DE, ET, EL, EN, FR, GA, HR, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV)

In force

Latest consolidated version: 27/03/2021

CELEX number: 32015R2283

Form: Regulation

Author: European Parliament, Council of the European Union

Date of document: 25/11/2015; Date of adoption

Number of pages: 22

○ 해당 규정 확인

<p style="text-align: center;">I</p> <p style="text-align: center;"><i>(Legislative acts)</i></p> <p style="text-align: center;"><b>REGULATIONS</b></p> <p style="text-align: center;"><b>REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL</b> <b>of 25 November 2015</b> <b>on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001</b></p> <p style="text-align: center;"><i>(Text with EEA relevance)</i></p> <p>THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,</p> <p>Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,</p> <p>Having regard to the proposal from the European Commission,</p> <p>After transmission of the draft legislative act to the national parliaments,</p> <p>Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,</p> <p>Acting in accordance with the ordinary legislative procedure <sup>(2)</sup>,</p> <p>Whereas:</p> <p>(1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests. Differences between national laws concerning the safety assessment and authorisation of novel foods may hinder the free movement of such food, thereby creating legal uncertainty and unfair conditions of competition.</p> <p>(2) A high level of protection of human health and of consumers' interests and the effective functioning of the internal market needs to be assured in the pursuit of Union food policies, whilst ensuring transparency. A high level of protection and improvement of the quality of the environment are among the objectives of the Union as established in the Treaty on European Union (TEU). It is important that all relevant Union legislation, including this Regulation, take those objectives into account.</p> <p>(3) Union legislation applicable to food is also applicable to novel foods placed on the market within the Union, including novel foods imported from third countries.</p>
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● 정보 제공 범위

- 해당 규정에서는 ▲ 신소재 식품의 범위 및 정의(제1장), ▲ 신소재 식품 시장 진입 요건(제2장), ▲ 신소재 식품 허가 절차(제3장) 등에 관한 내용을 다루고 있음



예시 | 제2장 유럽연합 내 신소재 식품 시장 진입 요건\*

CHAPTER II

REQUIREMENTS FOR PLACING NOVEL FOODS ON THE MARKET WITHIN THE UNION

Article 6

**Union list of authorised novel foods**

1. The Commission shall establish and update a Union list of novel foods authorised to be placed on the market within the Union in accordance with Articles 7, 8 and 9 (‘the Union list’).

2. Only novel foods authorised and included in the Union list may be placed on the market within the Union as such, or used in or on foods, in accordance with the conditions of use and the labelling requirements specified therein.

Article 7

**General conditions for inclusion of novel foods in the Union list**

The Commission shall only authorise and include a novel food in the Union list if it complies with the following conditions:

- (a) the food does not, on the basis of the scientific evidence available, pose a safety risk to human health;
- (b) the food’s intended use does not mislead the consumer, especially when the food is intended to replace another food and there is a significant change in the nutritional value;
- (c) where the food is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

\* 일부내용 발췌

조 항	내 용
제6조 승인된 신소재 식품 목록	<ol style="list-style-type: none"> <li>1. 집행위원회는 제7조, 제8조 및 제9조에 따라 유럽연합 내 시장 출시 승인된 신소재 식품 목록(Union List)을 수립하고 업데이트한다.</li> <li>2. 해당 목록에 승인 및 등재된 신소재 식품에 한해 유럽연합 내에서 단독으로 시장에 출시되거나 식품에 사용될 수 있으며, 이는 해당 목록에 명시된 사용조건과 라벨링 요건을 준수해야 한다.</li> </ol>
제7조 신소재 식품 목록 등재를 위한 일반 조건	<p>집행위원회는 다음 조건을 충족하는 경우에만 신소재 식품을 연합 목록에 승인 및 등재한다.</p> <ol style="list-style-type: none"> <li>(a) 현존하는 과학적 증거를 바탕으로 해당 식품이 인체 건강에 안전상의 위험을 초래하지 않을 것</li> <li>(b) 해당 식품의 의도된 사용이 소비자를 오도하지 않을 것, 특히 기존 식품을 대체하는 경우 영양가 측면서 중대한 변화가 있을 때 소비자가 혼동하지 않도록 할 것</li> <li>(c) 해당 식품이 기존 식품을 대체하려는 경우, 일반적인 섭취 시 소비자에게 영양적으로 불리하지 않도록 기존 식품과 본질적으로 다르지 않을 것</li> </ol>



## 예시 | 제3장 신소재 식품 허가 절차\*

<p style="text-align: center;">CHAPTER III</p> <p style="text-align: center;">AUTHORISATION PROCEDURES FOR A NOVEL FOOD</p> <p style="text-align: center;">SECTION I</p> <p style="text-align: center;"><i>General rules</i></p> <p style="text-align: center;"><i>Article 10</i></p> <p><b>Procedure for authorising the placing on the market within the Union of a novel food and updating the Union list</b></p> <p>1. The procedure for authorising the placing on the market within the Union of a novel food and updating of the Union list provided for in Article 9 shall start either on the Commission's initiative or following an application to the Commission by an applicant. The Commission shall make the application available to the Member States without delay. The Commission shall make the summary of the application, based on the information referred to in points (a), (b) and (e) of paragraph 2 of this Article, publicly available.</p> <p>2. The application for an authorisation shall include:</p> <ul style="list-style-type: none"><li>(a) the name and address of the applicant;</li><li>(b) the name and description of the novel food;</li><li>(c) the description of the production process(es);</li><li>(d) the detailed composition of the novel food;</li><li>(e) scientific evidence demonstrating that the novel food does not pose a safety risk to human health;</li><li>(f) where appropriate, the analysis method(s);</li><li>(g) a proposal for the conditions of intended use and for specific labelling requirements which do not mislead the consumer or a verifiable justification why those elements are not necessary.</li></ul> <p>3. Upon request by the Commission, the European Food Safety Authority ('the Authority') shall give its opinion as to whether the update is liable to have an effect on human health.</p> <p>4. When test methods are applied to engineered nanomaterials as referred to in points (a) (viii) and (ix) of Article 3(2), an explanation shall be provided by the applicants of their scientific appropriateness for nanomaterials and, where applicable, of the technical adaptations or adjustments that have been made in order to respond to the specific characteristics of those materials.</p> <p>5. The procedure for authorising the placing on the market within the Union of a novel food and updating the Union list as provided for in Article 9 shall end with the adoption of an implementing act in accordance with Article 12.</p> <p>6. By way of derogation from paragraph 5, the Commission may terminate the procedure at any stage, and decide not to proceed with an update, where it considers that such an update is not justified.</p> <p>In such cases, where applicable, the Commission shall take account of the views of Member States, the Authority's opinion and any other legitimate factors relevant to the update under consideration.</p> <p>The Commission shall inform the applicant and all Member States directly of the reasons for not considering the update to be justified. The Commission shall make the list of such applications publicly available.</p> <p>7. The applicant may withdraw its application at any time, thereby terminating the procedure.</p>
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\* 일부내용 발췌

조 항	내 용
<p>제1절 일반규칙</p> <p>제10조 유럽연합 내 신소재 식품 시장 진입 허가 절차 및 목록 업데이트</p>	<ol style="list-style-type: none"> <li>1. 제9조에 규정된 신소재 식품의 유럽연합 내 시장 출시 승인 및 목록 업데이트 절차는 집행위원회의 주도 또는 신청자의 집행위원회 신청을 통해 접수한다. 집행위원회는 신청서를 지체 없이 회원국에 제공해야 하며, 본 조 제2항 (a), (b), (e) 항목에 명시된 정보를 바탕으로 신청 요약본을 대중에 공개해야 한다.</li> <li>2. 허가 신청서에는 다음 항목을 포함한다: <ol style="list-style-type: none"> <li>(a) 신청자의 성명과 주소</li> <li>(b) 신소재 식품 명칭과 설명</li> <li>(c) 생산 공정의 설명</li> <li>(d) 신소재 식품의 상세 구성</li> <li>(e) 해당 식품이 인체 건강에 안전상의 위험을 초래하지 않음을 입증하는 과학적 증거</li> <li>(f) 필요한 경우, 분석 방법</li> <li>(g) 의도된 사용 조건과 소비자를 오도하지 않는 특정 라벨링 요구 사항 제안, 또는 이러한 요소가 필요하지 않다는 검증 가능한 증명</li> </ol> </li> <li>3. 집행위원회의 요청 시, 유럽식품안전청은 해당 업데이트가 인체 건강에 미치는 영향을 평가하는 의견을 제시해야 한다.</li> <li>4. 제3조 제2항 (a) (viii) 및 (ix)에서 언급된 엔지니어링된 나노물질에 대해 시험 방법이 적용될 경우, 신청자는 해당 나노물질에 대한 과학적 적절성과 필요한 기술적 수정 및 조정 사항을 설명해야 한다.</li> <li>5. 제9조에 규정된 신소재 시장 진입 허가 및 목록 업데이트 절차는 제12조에 따른 시행 행위의 채택으로 신청 마무리된다.</li> <li>6. 제5항의 예외로, 집행위원회는 절차의 어느 단계에서든 업데이트가 정당하지 않다고 판단할 경우 절차를 종료할 수 있다. 이 경우 집행위원회는 회원국의 의견, 유럽식품안전청의 의견 및 관련 정당한 요소를 고려해야 하며, 신청자와 모든 회원국에 해당 업데이트가 정당하지 않다고 판단한 이유를 직접 통보해야 한다. 또한, 이러한 신청 목록을 대중에게 공개해야 한다.</li> <li>7. 신청자는 언제든지 신청을 철회하여 절차를 종료할 수 있다.</li> </ol>



## 예시 | 제12조 신소재 식품 허가 절차\*

<i>Article 12</i>	
Authorisation of a novel food and updates of the Union list	
1.	<p>Within seven months from the date of publication of the Authority's opinion, the Commission shall submit to the committee referred to in Article 30(1) a draft implementing act authorising the placing on the market within the Union of a novel food and updating the Union list, taking into account the following:</p> <p>(a) the conditions provided for in points (a) and (b) of Article 7 and, where applicable, in point (c) of that Article;</p> <p>(b) any relevant provision of Union law, including the precautionary principle as referred to in Article 7 of Regulation (EC) No 178/2002;</p> <p>(c) the Authority's opinion;</p> <p>(d) any other legitimate factors relevant to the application under consideration.</p> <p>That implementing act shall be adopted in accordance with the examination procedure referred to in Article 30(3).</p>
2.	<p>Where the Commission has not requested an opinion from the Authority in accordance with Article 10(3), the seven-month period provided for in paragraph 1 of this Article shall start from the date on which a valid application is received by the Commission in accordance with Article 10(1).</p>

\* 일부내용 발췌

조 항	내 용
제12조 신소재 식품 허가 및 목록 업데이트	<ol style="list-style-type: none"> <li>1. 유럽식품안전청의 의견이 공표된 날로부터 7개월 이내에, 집행위원회는 제30조 제1항에 언급된 위원회에 연합 내 신규 식품의 시장 진입 승인 및 목록 업데이트를 위한 시행 행위 초안을 제출해야 한다. 이 과정에서 다음 사항을 고려해야 한다:             <ol style="list-style-type: none"> <li>(a) 제7조 (a) 및 (b)항, 그리고 해당하는 경우 (c)항에 규정된 조건</li> <li>(b) 연합 법률의 관련 조항, 특히 (EC) No 178/2002 규정 제7조에 언급된 예방 원칙</li> <li>(c) 유럽식품안전청의 의견</li> <li>(d) 검토 중인 신청 관련 기타 정당한 요소</li> </ol> <p>해당 시행 행위는 제30조 제3항에 규정된 심사절차에 따라 채택되어야 한다.</p> </li> <li>2. 집행위원회가 제10조 제3항에 의거하여 유럽식품안전청의 의견을 요청하지 않은 경우, 본 조 제1항에서 규정된 7개월 기간은 제10조 제1항에 따라 집행위원회가 유효한 신청서를 접수한 날부터 시작한다.</li> </ol>

## 인도

### [ 식품 안전 및 기준(유기농 식품) 규정 ]

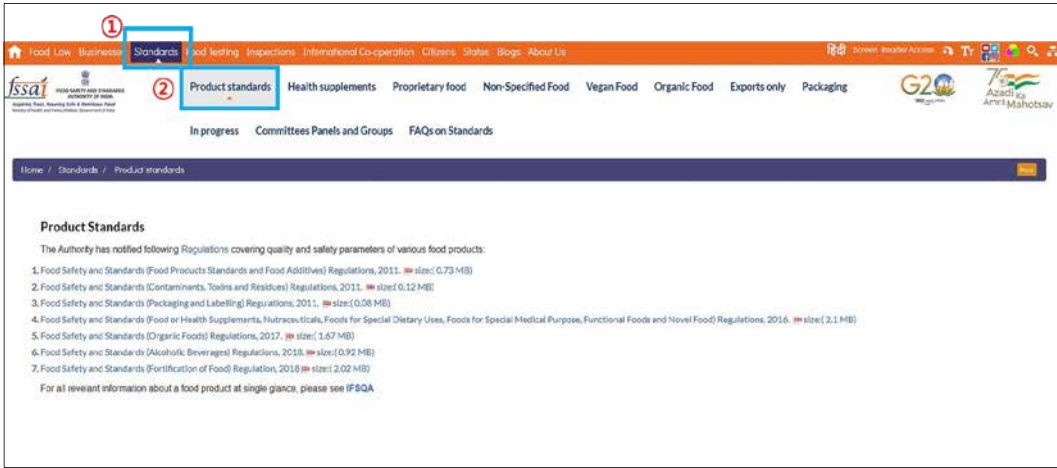
#### ● 개요

DB명	유기농 식품 규정
관리기관	식품안전기준청(FSSAI)
DB 내용	유기농 식품 규정
접속 주소	<a href="https://fssai.gov.in/cms/product-standards.php">https://fssai.gov.in/cms/product-standards.php</a>
정보 제공 건수	-

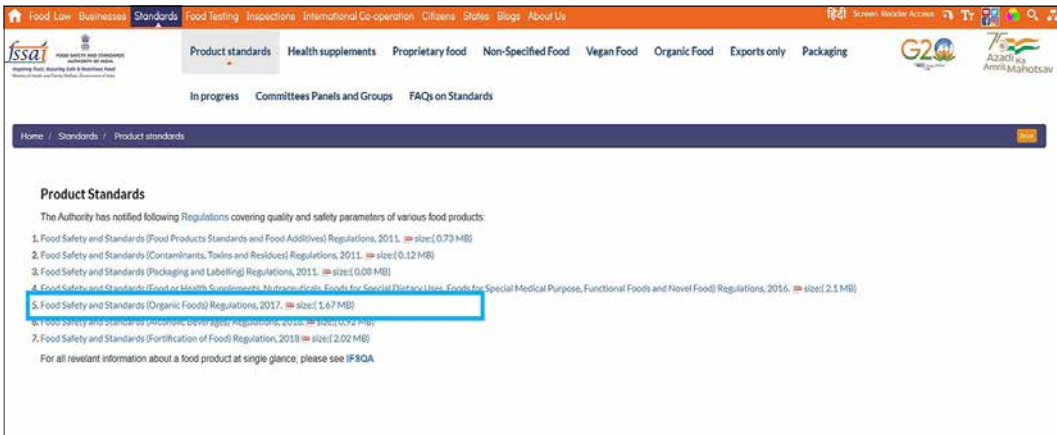
#### ● DB 접속 방법

#### ○ Food Safety and Standards Authority of India 접속

○ 상단의 'Standards' 클릭 후 'Product standards' 클릭




○ 목록 중 'Food Safety and Standards(Organic Foods) Regulations, 2017' 클릭



Part 1 .  
5.기 타

- 해당 규정 확인(웹사이트 오류가 빈번하여 해당 파일 다운로드 권장)

रजिस्ट्री सं० डी० एल०-33004/99	REGD. NO. D. L.-33004/99
 <b>भारत का राजपत्र</b> <b>The Gazette of India</b>	
असाधारण EXTRAORDINARY भाग III—खण्ड 4 PART III—Section 4 अधिकार से प्रकाशित PUBLISHED BY AUTHORITY	
सं. 04]	नई दिल्ली, मंगलवार, जनवरी 2, 2018/पौष 12, 1939
No. 04]	NEW DELHI, TUESDAY, JANUARY 2, 2018/PAUSHA 12, 1939
<b>स्वास्थ्य और परिवार कल्याण मंत्रालय</b> <b>(भारतीय खाद्य सुरक्षा और मानक प्राधिकरण)</b> <b>अधिसूचना</b> नई दिल्ली, 29 दिसम्बर, 2017	
<p><b>स. सीपीबी/03/स्टैंडर्ड्स/एफएसएसआई/2016.</b>—प्रारूप खाद्य सुरक्षा और मानक (जैव खाद्य) विनियम, 2017 जो भारत के राजपत्र, असाधारण, भाग III, खंड 4 में भारतीय खाद्य सुरक्षा और मानक प्राधिकरण की अधिसूचना सं. सीपीबी/03/स्टैंडर्ड्स/एफएसएसआई/2016, दिनांक 19 जून, 2017 द्वारा खाद्य सुरक्षा और मानक अधिनियम, 2006 (2006 का 34) की धारा 92 की उपधारा (1) की अपेक्षानुसार प्रकाशित किये गए थे जिनमें ऐसे व्यक्तियों से जिनकी उनसे प्रभावित होने की संभावना है, उस तारीख से जिसको उक्त प्रारूप विनियमों को अन्तर्विष्ट करने वाले राजपत्र की प्रतियाँ जनता को उपलब्ध कराई गई थीं, तीस दिन की अवधि कि समाप्ति के पहले आक्षेप और सुझाव आमंत्रित किये गए थे;</p> <p>और उक्त राजपत्र की प्रतियाँ जनता को 22 जून, 2017 को उपलब्ध करा दी गई थीं;</p> <p>और उक्त प्रारूप विनियम के सम्बन्ध में प्राप्त आक्षेपों और सुझावों पर भारतीय खाद्य सुरक्षा और मानक प्राधिकरण द्वारा विचार कर लिया गया है;</p>	

● 정보 제공 범위

- 유기농 식품 규정에 대한 내용을 4~5페이지에 영문으로 제공



예시 | 원료명: 유기농 식품 라벨링, 인증, 수입 및 상호 인정

<p style="text-align: center;"><b>CHAPTER II</b> <b>Organic Food Labelling and Certification</b></p> <p><b>3. Manufacture, pack, sell etc., of organic food.</b>— No person shall manufacture, pack, sell, offer for sale, market or otherwise distribute or import any organic food unless they comply with the requirements laid down under these regulations.</p> <p><b>4. Applicability of the systems.</b>— (1) The organic food offered or promoted for sale shall also comply with all the applicable provisions of one of the following systems, namely:—</p> <ul style="list-style-type: none"><li>(i) National Programme for Organic Production (NPOP);</li><li>(ii) Participatory Guarantee System for India (PGS-India).</li><li>(iii) Any other system or standards as may be notified by the Food Authority from time to time.</li></ul> <p>(2) The Organic food which is marketed through direct sales by the small original producer or producer organisation, as determined by the Food Authority from time to time, to the end consumer shall be exempted from the provisions of the systems referred in sub-regulation (1).</p> <p><b>5. Labelling.</b>— (1) Labelling on the package of organic food shall convey full and accurate information on the organic status of the product. Such product may carry a certification or quality assurance mark of one of the systems mentioned in regulation 4 in addition to the Food Safety and Standard Authority of India's organic logo.</p> <p>(2) All organic foods shall comply with the packaging and labelling requirements specified under the Food Safety and Standards (Packaging and Labelling) Regulations, 2011 in addition to the labelling requirements under one of the applicable systems mentioned in regulation 4.</p> <p><b>6. Traceability.</b>— shall be established upto the producer level as applicable under the systems mentioned in regulation 4 and it shall include any other requirements prescribed by the Food Authority to maintain the organic integrity of the food product.</p> <p><b>7. Requirement to comply with the provision of the other regulations made under the Act.</b>— Without prejudice to the provisions of these regulations, all organic food shall comply with the relevant provisions, as applicable, under the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011. The organic food shall also comply with relevant provisions, as applicable under the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011 except for residues of insecticides for which the maximum limits shall be 5% of the maximum limits prescribed or Level of Quantification (LoQ) whichever is higher.</p> <p><b>8. Display.</b>— The seller of organic food either exclusively or as part of his retail merchandise shall display such food in a manner distinguishable from the display of non-organic food.</p> <p style="text-align: center;"><b>CHAPTER III</b> <b>Imports and Reciprocity</b></p> <p><b>9. Import of organic food.</b>— (1) Organic food imports under bilateral or multilateral agreements on the basis of equivalence of standards between National Programme for Organic Production and the organic standards of the respective exporting countries shall not be required to be re-certified on import to India subject to their compliance with the provisions of the Act, the rules and regulation made there under.</p> <p>(2) The organic food consignments referred to in sub-regulation.—(1) shall be accompanied by a transaction certificate issued by an Accredited Certification Body covered under the terms of the equivalence agreement.</p>
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유기농 식품 라벨링 및 인증	
1. 유기농 식품 제조, 포장, 판매 등의 조건	- 모든 유기농 식품은 규정에 따라야 함
2. 적용 시스템	- 다음 시스템 중 하나를 준수해야 함 1. 국가 유기농 생산 프로그램 2. 인도의 참여 보증 시스템 3. 식품 당국이 수시로 공지하는 기타 시스템 - 소규모 생산자 또는 생산자 조직이 최종소비자에게 직접 판매하는 경우 일부 조항에서 면제 가능
3. 라벨링	- 유기농 식품 포장에는 제품의 유기 상태를 완전하고 정확하게 표시해야 함 - 규정에 언급된 시스템 인증 또는 품질 보증 마크를 포함할 수 있음 - 식품안전기준청의 유기농 로고와 포장 및 라벨링 요구사항을 준수해야 함
4. 이력추적	- 생산자 수준까지의 이력 추적이 가능해야 하며 유기농 식품의 무결성을 보장하기 위한 기타 요구사항을 포함함
5. 기타 규정 준수	- 모든 유기농 식품은 식품 안전 및 기준(식품 기준 및 식품 첨가물) 규정 2011과 식품 안전 및 기준(오염물질, 독소 및 잔류물질) 2011 규정을 준수해야함-단, 살충제 잔류물의 경우 최대 허용 한도의 5% 또는 검출 한계(LoQ) 중 더 높은 기준을 적용
6. 표시 방식	- 유기농 식품은 비유기농 식품과 명확히 구분된 방식으로 표시함
수입 및 상호 인정	
1. 유기농 식품의 수입 조건	- 국가 유기농 생산 프로그램과 수출국의 유기농 기준 간 동등성 협정에 따른 경우, 재인증 필요 없음 - 단, 관련 법 및 규정을 준수해야 함
2. 인증서 동반 조건	- 동등성 협정에 포함된 인증 기관에서 발행한 거래 인증서가 첨부되어야 함

## [ 식품 안전 및 기준(알코올 음료) 규정 ]

### ● 개요

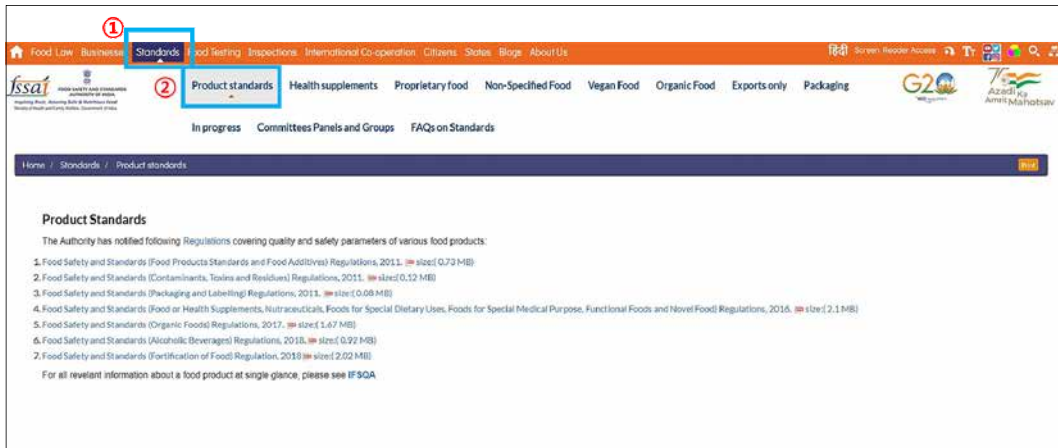
DB명	식품 안전 및 기준(알코올 음료) 규정
관리기관	식품안전기준청(FSSAI)
DB 내용	주류별 성분 요건 정보 제공
접속 주소	<a href="https://fssai.gov.in/cms/product-standards.php">https://fssai.gov.in/cms/product-standards.php</a>
정보 제공 건수	-

### ● DB 접속 방법

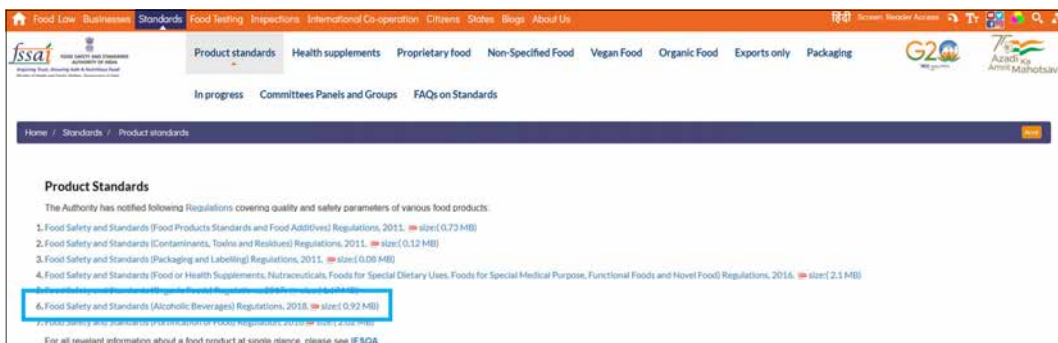
#### ○ Food Safety and Standards Authority of India 접속



○ 상단의 'Standards' 클릭 후 'Product standards' 클릭



○ 목록 중 'Food Safety and Standards (Alcoholic Beverages) Regulations, 2018' 클릭



- 해당 규정 확인(웹사이트 오류가 빈번하여 해당 파일 다운로드 권장)

### **Press note**

#### **Food Safety and Standards (Alcoholic Beverages) Regulations, 2018**

Number of Alcoholic Beverages is being manufactured in India or imported from the various countries since a long time. As per the FSS Act Alcoholic Beverages is also come under the definition of food and FSSAI has mandate for providing safe and wholesome food to public, therefore FSSAI framed the standards for Alcoholic Beverages and notified the same to ensure the safety of Alcoholic Beverages.

The Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 has the standard for only one Alcoholic Beverages i.e. Toddy at clause (1) of the Sub-Regulation 2.10.5 related to Beverages - ALCOHOLIC. Due to presence of various Alcoholic Beverages and their different requirements with respect to their standards and labelling the separate regulation for Alcoholic Beverages was proposes and notified.

This regulations i.e. Food Safety and Standards (Alcoholic Beverages Standards) Regulation, 2018, are the regulations specifying the standards for Alcoholic beverages namely Distilled Alcoholic Beverage (Brandy, Country Liqueur, Gin, Rum, Vodka and Whisky, Liqueur or Alcoholic cordial), Wines and, Beer. It also specifies the specific requirement for labelling of Alcoholic Beverages in addition to the labelling requirements of Food Safety and Standards (Packaging and Labelling) Regulations, 2011. The specific labelling requirements are declaration of alcohol content, labeling of standard drink, not to contain any nutritional information, no health claim, restriction on words 'non-intoxicating' or words implying similar meaning on label of beverage containing more than 0.5 per cent alcohol by volume, Labelling of wine, Allergen warning, statutory warning etc.

These regulation came into force from the date of their publication in Gazette, however the enforcement against these standards will starts from 1<sup>st</sup> April 2019.

● 정보 제공 범위

- 주류별 성분 요건을 표 형식으로 제공



예시 | 브랜드 및 증류주 성분 요건\*

**TABLE-1**  
[See regulation 2.1]

Sr. No.	Characteristics	Brandy or Grape Brandy	Blended Brandy	Country Liqueur or Plain Country Liqueur	Blended Country Liqueurs	Fenny		Gin	Liqueur or Cordial or Aperitif	Rum	White Rum	Vodka	Whisky	Malt or Grain Whisky or Single malt	Blended Whisky	Pot Distilled Spirits
						Cashew	Coconut									
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)	(15)	(16)	(17)
1.	Ethyl alcohol content at 20°C (per cent by volume), Max	36 to 50	36 to 50	19 to 43	19 to 43	19 to 43	19 to 43	36 to 50	15 to 50	36 to 50	36 to 50	36 to 50	36 to 50	36 to 50	36 to 50	36 to 50
2.	Residue on evaporation per cent (m/v), Max*	2.0	2.0	1.0	1.0	0.2	0.1	2.5	50.0	2.0	1.0	2.0	2.0	2.0	2.0	4.0
3.	Volatile acids as acetic acid (expressed as g/100 l of absolute alcohol), Max	100.0	100.0	100.0	50.0	60.0	200.0	10.0	100.0	50.0	50.0	10.0	50.0	150.0	100.0	150.0
4.	Higher alcohols as amyl alcohol (as g/100 l of absolute alcohol), Max	600.0	350.0	250.0	250.0	100.0	100.0	100.0	50.0	350.0	200.0	50.0	750	750.0	750	750.0
5.	Methyl alcohol (expressed as g/100 l of distilled absolute alcohol), Max	150.0	100.0	50.0	50.0	150.00	absent	20.0	10	20.0	10.0	10.0	10.0	30.0	20.0	300.0
6.	Total esters as ethyl acetate (expressed as g/100 l of absolute alcohol), Max	350.0	250.0	150.0	100.0	50.0	50.0	30.0	50.0	150.0	150.0	50.0	100	200.0	150.0	350.0
7.	Furfural (expressed as g/100 l of absolute alcohol), Max	12.0	12.0	12.0	12.0	5.0	2.0	12.0	12.0	10.0	5.0	12.0	6.0	12.0	6.0	12.0
8.	Aldehydes as acetaldehyde (expressed as g/100 l of absolute alcohol), Max	45.0	45.0	35.0	35.0	25.0	10.0	20.0	20	30.0	30.0	15.0	15.0	50.0	35.0	50.0

\* 일부내용 발취

번호	특 성	브랜드 또는 포도 브랜드	혼합 브랜드	국산 증류주 또는 일반 국산 증류주	혼합 국산 증류주
(1)	(2)	(3)	(4)	(5)	(6)
1.	20°C에서 에틸 알코올 함량(부피 백분율), 최대값	36~50	36~50	19~43	19~43
2.	증발잔류물 함량(질량/부피 백분율), 최대값	2.0	2.0	1.0	1.0
3.	휘발성 산(아세트산 기준, 순수 알코올 100 L당 g), 최대값	100.0	100.0	100.0	50.0
4.	고급 알코올(아밀 알코올 기준, 순수 알코올 100 L당 g), 최대값	600.0	350.0	250.0	250.0
5.	메틸 알코올(증류된 순수 알코올 100 L당 g), 최대값	150.0	100.0	50.0	50.0
6.	총 에스터(아세트산 에틸 기준, 순수 알코올 100 L당 g), 최대값	350.0	250.0	150.0	100.0
7.	푸르푸랄(순수 알코올 100 L당 g), 최대값	12.0	12.0	12.0	12.0
8.	알데히드(아세트알데하이드 기준, 순수 알코올 100 L당 g), 최대값	45.0	45.0	35.0	35.0

## [ 식품 안전 및 기준(강화 식품) 규정 ]

### ● 개요

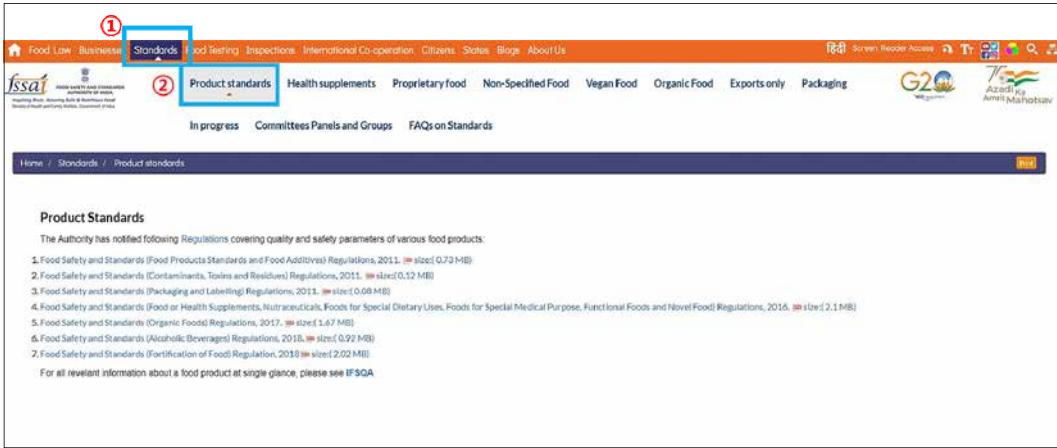
DB명	강화 식품 규정
관리기관	식품안전기준청(FSSAI)
DB 내용	품목별 식품첨가물 목록 제공
접속 주소	<a href="https://fssai.gov.in/cms/product-standards.php">https://fssai.gov.in/cms/product-standards.php</a>
정보 제공 건수	-

### ● DB 접속 방법

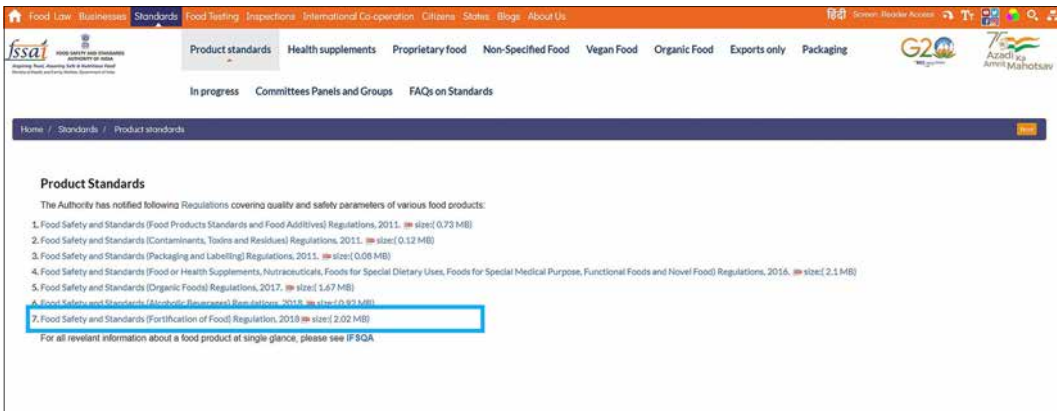
#### ○ Food Safety and Standards Authority of India 접속



○ 상단의 'Standards' 클릭 후 'Product standards' 클릭




○ 목록 중 'Food Safety and Standards(Fortification of Food) Regulations, 2018' 클릭



- 해당 규정 확인(웹사이트 오류가 빈번하여 해당 파일 다운로드 권장)

सिंहद्वारे सं. सं. एत-३३००४/१९
REGD. NO. D. L.-33004/99



**भारत का राजपत्र**  
**The Gazette of India**

असाधारण  
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 PART III—Section 4  
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सं. 2901 नई दिल्ली, बुधवार, अगस्त 3, 2018/श्रावण 12, 1940  
 No. 2901 NEW DELHI, FRIDAY, AUGUST 3, 2018/SHRAVANA 12, 1940

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**स्वास्थ्य और परिवार कल्याण मंत्रालय**  
**(भारतीय माघ सुरक्षा और मूलक प्रतिकल्प)**  
**अधिसूचना**  
 नई दिल्ली, 2 अक्टूबर, 2018

**प्रा. सं. 11/03/विनि/सुद्वीकरण/2014.**—माघ सुरक्षा और मूलक (द्वितीय माघ) विनियम, 2016, भारत के राजपत्र, असाधारण, भाग-III, सं. 4 में अधिसूचना सं. 11/03/विनि/सुद्वीकरण/2014 तारीख 23 दिसंबर, 2016 द्वारा माघ सुरक्षा और मूलक अधिनियम, 2006 (2006 का 34) की धारा 92 की उपधारा (1) की अध्यानुसार प्रकाशित किए गए थे जिसमें उक्त अधिनियम में किए गये उपाय प्रभावित होने की संभावना है, उन मारीख में जिसको उक्त अधिसूचना वाले राजपत्र की प्रतियाँ जलना को उपलब्ध करा दी गई थी, तीन दिन की अवधि म्याद होने में पूर्व अक्षर और मूलक आवृत्ति किए गए थे;

और उक्त राजपत्र की प्रतियाँ जलना को 3 अक्टूबर, 2017 को उपलब्ध करा दी गई थी;

और उक्त प्रारूप विनियम के. माघस्य में जलना में प्राप्त अक्षरों और मूलकों पर भारतीय माघ सुरक्षा और मूलक प्रतिकल्प द्वारा विचार कर लिया गया है;

अतः, अब उक्त अधिनियम की धारा 92 की उपधारा (2) के घट (18) द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए भारतीय माघ

● 부록 1 (영문 8페이지)에서 총 6건에 대한 강화식품 기준 제공

**SCHEDULE-I**  
STANDARDS FOR FORTIFICATION OF FOODS  
*[See sub-regulation (1) of regulation 4]*

1. 1) Iodized salt (when fortified with Iodine)  
2) Iron fortified iodized Salt (Double Fortified Salt) when fortified with Iron and Iodine Salt shall be fortified with Iodine<sup>1</sup> and may also be fortified with iron in combination<sup>2</sup> with iodine, at the level given in the table below:

Sl.No.	Component	Level of nutrients	Source of nutrients
1.	<b>Iodine content</b>		
	(a) Manufacture level	20-30 parts per million (on dry weight basis)	Potassium Iodate
	(b) Distribution channel including retail level	15-30 parts per million (on dry weight basis)	
2.	Iron content (as Fe)	850-1100 parts per million	Ferrous sulphate or Ferrous Fumarate

<sup>1</sup>The total matter insoluble in water where an anticaking agent has been added shall not exceed 2.2 per cent. and Sodium Chloride content on dry basis shall not be less than 97.0 per cent. by weight and it shall also conform other parameter as mentioned under clause (1) of sub-regulation 2.9.30 of the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011.

<sup>2</sup>Double fortified salt may contain Hydroxypropyl Methyl Cellulose, Titanium dioxide full Hydrogenated Soybean oil and Sodium Hexametaphosphate (all food grade) and anticaking agent not more than 2.0 per cent. On dry weight basis and the water insoluble matter wherein anticaking agent is used shall not exceed 2.2 per cent.

2. **Fortified Oil:** Vegetable Oil shall be fortified with the following micronutrients, at the level given in the table below:

Sl. No.	Nutrient	Level of nutrient	Source of nutrient
1.	Vitamin A	6 µg RE - 9.9 µg RE per gm of oil	Retinyl acetate or Retinyl palmitate
2.	Vitamin D	0.11 µg- 0.16 µg per gm of oil.	*Cholecalciferol or *Ergocalciferol (*Only from Plant Source)

Note : Vitamin A (retinol): 1 IU= 0.3 µg RE (Retinol Equivalent); Vitamin D (Cholecalciferol or Ergocalciferol): 1 IU= 0.025 µg

● 정보 제공 범위

- 요오드화 소금, 이중강화소금, 강화유, 강화우유, 강화아타(fortified atta), 강화 마이다 (fortified maida), 강화생쌀에 대한 영양성분명, 영양성분 수준, 영양성분 출처 등을 제공
- 총 6건에 대한 정보 제공하며 PDF 형식으로 다운로드 가능('24.11. 기준)



### 예시 | 원료명: 강화우유(fortified milk)

#### 3. Fortified Milk

Toned, double toned, skimmed milk or standardized milk shall be fortified with the following micronutrients, at the level given in the table below:

Sl. No.	Nutrients	Level of nutrient per litre of toned/double toned/skimmed milk/ Standardized Milk	Source of nutrient
1.	Vitamin A	270 µg RE - 450 µg RE	Retinyl acetate or Retinyl palmitate
2.	Vitamin D	5 µg - 7.5 µg	*Cholecalciferol or *Ergocalciferol (*Only from Plant source)

Note : Vitamin A (retinol): 1 IU= 0.3 µg RE (Retinol Equivalent); Vitamin D (Cholecalciferol or Ergocalciferol): 1 IU= 0.025 µg

#### ✓ 강화우유

조정우유(toned milk), 저지방우유(double toned milk), 탈지우유(skimmed milk) 또는 표준화된 우유는 아래 표에 명시된 수준으로 다음의 미량 영양소를 첨가하여 강화해야 함

번호	영양성분	영양성분 수준	영양성분 출처
1	비타민 A	270 µg RE - 450 µg RE	레티닐 아세테이트 또는 레티닐 팔미테이트
2	비타민 D	5 µg - 7.5 µg	*콜레칼시페롤 또는 *에르고칼시페롤 (*식물성 원료만 사용 가능)

#### 참고

- 비타민 A(레티놀): 1 IU = 0.3 µg RE (레티놀 등가물)
- 비타민 D(콜레칼시페롤 또는 에르고칼시페롤): 1 IU = 0.025 µg

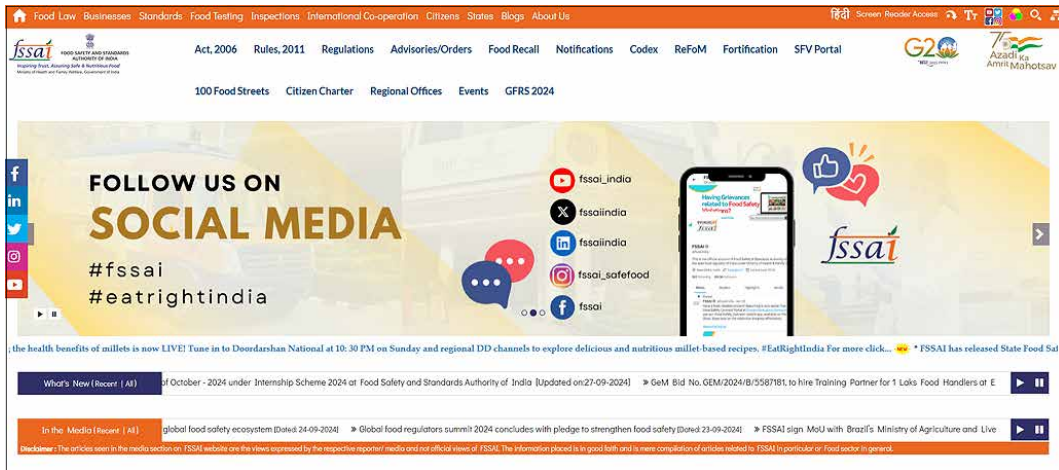
## [ 식품 안전 및 기준(독자적 식품) 규정 ]

### ● 개요

DB명	식품 안전 및 기준 (독자적 식품) 규정
관리기관	식품안전기준청(FSSAI)
DB 내용	독자적 식품의 정의, 성분 요건, 첨가물 사용 요건, 미생물 기준, 기타 규정 준수, 식품 안전 책임에 관한 규정 제공
접속 주소	<a href="https://fssai.gov.in/cms/proprietary-food.php">https://fssai.gov.in/cms/proprietary-food.php</a>
정보 제공 건수	-

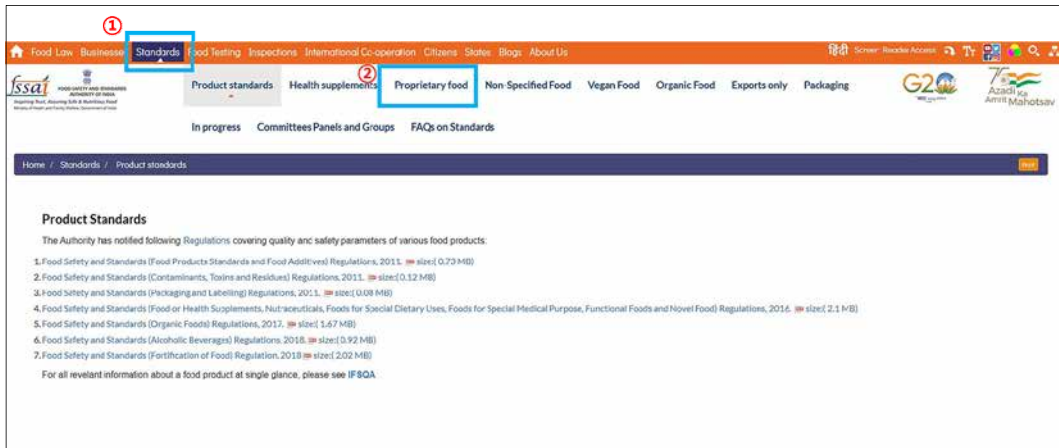
### ● DB 접속 방법

#### ○ Food Safety and Standards Authority of India 접속



Part 1 .  
5.기 타

○ 상단의 'Standards' 클릭 후 'Proprietary food' 클릭




○ 화면에서 중 'regulation on proprietary food' 클릭



○ 해당 규정 확인(웹사이트 오류가 빈번하여 해당 파일 다운로드 권장)

रजिस्ट्री सं० डी० एल०-33004/99
REGD. NO. D. L.-33004/99



# भारत का राजपत्र

## The Gazette of India

असाधारण  
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 भाग III—खण्ड 4  
 PART III—Section 4  
 प्राधिकार से प्रकाशित  
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सं. 376]	नई दिल्ली, बुधवार, अक्टूबर 13, 2016/आश्विन 21, 1938
No. 376]	NEW DELHI, THURSDAY, OCTOBER 13, 2016/ASVINA 21, 1938

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स्वास्थ्य और परिवार कल्याण मंत्रालय  
 (भारतीय खाद्य सुरक्षा और मानक प्राधिकरण)  
 अधिसूचना  
 नई दिल्ली, 10 अक्टूबर, 2016

फा.सं.11/12/वि.नि./प्रौ.ए.ए.ए.आई.-2016.—जबकि खाद्य सुरक्षा और मानक (खाद्य उत्पाद मानक और खाद्य सहयोग्य) संशोधन विनियम, 2016 का प्रारूप खाद्य सुरक्षा और मानक अधिनियम, 2006 (2006 का 34) की धारा 92 की उपधारा (1) के अधिनियम द्वारा भारतीय खाद्य सुरक्षा और मानक प्राधिकरण की अधिसूचना सं. फा.सं. 11/12/वि.नि./प्रौ.ए.ए.ए.आई.-2016, तारीख 19 अप्रैल, 2016 द्वारा भारत के राजपत्र, असाधारण, भाग III, खंड 4 में प्रकाशित किया गया था जिसमें उन व्यक्तियों से जिनके उससे प्रभावित होने की संभावना थी, उस तारीख से जिसको उक्त अधिसूचना वाले राजपत्र की प्रतियां जनता को उपलब्ध करा दी गयी थी, तीस दिनों की अवधि की समाप्ति के पूर्व आक्षेप और सुझाव आमंत्रित किए गए थे ;

और उक्त राजपत्र की प्रतियां जनता को 27 अप्रैल, 2016 को उपलब्ध करा दी गई थीं ;

और भारतीय खाद्य सुरक्षा और मानक प्राधिकरण द्वारा उक्त प्रारूप विनियमों के संशोधन में जनता से प्राप्त आक्षेपों और सुझावों पर विचार कर लिया गया है ;

अतः, अब, भारतीय खाद्य सुरक्षा और मानक प्राधिकरण, उक्त अधिनियम की धारा 16 के साथ पठित धारा 92 की उपधारा (2) के खंड (ड) द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, खाद्य सुरक्षा और मानक (खाद्य उत्पाद मानक और खाद्य सहयोग्य) विनियम, 2011 का संशोधन करने के लिए निम्नलिखित विनियम बनाती है, अर्थात् :-

**विनियम**

1. संक्षिप्त नाम और प्रारंभ - (1) इन विनियमों का संक्षिप्त नाम खाद्य सुरक्षा और मानक (खाद्य उत्पाद मानक और खाद्य सहयोग्य) नवों संशोधन विनियम, 2016 है।

(2) ये राजपत्र में इनके प्रकाशन की तारीख को प्रवृत्त होंगे तथा खाद्य कारोबार प्रचालकों को 1 जुलाई, 2017 से इन विनियमों के सभी प्रावधानों का अनुपालन करना होगा।

4825 CH/2016 (1)

Part 1 . 5. गि . ए

● 정보 제공 범위

- 독자적 식품의 정의, 성분 요건, 첨가물 사용 요건, 미생물 기준, 기타 규정 준수, 식품 안전 책임에 관한 규정



예시 | 식품 안전 및 기준(독자적 식품 규정)\*

**Regulations**

1. **Short title and commencement.**- (1) These regulations may be called the Food Safety and Standards (Food Products Standards and Food Additives) Ninth Amendment Regulations, 2016.  
  
(2) They shall come into force on the date of their publication in the Official Gazette and Food Business Operator shall comply with all the provisions of these regulations by 1st July, 2017.
2. In the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, in regulation 2.12 relating to 'Proprietary Food', for the sub-regulation 2.12.1, the following sub-regulation shall be substituted, namely:-

"2.12.1: For the purpose of these regulations,-

- ① (1) Proprietary food means an article of food that has not been standardised under these regulations, but does not include novel foods, foods for special dietary uses, foods for special medical purposes, functional foods, nutraceuticals, health supplements and such other food articles which the Central Government may notify in this behalf.

Provided that any deviation in quality parameters of a standardised food, as specified in the Food Safety and Standards Regulations made under the Food Safety and Standards Act, 2006 shall not qualify the resultant product as a proprietary food.

- ② (2) Proprietary food shall contain only those ingredients other than additives which are either standardised or permitted for use in the preparation of other standardised food under these Regulations, except the ingredients which may be specified by the Authority from time to time.

Provided that a proprietary food may also contain vitamins and minerals in quantities not exceeding one RDA of the respective micronutrients.

- ③ (3) Proprietary food shall use only such additives and at such levels, as specified for the Category or Sub-category under Appendix A of these Regulations, to which the food belongs. Such Category or Sub-category shall be clearly mentioned on the label along with the generic name, nature and composition of the proprietary food.

- ④ (4) Proprietary food shall comply with the microbiological requirements as specified in Appendix B of these Regulations. If no microbiological standards are specified for any foods or food categories in Appendix B of these regulations, proprietary foods falling under such food categories shall not contain any pathogenic microorganism at a level that may render the food product unsafe.

- ⑤ (5) Proprietary food shall also comply with the provisions, as applicable, of all other Regulations made under the Food Safety and Standards Act 2006. No health claims shall be made in respect of proprietary foods either on the product label or otherwise, unless it is substantiated by adequate and scientific evidence.

- ⑥ (6) The Food Business Operator shall be fully responsible for safety of the proprietary food in respect of human consumption."

\* 일부내용 발췌

① 독자적 식품

독자적 식품은 본 규정에서 표준화되지 않은 식품을 의미하되, 다음과 같은 식품은 포함하지 않는다.

- 신소재 식품
- 특수 식이 목적 식품
- 특수 의료 목적 식품
- 기능성 식품
- 뉴트라슈티컬
- 건강보조식품
- 중앙 정부가 이와 관련해 별도로 지정하는 기타 식품

식품 안전 및 기준법, 2006에 따른 식품 안전 및 기준 규정에서 표준화된 식품의 품질 기준에서 벗어난 경우, 해당 결과물은 독자적 식품으로 간주되지 않는다.

② 성분 요건

독자적 식품은 표준화된 식품 제조에 사용이 허용된 성분 또는 본 규정에서 표준화된 성분만 포함해야 한다. 다만, 당국이 별도로 지정하는 성분은 예외로 한다.

독자적 식품은 해당 미량 영양소의 1일 권장 섭취량(RDA)을 초과하지 않는 범위 내에서 비타민과 미네랄을 포함할 수 있다.

③ 첨가물 사용

독자적 식품은 본 규정의 부속서 A에 명시된 카테고리 또는 하위 카테고리별로 지정된 첨가물만 사용해야 하며, 사용 수준을 준수해야 한다. 해당 카테고리 또는 하위 카테고리는 라벨에 일반명, 성질 및 조성과 함께 명확히 표시해야 한다.

④ 미생물 기준

독자적 식품은 부속서 B에 명시된 미생물 기준을 준수해야 한다. 부속서 B에 특정 식품이나 식품 범주에 대한 미생물 기준이 명시되지 않은 경우, 해당 식품 범주에 속하는 독자적 식품은 식품을 불안전하게 만들 수 있는 병원성 미생물을 포함해서는 안 된다.

⑤ 기타 규정 준수

독자적 식품은 2006년 식품 안전 및 기준법에 따라 제정된 기타 모든 규정을 준수해야 하며, 제품 라벨 또는 기타 방식으로 건강 강조표시를 할 수 없다. 다만, 적절하고 과학적인 증거로 입증된 경우는 예외로 한다.

⑥ 식품 안전 책임

식품 사업자는 독자적 식품의 인체 소비 안전성에 대해 전적으로 책임을 져야 한다.

## 베트남

### [기능성식품 관리 규정]

#### ● 개요

DB명	기능성식품 관리 규정(No.11/VBHN-BYT)
관리기관	보건부 식품안전국(VFA)
DB 내용	미네랄 및 미량영양소 등 일일섭취량 정보를 제공함
접속 주소	<a href="https://vfa.gov.vn/van-ban.html">https://vfa.gov.vn/van-ban.html</a>
정보 제공 건수	미네랄, 미량영양소, 요오드 및 비타민 7종 등(24.11. 기준)

#### ● DB 접속 방법

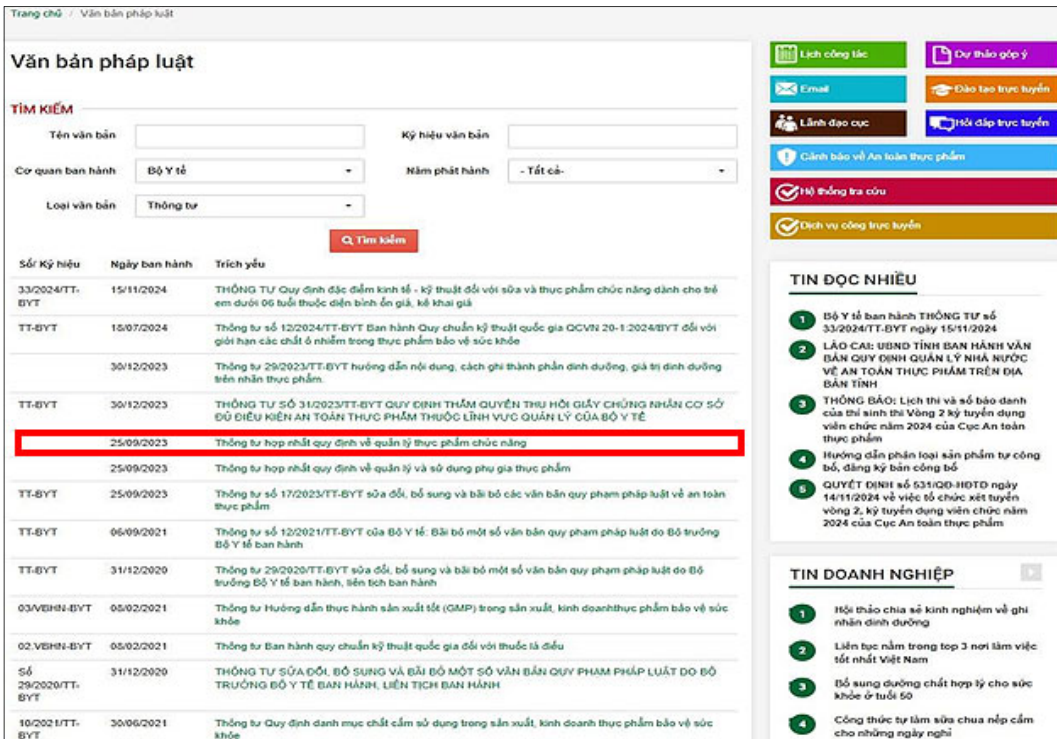
- ‘식품안전국 누리집’ 접속 후 ‘문서서비스(Văn bản)’ 클릭

The screenshot shows the official website of the Vietnam Food Administration (VFA). The top navigation bar includes 'Văn bản' (Documents) highlighted in red. The main content area features a news article titled 'Thông báo thủ đoạn giả danh các Đoàn thanh tra, kiểm tra' (Notice of disguised inspection and inspection teams). Below this, there is a photo of a meeting and a section titled 'Chỉ cục An toàn vệ sinh thực phẩm tỉnh Nam Định kiểm tra công tác bảo đảm an toàn thực phẩm tỉnh Hà Giang' (The Provincial Food Safety Agency of Nam Định inspects food safety work in Hà Giang province). The right sidebar contains various service links like 'Lịch công tác', 'Dự báo góp ý', 'Email', 'Đào tạo trực tuyến', 'Lãnh đạo cục', 'Hỏi đáp trực tuyến', ' Cảnh báo về An toàn thực phẩm', 'Hỗ trợ tra cứu', and 'Dịch vụ công trực tuyến'. At the bottom right, contact information for the VFA is provided, including the phone number 0243.232.1556 and email tiepnhantinhvipham@moh.gov.vn.

- ‘법률문서(Văn bản pháp luật)’ 화면으로 이동 후 카테고리 설정: 발행기관(cơ quan ban hành)-보건부(Bộ Y tế), 문서종류(Loại văn bản)-시행규칙(Thông tư), ‘찾기(Tìm kiếm)’ 클릭



- 시행규칙 목록 중 ‘기능성식품 관리 규정(No.11/VBHN-BYT)’ 클릭  
⇒ 접속 후 PDF 파일 다운로드



Part 1 .  
5.기 타

● 정보 제공 범위

● 베트남인을 위한 일일 권장영양섭취량(부록 01)

**PHỤ LỤC SỐ 01**  
**BẢNG NHU CẦU DINH DƯỠNG KHUYẾN NGHỊ CHO NGƯỜI VIỆT NAM**  
*(Ban hành kèm theo Thông tư số 43/2014/TT-BYT ngày 24 tháng 11 năm 2014 của Bộ trưởng Bộ Y tế)*

**①. Nhu cầu các khoáng chất và vi chất**

Nhóm tuổi, giới	② Ca (Calcium) (mg/ngày)	Mg (Magnesium) (mg/ngày)	P (Phosphorus) (mg/ngày)	Selen * (µg/ngày)
<i>Trẻ em</i>				
< 6 tháng	300	36	90	6
6-11 tháng	400	54	275	10

① 미네랄 및 미량영양소

② 칼슘(mg/일)

● 최대허용량(부록 02)

**PHỤ LỤC SỐ 02**  
**NGŨƠNG DUNG NẠP TỐI ĐA**  
*(Ban hành kèm theo Thông tư số 43/2014/TT-BYT ngày 24 tháng 11 năm 2014 của Bộ trưởng Bộ Y tế)*

**①. Vitamin**

Nhóm tuổi	Vitamin A (µg/ngày)	② Vitamin C (mg/ngày)	Vitamin D (µg/ngày)	Vitamin E (mg/ngày)	Vitamin K (µg/ngày)	Vitamin B1 (mg/ngày)	Riboflavin (mg/ngày)	Niacin (mg/ngày)	Vitamin B6 (mg/ngày)	Acid Folic (µg/ngày)	Vitamin B12 (µg/ngày)	Pantothenic (mg/ngày)	Biotin (µg/ngày)
<i>Trẻ em</i>													
0-6 tháng	600	KC	25	KC	KC	KC	KC	KC	KC	KC	KC	KC	KC
6-12 tháng	600	KC	38	KC	KC	KC	KC	KC	KC	KC	KC	KC	KC

① Vitamin

② Vitamin C(mg/일)

## [ 식품에 사용되는 미량영양소 목록을 정하는 시행규칙 ]

### ● 개요

DB명	식품에 사용되는 미량영양소 목록을 정하는 시행규칙 (No.44/2015/TT-BYT)
관리기관	보건부 식품안전국(VFA)
DB 내용	식품에 사용되는 비타민 및 미네랄 목록 정보를 제공함
접속 주소	<a href="https://vfa.gov.vn/van-ban.html">https://vfa.gov.vn/van-ban.html</a>
정보 제공 건수	비타민 13종, 미네랄 15종

### ● DB 접속 방법

- ‘식품안전국 누리집’ 접속 후 ‘문서서비스(Văn bản)’ 클릭

The screenshot shows the official website of the Vietnam Food Administration (VFA). The navigation menu includes 'Văn bản' (Documents), which is highlighted in red. Below the menu, there is a news section with a headline: 'Chi cục An toàn vệ sinh thực phẩm tỉnh Nam Định kiểm tra công tác bảo đảm an toàn thực phẩm tỉnh Hà Giang'. The page also features a sidebar with various service icons and contact information for the VFA.

- ‘법률문서(Văn bản pháp luật)’ 화면으로 이동 후 카테고리 설정: 발행기관(cơ quan ban hành)-보건부(Bộ Y Tế), 문서종류(Loại văn bản)-시행규칙(Thông tư), ‘찾기(Tìm kiếm)’ 클릭

Trang chủ / Văn bản pháp luật

## Văn bản pháp luật

**TÌM KIẾM**

Tên văn bản  Ký hiệu văn bản

Cơ quan ban hành  Năm phát hành

Loại văn bản

- 시행규칙 목록 중 ‘식품에 사용되는 미량영양소 목록을 정하는 시행규칙 (No.44/2015/TT-BYT)’ 클릭 ⇒ 접속 후 PDF 파일 다운로드

49/2015/TT-BYT	11/12/2015	Thông tư Quy định về công bố hợp quy và công bố phù hợp quy định đối với thuốc lá
47/2015/TT-BYT	01/12/2015	Thông tư số 47/2015/TT-BYT ban hành quy chuẩn kỹ thuật quốc gia về chất hỗ trợ chế biến thực phẩm - Dung môi
46/2015/TT-BYT	01/12/2015	Thông tư số 46/2015/TT-BYT ban hành quy chuẩn quốc gia về hương liệu thực phẩm - Các chất tạo hương vani
44/2015/TT-BYT	30/11/2015	Thông tư số 44/2015/TT-BYT ban hành danh mục vi chất dinh dưỡng sử dụng trong thực phẩm
35/2015/TT-BYT	28/10/2015	Thông tư số 35/2015/TT-BYT là QCVN 12-4:2015/BYT - Quy chuẩn kỹ thuật quốc gia về vệ sinh an toàn đối với bao bì, dụng cụ làm bằng thủy tinh, gốm, sứ và tráng men tiếp xúc trực tiếp với thực phẩm.
23/2015/TT-BYT	28/08/2015	Thông tư Ban hành Quy chuẩn kỹ thuật quốc gia đối với thuốc lá điếu

● 정보 제공 범위

● 식품 내 사용 가능한 비타민 및 미네랄 목록(부록)

**PHỤ LỤC**  
DANH MỤC VITAMIN VÀ CHẤT KHOÁNG SỬ DỤNG TRONG THỰC PHẨM  
(Ban hành kèm theo Thông tư số 44/2015/TT-BYT ngày 30 tháng 11 năm 2015)

**1. Các vitamin:**

TT	① Tên vitamin	② Dạng sử dụng
1.	Vitamin A	- Retinol - Retinyl acetat - Retinyl palmitat - Beta-caroten
2.	Vitamin D	- Cholecalciferol - Ergocalciferol

① 비타민 명칭

② 사용형태

**2. Các chất khoáng:**

TT	① Tên chất khoáng	② Dạng sử dụng
1.	Calci (Ca)	- Calci carbonat - Calci clorid - Các muối calci citrat - Calci gluconat - Calci glycerophosphat - Calci lactat - Các muối calci phosphat - Calci hydroxyd - Calci oxyd - Calci sulfat - Calci acetat - Calci L-ascorbat

① 미네랄 명칭

② 사용형태

## 5-3. 기타

### ■ 유럽연합

#### [식품, 사료 정보 포털 데이터베이스(유아용 조제분유 및 성장기 조제분유)]

##### ● 개요

DB명	식품, 사료 정보 포털 데이터베이스
관리기관	유럽위원회(EC)/유럽식품안전청(EFSA)
DB 내용	유아용 조제분유 및 성장기 조제분유
접속 주소	<a href="https://ec.europa.eu/food/food-feed-portal/screen/iffof/search">https://ec.europa.eu/food/food-feed-portal/screen/iffof/search</a>
정보 제공 건수	6건('24.11. 기준) - 단백질 가수분해물로 제조된 후속 조제분유 - 대두 단백질 분리물(단독 또는 우유 단백질이나 염소우유 단백질과 혼합)로 제조된 유아용 조제분유 - 단백질 가수분해물로 제조된 유아용 조제분유 - 대두 단백질 분리물(단독 또는 우유 단백질이나 염소우유 단백질과 혼합)로 제조된 성장기 조제분유 - 우유 단백질이나 염소우유 단백질로 제조된 성장기 조제분유 - 우유 단백질이나 염소우유 단백질로 제조된 유아용 조제분유

● DB 접속 방법

○ 유럽위원회의 'Food and Feed Information Portal Database' 접속

The screenshot shows the homepage of the Food and Feed Information Portal Database. At the top, there is the European Commission logo and a search bar. Below the header, the page is organized into several columns, each representing a different category of substances or products. Each category includes a short introductory text and a list of search options or links.

- Decontamination Substances:** The Commission has established a European Union data base of substances, other than potable water, authorized to remove surface contamination from products of animal origin in accordance with Article 3(2) of Regulation (EC) No 853/2004.
  - Search for Decontamination Substances
- Feed Additives:** The Commission has established the European Union Register of Feed Additives, which is regularly updated, and it makes reference/links to the relevant authorisation Regulations. Those Regulations include the specific requirements for placing the additives on the EU and EEA market.
  - Search Feed Additives
  - Search Feed Additives authorisations
  - Download Register in Excel format
  - Latest updates to the Register
  - Archived expired authorisations (PDF)
  - APIs
  - Disclaimer
- Food Additives:** This database is a searchable tool informing about the food additives approved for use in food in the EU and their conditions of use. It is based on the Union list of approved food additives laid down in Annex II to Regulation (EC) No 1333/2008.
  - Search for Additives
  - Browse by categories
  - European Legislation on Food Additives
  - Information documents
  - APIs
  - Disclaimer
- Food Allergens:** This database is a searchable tool informing on substances or products causing allergies or intolerances as listed in Annex II to Regulation
- Food Contact Materials:** This database is a searchable tool informing about Food Contact Materials Union Register of recycling installations, facilities, companies.
- Food Flavouring:** This database is a searchable tool informing about the flavouring substances approved for use in food in the EU and their conditions of

○ 화면 하단의 'Infant Formulae & Follow-on Formulae manufactured from protein hydrolysates'의 'Search for Infact Formulae and Follow-on Formulae' 클릭

This screenshot shows a specific search page within the database. It features a grid of search categories. The 'Infant Formulae & Follow-on Formulae manufactured from protein hydrolysates' section is highlighted, and its search link is enclosed in a red rectangular box.

- Genetically Modified Organisms:** These search engines cover the Community register of GM food and feed (Regulation (EC) 1829/2003), the pending, withdrawn and expired GM products (Regulation (EU) 619/2011) and GMOs authorised under Directive 2001/18/EC.
  - Search genetically modified Food and Feed
  - Search Genetically Modified Organisms - Part B notifications (experimental releases)
  - Search Part C notifications (placing on the market)
- Health Claims:** The search tool only allows searches for health claims, and not nutrition claims.
  - EU Register of Health Claims
  - Some health claims subject to the individual authorisation procedure
  - Download Register in Excel format
  - APIs
- Infant Formulae & Follow-on Formulae manufactured from protein hydrolysates:** The search tool allows for searches for both infant formulae and follow-on formulae.
  - Search for Infant Formulae and Follow-on Formulae
- Novel Food:** The Implementing Regulation establishing the list of novel foods compiles all the authorised novel foods in the European Union to date. It includes their conditions of use, labelling requirements, and their specifications.
  - Union List of authorised novel foods
  - Novel Food status Catalogue
  - Latest updates to the Novel Food status Catalogue
  - APIs
- Nutrients:** This database is a searchable tool informing about the nutritional substances such as vitamins, minerals and others that are approved for use in the EU.
  - Search for Nutrients
  - Disclaimer
- Smoke flavourings:** This database is a searchable tool informing about the smoke flavouring products approved for use in the EU and their conditions of use. It is based on the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavouring laid down in Annex to Regulation (EC) No 1321/2013.
  - Search for Smoke flavourings
  - Browse by categories
  - European Legislation on Smoke flavourings
  - APIs
  - Disclaimer

Part 1 .  
5.기 타

○ 총 6건의 정보 제공

**SEARCH OPTIONS**

Type of formulae

All ▼

Search

Clear filters

### Infant Formulae & Follow-on formulae (6 matching records)

Filter results... Search

◆ Name

---

Follow-on formula manufactured from protein hydrolysates

---

Infant formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins

---

Infant formula manufactured from protein hydrolysates

---

Follow-on formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins

---

Follow-on formula manufactured from cows' milk or goats' milk proteins

---

Infant formula manufactured from cows' milk or goats' milk proteins

○ 해당 원료의 상세 정보 확인

Characteristics

[Compositional Requirements](#)

Annexes

Legislations

## Characteristics

Formula type	Infant Formulae
Formula name	Infant formula manufactured from cows' milk or goats' milk proteins

## Compositional Requirements

Energy	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="padding: 2px;">Minimum</th> <th style="padding: 2px;">Maximum</th> </tr> <tr> <td style="padding: 2px;">250 kJ/100 ml (60 kcal/100 ml)</td> <td style="padding: 2px;">293 kJ/100 ml (70 kcal/100 ml)</td> </tr> </table>	Minimum	Maximum	250 kJ/100 ml (60 kcal/100 ml)	293 kJ/100 ml (70 kcal/100 ml)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="padding: 2px;">Minimum</th> <th style="padding: 2px;">Maximum</th> </tr> <tr> <td style="padding: 2px;">0,43 g/100 kJ (1,8 g/100 kcal)</td> <td style="padding: 2px;">0,6 g/100 kJ (2,5 g/100 kcal)</td> </tr> </table>	Minimum	Maximum	0,43 g/100 kJ (1,8 g/100 kcal)	0,6 g/100 kJ (2,5 g/100 kcal)
Minimum	Maximum									
250 kJ/100 ml (60 kcal/100 ml)	293 kJ/100 ml (70 kcal/100 ml)									
Minimum	Maximum									
0,43 g/100 kJ (1,8 g/100 kcal)	0,6 g/100 kJ (2,5 g/100 kcal)									

(Protein content = nitrogen content × 6,25)

For an equal energy value, infant formula manufactured from cows' milk or goats' milk proteins must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine: cysteine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine: phenylalanine ratio is not greater than 2. The ratio of methionine: cysteine and of tyrosine: phenylalanine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3).

The L-carnitine content shall be at least equal to 0,3 mg/100 kJ(1,2 mg/100 kcal).

**TAURINE**

If added to infant formula, the amount of taurine shall not be greater than 2,9

● 정보 제공 범위

- 해당 원료 특성, 성분 요건, 부속서, 관련 규정에 관한 정보 제공

 예시 | 원료명: 소 또는 염소의 우유 단백질로 제조된 유아용 분유

[Characteristics](#)

[Compositional Requirements](#)

[Annexes](#)

[Legislations](#)

**① Characteristics**

Formula type	Infant Formulae	
Formula name	Infant formula manufactured from cows' milk or goats' milk proteins	

**② Compositional Requirements**

	Minimum	Maximum
Energy	250 kJ/100 ml	293 kJ/100 ml
	(60 kcal/100 ml)	(70 kcal/100 ml)
Proteins	0.43 g/100 kJ	0.6 g/100 kJ
	(1.8 g/100 kcal)	(2.5 g/100 kcal)

(Protein content = nitrogen content × 6,25)

For an equal energy value, infant formula manufactured from cows' milk or goats' milk proteins must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine: cysteine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine: phenylalanine ratio is not greater than 2. The ratio of methionine: cysteine and of tyrosine: phenylalanine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3).

The L-carnitine content shall be at least equal to 0,3 mg/100 kJ(1,2 mg/100 kcal).

TAURINE

\* 일부만 발췌

① 특성

- 분유 유형: 유아용 분유
- 분유 명칭: 소 또는 염소의 우유 단백질로 제조된 유아용 분유

② 성분 요건: (생략)

## [영유아용 식품, 특수의료목적 식품, 체중 조절용 완전 대체식품에 관한 규정]

### ● 개요

<b>DB명</b>	식품, 사료 정보 포털 데이터베이스
<b>관리기관</b>	유럽위원회(EC)/유럽식품안전청(EFSA)
<b>DB 내용</b>	영유아용 식품, 특수의료목적 식품, 체중조절용 완전 대체식품에 관한 규정[Regulation (EU) No 609/2013]의 부속서에서 원료 목록 제공
<b>접속 주소</b>	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R0609&qid=1731237974212
<b>정보 제공 건수</b>	-

### ● DB 접속 방법

#### ○ 유럽위원회의 'EUR-Lex' 접속

The screenshot displays the EUR-Lex website interface. At the top, there is the European Union logo and the text 'European Union'. Below this, the 'EUR-Lex' logo is prominent, followed by the tagline 'Access to European Union law'. A search bar with the placeholder 'QUICK SEARCH' and a 'SEARCH' button is visible. To the right of the search bar, there are links for 'My EUR-Lex' and 'English', along with an 'Experimental features' toggle. Below the search bar, a 'LAW IN FOCUS' banner highlights 'The EU and the Istanbul Convention'. The main content area is divided into several sections: 'EU law' (with sub-sections like Treaties, Legal acts, Consolidated texts, etc.), 'EU case-law' (with sub-sections like Case-law, Reports of cases, Directory of case-law), and 'National law and case-law' (with sub-sections like National transposition, National case-law, JURE case-law). There is also an 'Information' section with sub-sections like Themes in focus, EUR-Lex developments, Statistics, EU register, and EU budget online. On the right side, there is an 'Official Journal' section with links to OJ L Series and OJ C Series, and a search box for 'Find results by document number' and 'Find results by CELEX number'. At the bottom right, there are buttons for 'Measures in solidarity with Ukraine' and 'EU Law Tracker - NEW'.

- 검색란에 'EU 609/2013' 입력 후 클릭

**EUR-Lex**  
Access to European Union law

EUROPA > EUR-Lex home > EU law

Q EU 609/2013 **SEARCH**

Search tips Need more search options? Use the Advanced search

**LAW IN FOCUS**  
The EU and the Istanbul Convention

Pause ● ○ ○ ○

- 해당 규정 클릭

Search Results

Search criteria

Search for: EU 609/2013, Search language: English

Save to My searches Create in My RSS alerts Save to My items

Results 1 - 10 of 425 Sort by Relevance 1 2 > >>

Customise shown information Export

Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 Text with EEA relevance

OJ L 181, 29/06/2013, p. 35-36 (BG, ES, CS, DA, DE, ET, EL, EN, FR, GA, IT, LV, LI, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV)  
This document has been published in a special edition(s) ( HR)

In force

Latest consolidated version: 21/03/2023 Author: European Parliament, Council of the European Union

CELEX number: 32013R0609 Date of document: 12/06/2013

Form: Regulation Number of pages: 22

PDF HTML

○ 해당 규정 화면 아래로 이동하여 부속서 목록 확인

ANNEX						
Union list as referred to in Article 15(1)						
Substance		Category of food				
		Infant formula and follow on formula	Processed cereal-based food and baby food	Food for special medical purposes	Total diet replacement for weight control	
Vitamins	Vitamin A	retinol	X	X	X	X
		retinyl acetate	X	X	X	X
		retinyl palmitate	X	X	X	X
		beta-carotene		X	X	X
	Vitamin D	ergocalciferol	X	X	X	X
		cholecalciferol	X	X	X	X
	Vitamin E	D-alpha tocopherol	X	X	X	X
		DL-alpha tocopherol	X	X	X	X
		D-alpha tocopheryl acetate	X	X	X	X
		DL-alpha tocopheryl acetate	X	X	X	X
		D-alpha-tocopheryl acid succinate			X	X
		D-alpha-tocopheryl polyethylene glycol-1000 succinate (TPGS)			X	
	Vitamin K	phylloquinone (phytomenadione)	X	X	X	X
		Menaquinone (?)			X	X
	Vitamin C	L-ascorbic acid	X	X	X	X

● 정보 제공 범위

- 유아용 조제분유 및 성장기용 조제분유, 가공된 곡물 기반 식품 및 이유식, 특수 의료 목적 식품, 체중 조절용 완전 대체 식품에 대한 원료 목록을 제공



예시 | 원료명: 비타민 A

ANNEX						
Union list as referred to in Article 15(1)						
Substance			Category of food			
			Infant formula and follow on formula	Processed cereal-based food and baby food	Food for special medical purposes	Total diet replacement for weight control
Vitamins	Vitamin A					
		retinol	X	X	X	X
		retinyl acetate	X	X	X	X
		retinyl palmitate	X	X	X	X
		beta-carotene		X	X	X

원료		식품 분류			
		유아용 조제분유 및 성장기용 조제분유	가공된 곡물 기반 식품 및 이유식	특수의료 목적식품	체중조절용 완전 대체식품
비 타 민 A	레티놀	X	X	X	X
	레티닐 아세테이트	X	X	X	X
	레티닐 팔미테이트	X	X	X	X
	베타카로틴		X	X	X

## ■ 호주

### [ 호주 검역검사국(BICON) 수입 요건 검색 ]

#### ● 개요

DB명	호주 검역검사국(BICON) 수입 요건 검색
관리기관	호주농수산임업국(DAFF)
DB내용	수입 동식물, 미네랄, 바이오 의약품 수입 요건
접속 주소	https://bicon.agriculture.gov.au
정보 제공 건수	20,000건('24.11. 기준)

#### ● DB 접속 방법

##### ○ 호주농수산임업국의 'BICON' 접속

The screenshot displays the BICON website interface. At the top, there is a navigation bar with the Australian Government logo and the text 'BICON Australian Biosecurity Import Conditions'. A search bar is located in the top right corner. Below the navigation bar, there is a 'Welcome to BICON' section with a brief description of the database. The main content area is titled 'Search for Import Item' and includes a search form with a 'Quick Search' button and a search input field. Below the search form, there are two alert boxes: one for '1 new alerts' and one for '1 change notices', both with links to view the alerts.

- 화면 중간의 검색란에 검색하고 자 하는 수입 품목 입력 후 클릭(빠른검색, 학명, 관세코드로 검색 가능)

## Search for Import Item

Search for the commodity you want to import. You can also search for your import by scientific name or tariff code. Refer to the [BICON Help](#) page for tips on searching.

Quick Search
Scientific Name
Tariff Code

Search

Import into Australia
Effective on 17 December 2024
Advanced search ▼

- 관련 수입 요건 클릭

Quick Search
Scientific Name
Tariff Code

Search

Import into Australia
Effective on 17 December 2024
Advanced search ▼

### Search Results

Select an import item that best matches what you want to import to continue the process.

i Non commodity conditions apply to all packaging, containers and transport methods used to bring goods into the country. Refer to the Non Commodity case to review the [non commodity](#) conditions related to your import.

Showing 1 - 10 results of 10 Results per page 10 ▼

[Human therapeutics and medicines](#) ▲ Alerts ● Changes

Effective 15 December 2024 to present

This case describes the requirements for the importation of human therapeutics and **medicines**. This case includes human material for human therapeutic use e.g. organs for transplant, blood products for transfusions. This case may include, but is not limited to, **complementary medicines** (including Chinese **medicines**) containing animal and/or microbial derived material.

**Matched term:** medicines, complementary, Medicine

[Dietary supplements and natural medicines of plant origin for human consumption](#)

Effective 25 October 2024 to present

This case describes the requirements for the importation of dietary supplements and natural **medicines** of plant origin for human consumption. For human therapeutics and **medicines** containing biological material of animal or microbial please refer to the BICON case Human therapeutics and **medicines**. For protein powders and supplements (e.g. performance enhancement supplements), please refer to the BICON case Protein powders and body building supplements for human consumption. For products containing mushrooms please refer to the BICON case [read more](#)

**Matched term:** medicines, Complementary, medicine

Part 1 .  
5.기 타

○ 수입 품목에 해당하는 답변을 클릭하고 ‘다음’ 이동

### Case: Human therapeutics and medicines

Effective 15 Dec 2024

This case contains a number of different import scenarios with associated import conditions. You can refine the import scenarios by answering the questions below.

**Is the product for human therapeutic use as defined by the Therapeutic Goods Act 1989?**

For human therapeutic goods that are 100% synthetic please refer to BICON case for [Synthetic material](#).  
For human therapeutic goods containing meat (excl. avian and pork) sourced, manufactured and exported from New Zealand and/or Australia please refer to the BICON case for [Unretorted meat](#).  
For the import of human milk and human milk products please refer to the BICON case for [Human fluids and tissues](#).  
For the definition of human therapeutic use, please see [Section 3 of the Therapeutic Goods Act 1989](#).

No  
 Yes

Previous Next

[Skip to import conditions](#)

○ 수입 품목에 해당하는 답변을 클릭하고 ‘다음’ 이동

### Case: Human therapeutics and medicines

Effective 15 Dec 2024

This case contains a number of different import scenarios with associated import conditions. You can refine the import scenarios by answering the questions below.

**Which of the following best describes the goods?**

For more information on approved ingredients please refer to the following:  
[Approved biological ingredients](#)  
[Fermentation-derived active ingredients list](#) #  
For the import of commercial consignments of test kits, including COVID-19 rapid antigen tests, please refer to the BICON case [Test kits](#).  
For meat products including deer velvet and ovine placenta from New Zealand refer to the BICON case [Uncanned, unretorted meat](#).

Personal use (commercially prepared and packaged)  
 Human derived materials (excluding antibodies, cell lines and human milk)  
 Only contains approved biological ingredients  
 Only contains listed semi-synthetic, fermentation-derived ingredients  
 TGA AUST R human therapeutics and medicines  
 ARTG registered Medical Devices included Class III  
 Human therapeutics and medicines for use in a clinical trial (including accountability and disposal)  
 Therapeutics with ingredients of plant or mushroom origin only

Previous Next

## ○ 상세 정보 확인

### Case: Human therapeutics and medicines

Effective 15 Dec 2024

#### Therapeutic use — Personal use (commercially prepared and packaged)

##### Import Conditions

Import conditions define the biosecurity requirements which must be met for your import. Where import conditions have been developed, they will be listed below.

For the purposes of human therapeutics and medicines, personal use means:

1. for personal use by the person bringing in or importing the goods; or
2. for use by any spouse, de facto partner, child, parent or sibling of the person bringing in or importing the goods.

For COVID-19 rapid antigen tests imported for personal use, please refer to the Australian Register of Therapeutic Goods for the [list of approved tests](#).

##### Import conditions prior to arrival in Australian territory

a. A Department of Agriculture, Fisheries and Forestry import permit is not required.

b. The imported product must be for personal human therapeutic use as defined in [Section 3 of the Therapeutic Goods Act 1989](#), and

1. be imported in quantities of no more than three months supply
2. must be commercially prepared and packaged
3. must not contain bee pollen.

To demonstrate compliance with this requirement you must present the following on a [Product label](#), [Letter](#), [Brochure](#) or [Internet website](#):

1. Evidence that the goods are for human therapeutic use.
2. Evidence that the product is imported in a quantity of no more than three months' supply.
3. Evidence that the product is commercially prepared and packaged (eg. diagnostic kits, capsules, tablets, vials for injection, liquid, powder or ointment).
4. Evidence that the goods do not contain bee pollen.

If a letter is presented it must be from a health care provider (e.g. Doctor, Medical practitioner, naturopath or alternative health provider)

##### Import conditions after arrival in Australian territory

- c. The goods may be subject to inspection to verify the above.
- d. The goods must be clearly identifiable.

##### What happens next?

When you are importing into Australia a departmental officer will assess the risk posed by your import and determine the appropriate outcome to apply. You may use the link below to view the likely outcomes for this particular import scenario. Please be aware that the assessment conducted may result in an outcome that is not listed.

[View Outcome Outcomes](#)

## ● 정보 제공 범위

- 수입 동식물, 미네랄, 바이오 의약품 수입 요건을 수입 품목에 맞춤화하여 일반 수입 조건, 호주 도착 전후 수입 조건 등에 관한 정보를 검색할 수 있음



### 예시 | 사례: 인체 소비용 식물 유래 건강 보조제 및 천연의약품

**Case: Dietary supplements and natural medicines of plant origin for human consumption**  
Effective 25 Oct 2024

**Plant origin — Not for personal use — Approved pharmaceutical excipients**

**① Import Conditions**  
Import conditions define the biosecurity requirements which must be met for your import. Where import conditions have been developed, they will be listed below.

**② Import conditions prior to arrival in Australian territory**

- a. A Department of Agriculture, Fisheries and Forestry import permit is not required.
- b. The product must only contain ingredients of plant origin that are in the [approved biological excipients](#).  
To demonstrate compliance with this requirement you must present the following on a [Food product label](#), [Manufacturer's declaration](#) or [Supplier's declaration](#):  
Details of a full list of ingredients totalling 100%.

**③ Related Information:**

- [Table: Pharmaceutical excipients](#)
- c. The product must be used for human consumption use only.  
To demonstrate compliance with this requirement you must present the following on an [Importer declaration](#):  
A statement that the product is to be used for human consumption use only.
- d. The product must be [commercially packaged](#) and [ready for retail](#) sale without any further processing.

**④ Additional Information**

- e. Under the [Biosecurity Charges Imposition \(General\) Regulation 2016](#) and Chapter 9, Part 2 of the [Biosecurity Regulation 2016](#), fees are payable to the Department of Agriculture, Fisheries and Forestry for all services. Detail on how the department applies fees and levies may be found in the [Charging guidelines](#).
- f. In addition to the conditions for the goods being imported, non-commodity concerns must be assessed including container cleanliness, packaging and destination concerns, and may be subject to inspection and treatment on arrival. Please refer to the [Non-Commodity Cargo Clearance BICON](#) case for further information.

**i** You may require a wildlife trade permit and/or other approvals from the Wildlife Trade Office. More information is available on the [International wildlife trade webpage](#).

**What happens next?**  
When you are importing into Australia a departmental officer will assess the risk posed by your import and determine the appropriate outcome to apply. You may use the link below to view the likely outcomes for this particular import scenario. Please be aware that the assessment conducted may result in an outcome that is not listed.

[View Onshore Outcomes](#)

### ① 수입 조건

수입 조건은 수입 시 충족해야 하는 생물보안 요건을 명시하고 있으며 수입 조건은 다음과 같다.

### ② 호주 도착 전 수입 조건

#### 1. 수입 허가서 필요없음

- 호주농수산임업국 수입허가서 필요없음

## 2. 성분 요건

- 제품에는 승인된 생물학적 첨가제에 포함된 식물 유래 성분만 포함되어야 함
- 식품 제품 라벨, 제조업체 신고서 또는 공급업체 신고서에 전체 성분 목록 (총 100%)을 명시해야 함

### ③ 관련정보

표: 제약 부형제

#### 3. 제품은 인체 소비용으로만 사용해야 함

수입업자 신고서에 제품이 인체 소비용임을 명시해야 함

#### 4. 제품은 상업적으로 포장되어 추가 가공 없이 소매 판매가 가능해야 함

### ④ 추가정보

- 2016년 생물보안 부과 관련 일반 규정[Biosecurity Charges Imposition (General) Regulation 2016] 및 2016년 생물보안 규정(Biosecurity Regulation 2016) 제9장 제2절에 따라 호주농수산임업국은 모든 서비스에 대해 수수료를 부과한다. 수수료 및 부담금 적용 방식 관련 세부 사항은 부과 지침(Charging Guidelines)에서 확인할 수 있다.
- 수입되는 상품 조건 외에도 컨테이너 청결 상태, 포장 및 목적지 정보 등 비상품(non-commodity) 관련 사항이 평가되어야 하며, 도착 시 검사 또는 처리 과정을 거칠 수 있다. 추가 정보는 비상품 화물 통관 사례(Non-Commodity Cargo Clearance BICON case)를 참조한다.

## 일본

### [제조업체 고유 기호 제도 신고 데이터베이스]

#### ● 개요

DB명	제조업체 고유 기호 제도 신고 데이터베이스
관리기관	소비자청
DB 내용	제조소의 소재지 및 제조자의 성명 또는 명칭의 표시가 의무이나, 동일한 식품을 2곳 이상의 장소에서 생산하는 경우 신고하여 고유 번호를 부여하는 제도
접속 주소	https://www.caa.go.jp/policies/policy/food_labeling/unique_code
정보 제공 건수	-

#### ● DB 접속 방법

- ‘소비자청’ 접속 후 ‘정책(製作)’ 탭의 ‘식품표시(食品表紙)’ 클릭



- ‘소비자청’ 접속 후 ‘제조소고유기호 신고 정보를 확인하려는 분께’ 탭의 ‘제조소고유기호 제도 신고 데이터베이스’ 클릭



- ‘제조소고유기호 검색(製造所固有記号の検索)’ 버튼 클릭



Part 1 .  
5.기 타

- ‘제조소고유기호(製造所固有記号)’에 입력 후 정보 확인 가능

### 製造所固有記号検索

---

■ 製造所固有記号検索

製造所固有記号 ※入力必須	<input type="text"/> ※完全一致検索
製造者又は販売者	<input type="text"/> ※部分一致検索 <small>※株式会社、(株)、様、株などの法人の形態を示す文字の入力は不要です。</small>
住所	<input type="text"/> ※前方一致検索
履歴を含めて検索	<input type="checkbox"/>


※各検索項目は、単一のキーワードのみ入力が可能です。複数のキーワードによる検索は行えません。  
 ※検索結果が多い場合は、製造所又は販売者、住所を入力し検索してください。

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● 정보 제공 범위

- 법인번호, 제조자, 주소, 고유기호 등 검색 서비스 제공

 예시 | 식품명: 이치란 라멘(イチランラーメン)\_고유번호: IHBK



- ① 법인번호: 0001006278
- ② 제조자 또는 판매자: 주식회사 이치란(株式会社一蘭)
- ③ 주소: 福岡県福岡市博多区中洲5丁目3番2号 一蘭本社ビル
- ④ 제조소고유기호: IHBK
- ⑤ 제조자의 명칭: 주식회사 히가시마루(株式会社ヒガシマル)
- ⑥ 제조소의 소재지: 鹿児島県いちき串木野市西薩町15-2

## ■ 대만

### [ 건강식품 검사등록허가증 정보 조회 ]

#### ● 개요

DB명	건강식품 검사등록허가증 정보 조회
관리기관	위생복지부 식품약물관리서
DB 내용	관련 법규*에 따라 건강식품 검사등록허가증을 취득한 건강식품 정보 제공 * 「건강식품관리법」 제7조에 따라 건강식품 제조·수입 시 위생복지부에 검사등록을 신청하고 허가증을 발급받아야 함
접속 주소	<a href="https://consumer.fda.gov.tw/Food/InfoHealthFood.aspx?noDelD=162">https://consumer.fda.gov.tw/Food/InfoHealthFood.aspx?noDelD=162</a>
정보 제공 건수	424건('24.11. 기준) - 개별심사: 359건 - 규격표준심사: 65건
기타	제품명에 원료 또는 성분명이 사용된 경우 원료 또는 성분명으로 검색 가능하며 영문 제품명 검색란이 제공되지 않아 영문 검색이 제한적임. 제품 등록 상황에 따라 정보가 수시로 업데이트됨

● DB 접속 방법

- ‘식품약물 소비자 카테고리’ 접속 후 ‘통합 조회 서비스(整合查詢服務)’ 클릭



- ‘통합 조회 서비스’ 화면으로 이동 후 ‘1.식품(1.食品)’ 클릭



- ‘식품(食品)’ 화면으로 이동 후 ‘1.승인정보 조회(核可資料查詢)’ 클릭

The screenshot shows the FDA's Integrated Query Service (整合查詢服務) website. The header includes the FDA logo and the text '衛生福利部食品藥物管理署 Food and Drug Administration' and 'FDA 食品藥物消費者專區'. The main navigation bar contains links for '食品', '西藥', '檢驗方法查詢', '食品藥物管理署官網業務專區', and '食品藥物管理署官網法規資訊'. Below this, there are links for '化粧品禁限用成分管理規定' and '人體器官保存庫'. The breadcrumb trail reads '首頁 > 整合查詢服務 > 食品'. The main content area is titled '食品' and contains a table with 7 items. The first item, '核可資料查詢', is highlighted with a blue box.

項次	標題
1	核可資料查詢
2	食品原料整合查詢平臺
3	遠境檢驗不符合食品資訊查詢(另開新視窗)
4	食品法規查詢
5	HACCP 查詢
6	吃的健康
7	食品相關法規暨綠標臺灣查詢(另開新視窗)

- ‘승인정보 조회’ 화면에서 ‘2.건강식품 검사등록허가증 정보 조회(健康食品查驗登記許可證資料查詢)’ 클릭

The screenshot shows the FDA's Integrated Query Service (整合查詢服務) website. The header and navigation bar are identical to the previous screenshot. The breadcrumb trail reads '首頁 > 整合查詢服務 > 食品 > 核可資料查詢'. The main content area is titled '核可資料查詢' and contains a table with 8 items. The second item, '健康食品查驗登記許可證資料查詢', is highlighted with a blue box.

項次	標題
1	食品添加物查驗登記許可證資料查詢
2	健康食品查驗登記許可證資料查詢
3	特定疾病配方食品查驗登記許可證資料查詢
4	輸入錠狀膠囊狀食品查驗登記許可文件資料查詢
5	國產維生素類錠狀膠囊狀食品查驗登記許可證資料查詢
6	基因改造食品原料查驗登記許可證資料查詢
7	Current Approvals of Genetically Modified Food Raw Materials in Taiwan
8	嬰兒與較大嬰兒配方食品查驗登記許可證資料查詢

- ‘건강식품 검사등록허가증 정보 조회’ 접속 완료

The screenshot shows the 'Health Food Inspection Registration Permit Information Query' page. It features a search form with fields for 'Category' (set to 'All'), 'Applicant', 'Health Benefit Item' (set to 'All'), 'Permit Number', 'Chinese Name', and 'Keyword'. Below the form are buttons for 'Search', 'Reset', and 'Export EXCEL'. A filter bar shows 'All (424)', 'Health (359)', and 'Health (65)'. The main content is a table with 5 rows of search results.

項次	許可證字號	中文品名	保健功效	申請商	詳閱
1	衛署健食規字第000001號	濟生活力深海魚油膠囊	調節血脂, 魚油 (規格標準) - 調節血脂	濟生醫藥科技股份有限公司	<a href="#">詳閱</a>
2	衛署健食規字第000003號	台禮精煉魚油膠囊	調節血脂, 魚油 (規格標準) - 調節血脂	台灣禮業股份有限公司	<a href="#">詳閱</a>
3	衛署健食規字第000004號	增樂紅麴膠囊	調節血脂, 紅麴 (規格標準) - 調節血脂	普新科技股份有限公司	<a href="#">詳閱</a>
4	衛署健食規字第000005號	台禮紅麴膠囊	調節血脂, 紅麴 (規格標準) - 調節血脂	台灣禮業股份有限公司	<a href="#">詳閱</a>
5	衛署健食規字第000006號	懷特特寶天然紅麴膠囊	調節血脂功能, 紅麴 (規格標準) - 調節血脂功能	懷特生技新藥股份有限公司	<a href="#">詳閱</a>

- 검색 화면에서 검색어 또는 관련 내용 입력 후 ‘검색(搜尋)’ 버튼 클릭

The screenshot shows the search form with numbered callouts: ① 類別 (Category), ② 申請商 (Applicant), ③ 保健功效項目 (Health Benefit Item), ④ 許可證字號 (Permit Number), ⑤ 中文品名 (Chinese Name), and ⑥ 關鍵字 (Keyword). The 'Search' button is highlighted.

- ① 유형
- ② 신청업체
- ③ 보건효능 항목
- ④ 허가증 번호
- ⑤ 중문 제품명
- ⑥ 키워드

Part 1 .  
5.기 타

○ 검색 결과에서 해당하는 제품의 '상세(하이퍼링크)' 버튼 클릭

**健康食品查驗登記許可證資料查詢**

類別:       許可證字號:

申請商:       中文品名:

保健功效項目:       關鍵字:

項次	許可證字號	中文品名	保健功效	申請商	詳細
1	衛署健食字第 A00070號	如新葛茂益生菌配方 ( 膠囊食品 )	胃腸功能改善	美商如新葛茂股份有限公司台灣分公司	<a href="#">詳細</a>
2	衛署健食字第 A00130號	APF益生菌膠囊	輔助調整過敏體質功能, 免疫調節功能	景岳生物科技股份有限公司	<a href="#">詳細</a>
3	衛署健食字第 A00184號	桂格雙效益生菌高鈣奶粉	調節血脂功能, 胃腸功能改善	佳格食品股份有限公司	<a href="#">詳細</a>
4	衛署健食字第 A00201號	Dr. Hsu益生菌	輔助調整過敏體質, 胃腸功能改善	德和生物科技股份有限公司	<a href="#">詳細</a>
5	衛署健食字第 A00217號	樂亦暢益生菌膠囊	胃腸功能改善	景岳生物科技股份有限公司	<a href="#">詳細</a>

○ 해당 제품의 상세 정보 확인

衛生福利部食品藥物管理署 Food and Drug Administration **整合查詢服務**  
**FDA 食品藥物消費者專區**

食品 ▾ 西藥 ▾ 檢驗方法查詢 食品藥物管理署官網業務專區 食品藥物管理署官網法規資訊 化粧品禁用成分管理規定

人體器官保存庫 ▾

[首頁](#) > [整合查詢服務](#) > [食品](#) > [核可資料查詢](#) > [健康食品查驗登記許可證資料查詢](#)

**健康食品查驗登記許可證資料查詢**

類別:  **桂格雙效益生菌高鈣奶粉**

許可證字號	衛署健食字第A00184號
中文品名	桂格雙效益生菌高鈣奶粉
核可日期	2010/08/04
申請商	佳格食品股份有限公司
現況	核可
保健功效相關成分	極乳酸菌,比菲德氏菌
保健功效	調節血脂功能, 胃腸功能改善
保健功效宣稱	胃腸功能改善: (1)有助於增加腸內益菌。(2)有助於減少腸內害菌。(3)有助於改善腸內細菌菌相。(4)幫助腸道蠕動。調節血脂: 核動物實驗結果: (1)有助於降低低血中總膽固醇。(2)有助於降低低血中低密度脂蛋白膽固醇。(3)有助於降低低血中三酸甘油脂。
警語	有乳糖不耐症者, 食用前請先洽詢醫師或營養師意見。
注意事項	1.請洽詢醫師或營養師有關於食用本產品之意見。均衡的飲食及適當的運動為身體健康的基礎。2.健康食品不具治療、矯正人類疾病之醫療效能。3.本產品供保健用, 請依建議攝取量食用。

● 정보 제공 범위

- 해당 제품의 허가증번호, 중문 제품명, 승인일자, 신청업체, 허가증 현황, 보건효능 관련 성분, 보건효능 등 정보 제공

**예시** | 검색어: 프로바이오틱스

健康食品查驗登記許可證資料查詢	
類別：衛署(部)健食字 桂格雙效益生菌高鈣奶粉	
① 許可證字號	衛署健食字第A00184號
② 中文品名	桂格雙效益生菌高鈣奶粉
③ 核可日期	2010/08/04
④ 申請商	佳格食品股份有限公司
⑤ 證況	核可
⑥ 健功效相關成分	總乳酸菌,比菲德氏菌
⑦ 保健功效	調節血脂功能, 胃腸功能改善
⑧ 保健功效宣稱	胃腸功能改善：(1)有助於增加腸內益菌。(2)有助於減少腸內害菌。(3)有助於改善腸內細菌菌相。(4)幫助腸道運動。調節血脂：經動物實驗結果：(1)有助於降低血中總膽固醇。(2)有助於降低血中低密度脂蛋白膽固醇。(3)有助於降低血中三酸甘油酯。
⑨ 警語	有乳糖不耐症者，食用前請先洽詢醫師或營養師意見。
⑩ 注意事項	1.請洽詢醫師或營養師有關於食用本產品之意見；均衡的飲食及適當的運動為身體健康的基礎。2.健康食品不具治療、矯正人類疾病之醫療效能。3.本產品供保健用，請依建議攝取量食用。

- ① 허가증번호: 위서건식자 제A00184호\*  
\* 하이퍼링크 클릭 시 '건강식품 검사등록허가 정보 요약' pdf 파일 다운로드 가능(원료 성분, 보건효능 성분표, 영양성분표, 안전성 및 기능성 평가 요약 정보 등)
- ② 중문 제품명: 웨이커 더블핏 프로바이오틱스 고칼슘 밀크파우더
- ③ 승인일자: 2010/08/04
- ④ 신청업체: Standard Foods Corporation(佳格食品股份有限公司)
- ⑤ 허가증현황: 승인
- ⑥ 보건효능 관련 성분: 총 유산균, Bifidobacterium bifidum
- ⑦ 보건효능: 혈중지질기능 조절, 위장기능 개선
- ⑧ 보건효능 강조: 위장기능 개선: (1) 장내 유익균 증가에 도움  
(2) 장내 유해균 감소에 도움 (이하 생략)
- ⑨ 경고문구: “유당불내증이 있는 경우 섭취 전 의사나 영양사와 상담하십시오”
- ⑩ 주의사항: “본 제품 섭취와 관련하여 의사나 영양사와 상담하십시오” (이하 생략)

Part 1.  
5.기 타

## [ 수입 정제·캡슐형태 식품 검사등록 허가문서 정보 조회 ]

### ● 개요

<b>DB명</b>	수입 정제·캡슐형태 식품 검사등록 허가문서 정보 조회
<b>관리기관</b>	위생복지부 식품약물관리서
<b>DB 내용</b>	관련 법규*에 따라 검사등록된 수입 정제·캡슐형태 식품 정보 제공 * 「식품안전위생관리법」 제21조 및 위생복지부 2014.1.8 공고에 따라 수입 정제·캡슐형태 식품은 의무 검사등록 대상임
<b>접속 주소</b>	<a href="https://consumer.fda.gov.tw/Food/CapsuleAuditQuery.aspx?nodeID=165">https://consumer.fda.gov.tw/Food/CapsuleAuditQuery.aspx?nodeID=165</a>
<b>정보 제공 건수</b>	7,628건('24.11. 기준)
<b>기타</b>	제품명에 원료 또는 성분명이 사용된 경우 원료 또는 성분명으로 검색 가능하며 제품별 성분을 영문으로 제공하고 있어 영문 검색이 용이함. 제품 등록 상황에 따라 정보가 수시로 업데이트됨

● DB 접속 방법

- ‘식품약품 소비자 카테고리’ 접속 후 ‘통합 조회 서비스(整合查詢服務)’ 클릭



- ‘통합 조회 서비스’ 화면으로 이동 후 ‘1.식품(1.食品)’ 클릭



Part 1.  
5.기 타

- ‘식품(食品)’ 화면으로 이동 후 ‘1.승인정보 조회(核可資料查詢)’ 클릭

The screenshot shows the '食品' (Food) section of the FDA's Integrated Query Service. The page title is '食品' and it features a table with 7 items. The first item, '核可資料查詢' (Approval Information Query), is highlighted with a blue box.

項次	標題
1	核可資料查詢
2	食品原料整合查詢平臺
3	邊境檢驗不符合食品資訊查詢(另開新視窗)
4	食品法規查詢
5	HACCP 查詢
6	吃的健康
7	食品相關法規暨解釋彙編查詢(另開新視窗)

- ‘승인정보 조회’ 화면에서 ‘4.수입 정제·캡슐형태 식품 검사등록 허가문서 정보 조회(輸入錠狀膠囊狀食品查驗登記許可文件資料查詢)’ 클릭

The screenshot shows the '核可資料查詢' (Approval Information Query) section of the FDA's Integrated Query Service. The page title is '核可資料查詢' and it features a table with 8 items. The fourth item, '輸入錠狀膠囊狀食品查驗登記許可文件資料查詢' (Approval Information Query for Imported Tablet and Capsule Food), is highlighted with a blue box.

項次	標題
1	食品添加物查驗登記許可證資料查詢
2	健康食品查驗登記許可證資料查詢
3	特定疾病配方食品查驗登記許可證資料查詢
4	輸入錠狀膠囊狀食品查驗登記許可文件資料查詢
5	國產維生素類錠狀膠囊狀食品查驗登記證資料查詢
6	基因改造食品原料查驗登記許可證資料查詢
7	Current Approvals of Genetically Modified Food Raw Materials in Taiwan
8	嬰兒與較大嬰兒配方食品查驗登記許可證資料查詢

- ‘수입 정제·캡슐형태 식품 검사등록 허가문서 정보 조회’ 접속 완료

衛生福利部食品藥物管理署  
Food and Drug Administration  
FDA 食品藥物消費者專區 **整合查詢服務**

食品 ▾ 西藥 ▾ 檢驗方法查詢 食品藥物管理署官網業務專區 食品藥物管理署官網法規資訊

化粧品禁限用成分管理規定 人體器官保存庫 ▾

首頁 > 整合查詢服務 > 食品 > 核可資料查詢 > 輸入錠狀膠囊狀食品查驗登記許可文件資料查詢

### 輸入錠狀膠囊狀食品查驗登記許可文件資料查詢

核備函字號:  中文品名:

英文品名:  食品申請商:

成分1:  成分2:

成分3:  關鍵字:

共有 7628 筆搜尋結果

項次	核備函字號	中文品名	英文品名	有效日期	申請商名稱
1	1086036857	美樂家勁捷能加強錠狀食品	REPLENEX EXTRA STRENGTH	2030/02/03	美商亞洲美樂家有限公司台灣分公司
2	0980409752	攝健攝聖寶膠囊食品	PROSTAWELL CAPSULE	2030/02/02	安祥生物科技股份有限公司

- 검색 화면에서 검색어 또는 관련 내용 입력 후 ‘검색(搜尋)’ 버튼 클릭

### 輸入錠狀膠囊狀食品查驗登記許可文件資料查詢

① 核備函字號:  ② 中文品名:

③ 英文品名:  ④ 食品申請商:

⑤ 成分1:  ⑥ 成分2:

⑦ 成分3:  ⑧ 關鍵字:

- ① 허가문서번호
- ② 중문 제품명
- ③ 영문 제품명
- ④ 식품 신청업체
- ⑤ 성분1
- ⑥ 성분2
- ⑦ 성분3
- ⑧ 키워드

- 검색 결과에서 해당하는 제품의 '중문 제품명(하이퍼링크)' 버튼 클릭

**輸入錠狀膠囊狀食品查驗登記許可文件資料查詢**

核備函字號:       中文品名:

英文品名:       食品申請商:

成分1:       成分2:

成分3:       關鍵字:

[搜尋](#) [重置](#) [匯出EXCEL](#)

共有 136 筆搜尋結果

項次	核備函字號	中文品名	英文品名	有效日期	申請商名稱
1	1086614926	美國斯旺森特級益生菌	SWANSON PROBIOTIC	2030/01/15	景福國際有限公司
2	1139077541	女性益生菌與甘露糖膠囊	PROBIOLADY MANNOSE	2029/11/13	慧聯國際有限公司
3	1139054568	<a href="#">艾多美 SCI 益生菌膠囊</a>	ATOMY SCI MICROBIOME	2029/11/12	艾多美股份有限公司
4	1086018634	複合益生菌	JAMIESON PROBIOTIC 30B	2029/10/14	好市多股份有限公司
5	1139057423	全效鮮活益生菌100	INTENSE PROBIOTICS 100	2029/10/09	保瑞聯邦股份有限公司
6	1139062373	益生菌膠囊	ACIDOPHILUS CAPSULE	2029/09/06	台灣保立康藥業有限公司

- 해당 제품의 상세 정보 확인

**輸入錠狀膠囊狀食品查驗登記許可文件資料查詢**

類別 - 輸入錠狀膠囊狀食品 **艾多美 SCI 益生菌膠囊**

核備函字號	1139054568
核備函類別	輸入錠狀膠囊狀食品
中文品名	艾多美 SCI 益生菌膠囊
英文品名	ATOMY SCI MICROBIOME
發證日期	2024/11/12
有效日期	2029/11/12
申請商名稱	艾多美股份有限公司
申請商電話	07-9721102
申請商地址	高雄市鼓山區龍德路473號4樓
劑型	
成分	PROBIOTIC BLEND(LACTOBACILLUS RHAMNOSUS · BIFIDOBACTERIUM ANIMALIS SUBSP. LACTIS · LACTOBACILLUS PLANTARUM · LACTOBACILLUS REUTERI · BIFIDOBACTERIUM BREVE · LACTOBACILLUS CASEI · LACTOBACILLUS HELVETICUS · STREPTOCOCCUS THERMOPHILUS),HYDROXYPROPYL METHYLCELLULOSE,INDIGESTIBLE MALTODEXTRIN,RICE BRAN POWDER,FRUCTOOLIGOSACCHARIDES,CALCIUM CARBONATE,LACTOBACILLUS RHAMNOSUS,MAGNESIUM STEARATE,WATER,SACCHAROMYCES CEREVISIAE,CARRAGEENAN,SORBITAN ESTERS OF FATTY ACIDS,MAGNESIUM CHLORIDE,KLUYVEROMYCES MARXIANUS(KLUYVEROMYCES MARXIANUS · MALTODEXTRIN),GLYCEROL,POTASSIUM CHLORIDE,
產地	韓國
證書文件編號	DHC08390545681

● 정보 제공 범위

- 해당 제품의 허가문서번호, 허가문서유형, 중문 및 영문 제품명, 허가문서발급일, 유효일자, 신청업체 정보, 제형, 성분, 원산지 등의 정보 제공



예시 | 검색어: 프로바이오틱스

輸入錠狀膠囊狀食品查驗登記許可文件資料查詢	
類別 - 輸入錠狀膠囊狀食品 艾多美 SCI 益生菌膠囊	
① 核對證字號	1139054568
② 核對證類別	輸入錠狀膠囊狀食品
③ 中文品名	艾多美 SCI 益生菌膠囊
④ 英文品名	ATOMY SCI MICROBIOME
⑤ 發證日期	2024/11/12
⑥ 有效日期	2029/11/12
⑦ 申請商名稱	艾多美股份有限公司
⑧ 申請商電話	07-9721102
⑨ 申請商地址	高雄市鼓山區龍德路473號4樓
⑩ 劑型	
⑪ 成分	PROBIOTIC BLEND(LACTOBACILLUS RHAMNOSUS - BIFIDOBACTERIUM ANIMALIS SUBSP. LACTIS - LACTOBACILLUS PLANTARUM - LACTOBACILLUS REUTERI - BIFIDOBACTERIUM BREVE - LACTOBACILLUS CASEI - LACTOBACILLUS HELVETICUS - STREPTOCOCCUS THERMOPHILUS),HYDROXYPROPYL METHYLCELLULOSE,INDIGESTIBLE MALTODEXTRIN,RICE BRAN POWDER,FRUCTOOLIGOSACCHARIDES,CALCIUM CARBONATE,LACTOBACILLUS RHAMNOSUS,MAGNESIUM STEARATE,WATER,SACCHAROMYCES CEREVISIAE,CARRAGEENAN,SORBITAN ESTERS OF FATTY ACIDS,MAGNESIUM CHLORIDE,KLUYVEROMYCES MARXIANUS(KLUYVEROMYCES MARXIANUS - MALTODEXTRIN),GLYCEROL,POTASSIUM CHLORIDE,
⑫ 產地	韓國
⑬ 證照文件編號	DHC0B390545681

- ① 허가문서번호: 1139054568
- ② 허가문서유형: 수입 정제·캡슐형태 식품
- ③ 중문 제품명: 애터미 SCI 마이크로바이옴(艾多美 SCI 益生菌膠囊)
- ④ 영문 제품명: ATOMY SCI MICROBIOME
- ⑤ 허가문서발급일: 2024/11/12
- ⑥ 유효일자: 2029/11/12
- ⑦ 신청업체 명칭: ATOMY CO., LTD.(艾多美股份有限公司)
- ⑧ 신청업체 전화번호: 07-9721102
- ⑨ 신청업체 주소: 가오슝(高雄)시 구산(鼓山)구 룡더(龍德)로 473호 4층
- ⑩ 제형: -
- ⑪ 성분: PROBIOTIC BLEND (이하 생략)
- ⑫ 원산지: 한국
- ⑬ 통관문서일련번호: DHC0B390545681

## [ 대만산 비타민류 정제·캡슐형태 식품 검사등록증 정보 조회 ]

### ● 개요

<b>DB명</b>	대만산 비타민류 정제·캡슐형태 식품 검사등록증 정보 조회
<b>관리기관</b>	위생복지부 식품약물관리서
<b>DB 내용</b>	<p>관련 법규*에 따라 검사등록된 대만산 비타민류 정제·캡슐형태 식품 정보 제공</p> <p>* 「식품안전위생관리법」 제21조 등에 의거하여 대만산 정제·캡슐형태 식품에 포함된 비타민의 하루 최대섭취량이 '대만산 비타민류 정제·캡슐형태 식품 의무 검사등록 인정 기준표'의 인정 기준범위에 해당하는 경우 검사등록 의무 대상임</p>
<b>접속 주소</b>	<a href="https://consumer.fda.gov.tw/Food/DomesticFormulationsQuery.aspx?nodeID=166">https://consumer.fda.gov.tw/Food/DomesticFormulationsQuery.aspx?nodeID=166</a>
<b>정보 제공 건수</b>	1,519건('24.11. 기준)
<b>기타</b>	제품명에 원료 또는 성분명이 사용된 경우 원료 또는 성분명으로 검색 가능하며 제품별 성분을 중문으로 제공하고 있음. 제품 등록 상황에 따라 정보가 수시로 업데이트됨

● DB 접속 방법

- ‘식품약품 소비자 카테고리’ 접속 후 ‘통합 조회 서비스(整合查詢服務)’ 클릭



- ‘통합 조회 서비스’ 화면으로 이동 후 ‘1.식품(1.食品)’ 클릭



Part 1.  
5.기 타

- ‘식품(食品)’ 화면으로 이동 후 ‘1.승인정보 조회(核可資料查詢)’ 클릭

The screenshot shows the FDA Integrated Query Service (整合查詢服務) website. The header includes the FDA logo and the text '衛生福利部食品藥物管理署 Food and Drug Administration FDA 食品藥物消費者專區'. The main navigation bar contains links for '食品', '西藥', '檢驗方法查詢', '食品藥物管理署官網業務專區', and '食品藥物管理署官網法規資訊'. Below this, there are links for '化粧品禁限用成分管理規定' and '人體器官保存庫'. The breadcrumb trail shows '首頁 > 整合查詢服務 > 食品'. The main content area is titled '食品' and contains a table with the following items:

項次	標題
1	核可資料查詢
2	食品原料整合查詢平臺
3	邊境檢驗不符合食品資訊查詢(另開新視窗)
4	食品法規查詢
5	HACCP 查詢
6	吃的健康
7	食品相關法規暨解釋彙編查詢(另開新視窗)

- ‘승인정보 조회’ 화면에서 ‘5.대만산 비타민류 정제·캡슐 형태 식품 검사등록증 정보 조회(國產維生素類錠狀膠囊狀食品查驗登記證資料查詢)’ 클릭

The screenshot shows the FDA Integrated Query Service website with the '核可資料查詢' (Approval Information Query) menu selected. The breadcrumb trail shows '首頁 > 整合查詢服務 > 食品 > 核可資料查詢'. The main content area is titled '核可資料查詢' and contains a table with the following items:

項次	標題
1	食品添加物查驗登記許可證資料查詢
2	健康食品查驗登記許可證資料查詢
3	特定疾病配方食品查驗登記許可證資料查詢
4	輸入錠狀膠囊狀食品查驗登記許可文件資料查詢
5	國產維生素類錠狀膠囊狀食品查驗登記證資料查詢
6	基因改造食品原料查驗登記許可證資料查詢
7	Current Approvals of Genetically Modified Food Raw Materials in Taiwan
8	嬰兒與較大嬰兒配方食品查驗登記許可證資料查詢

- ‘대만산 비타민류 정제·캡슐형태 식품 검사등록증 정보 조회’ 접속 완료

The screenshot shows the 'Integrated Query Service' (整合查詢服務) page on the FDA website. The search results are for 'Domestic Vitamin-like Capsule Food Inspection Registration Information Query' (國產維生素類錠狀膠囊狀食品查驗登記證資料查詢). The search criteria include:
 

- Inspection Registration No.: 1086615946
- Chinese Name: 持續型B12糖衣錠
- English Name: Hydro B12 S.C.Tablets
- Applicant: 井田生化科技股份有限公司
- Valid Date: 2030/02/04

 A second result is also visible:
 

- Inspection Registration No.: 1086612345
- Chinese Name: 綜合B群複方錠
- English Name: B-Complex Tablets
- Applicant: 永信藥品工業股份有限公司
- Valid Date: 2030/01/17

- 검색 화면에서 검색어 또는 관련 내용 입력 후 ‘검색(搜尋)’ 버튼 클릭

The screenshot shows the search form with numbered callouts:
 

- ① 查驗登記證號 (Inspection Registration No.)
- ② 中文品名 (Chinese Name)
- ③ 英文品名 (English Name)
- ④ 食品申請商 (Food Applicant)
- ⑤ 成分1 (Ingredient 1)
- ⑥ 成分2 (Ingredient 2)
- ⑦ 成分3 (Ingredient 3)
- ⑧ 關鍵字 (Keyword)

- ① 검사등록증번호
- ② 중문 제품명
- ③ 영문 제품명
- ④ 식품 신청업체
- ⑤ 성분1
- ⑥ 성분2
- ⑦ 성분3
- ⑧ 키워드

Part 1.  
5.기 타

○ 검색 결과에서 해당하는 제품의 '중문 제품명(하이퍼링크)' 버튼 클릭

**國產維生素類錠狀膠囊狀食品查驗登記證資料查詢**

查驗登記證號:       中文品名:

英文品名:       食品申請商:

成分1:       成分2:

成分3:       關鍵字:

[搜尋](#) [重置](#) [匯出EXCEL](#)

共有 **06** 筆搜尋結果

序次	查驗登記證號	中文品名	英文品名	有效日期	申請商名稱
1	1139066811	<a href="#">Relove 維生素C膠囊</a>	Relove- Acerola Cherry Vitamin C capsule	2029/11/05	大江生醫股份有限公司
2	1139062034	<a href="#">維生素C500純素膠囊</a>		2029/10/28	亨亨生醫有限公司
3	1086606406	<a href="#">維生素C糖衣錠 100毫克</a>	Vitamin C Sugar Coated Tablets 100mg	2029/09/24	康供實業股份有限公司
4	1139050563	<a href="#">維生素C錠500mg</a>		2029/09/09	利康製藥股份有限公司
5	1139035222	<a href="#">哈克蘇康-維生素C口含錠(葡萄口味)</a>	HAC-Vitamin C Troches(Grape Flavor)	2029/09/03	永信藥品工業股份有限公司

○ 해당 제품의 상세 정보 확인

**國產維生素類錠狀膠囊狀食品查驗登記證資料查詢**

類別: 國產維生素類錠狀膠囊狀食品 **Relove 維生素C膠囊**

查驗登記證號	1139066811
查驗登記類別	國產維生素類錠狀膠囊狀食品
中文品名	Relove 維生素C膠囊
英文品名	Relove- Acerola Cherry Vitamin C capsule
發證日期	2024/11/05
有效日期	2029/11/05
申請商名稱	大江生醫股份有限公司
申請商電話	02-87977811
申請商地址	台北市內湖區港墘路187號8樓
劑型	
成分	L-抗壞血醇,難消化性麥芽糊精,複合維生素C粉(L-抗壞血醇,難消化性麥芽糊精,中鏈三酸甘油酯,硬脂鈣,卵磷脂,植物園醇),鈉糖苷鈉,西印度櫻桃果汁粉(西印度櫻桃濃縮汁,麥芽糊精),硬脂鈣,硬脂醇錫,米草提取物(含神經醇酸)[環狀糊精,米草提取物(含神經醇酸)],薔薇草提取物,膠囊殼(羟丙基中羧纖維素,水,羧甲基澱粉,氧化鈣),

● 정보 제공 범위

- 해당 제품의 검사등록증번호 및 유형, 중문 및 영문 제품명, 검사등록증발급일, 유효일자, 신청업체 정보, 제형, 성분 등의 정보 제공



예시 | 검색어: 비타민 C

國產維生素類錠狀膠囊狀食品查驗登記證資料查詢	
類別: 國產維生素錠狀膠囊狀食品 <b>Relove 維生素C膠囊</b>	
① 查驗登記證號	1139066811
② 查驗登記類別	國產維生素錠狀膠囊狀食品
③ 中文品名	Relove 維生素C膠囊
④ 英文品名	Relove- Acerola Cherry Vitamin C capsule
⑤ 發證日期	2024/11/05
⑥ 有效日期	2029/11/05
⑦ 申請商名稱	大江生醫股份有限公司
⑧ 申請商電話	02-87977811
⑨ 申請商地址	台北市內湖區港墘路187號8樓
⑩ 劑型	
⑪ 成分	L-抗壞血酸, 腸消化性麥芽糊精, 複合維生素C粉(L-抗壞血酸, 腸消化性麥芽糊精, 中鏈三酸甘油酯, 磷酸鈣, 卵磷脂, 植物固醇), 殼聚糖, 西印度櫻桃果汁粉(西印度櫻桃濃縮汁, 麥芽糊精), 磷酸鈣, 硬脂酸鎂, 米苳取物(含神經醯胺)[環狀糊精, 米苳取物(含神經醯胺)], 薑黃萃取粉, 膠囊殼(羟丙基甲基纖維素, 水, 鹿角菜膠, 氯化鉀).

- ① 검사등록증번호: 1139066811
- ② 검사등록증유형: 대만산 비타민 정제·캡슐형태 식품
- ③ 중문 제품명: Relove 비타민 C 캡슐(Relove 維生素C42膠囊)
- ④ 영문 제품명: Relove- Acerola Cherry Vitamin C capsule
- ⑤ 검사등록증발급일: 2024/11/05
- ⑥ 유효일자: 2029/11/05
- ⑦ 신청업체 명칭: TCI Co.,Ltd.(大江生醫股份有限公司)
- ⑧ 신청업체 전화번호: 02-87977811
- ⑨ 신청업체 주소: 타이페이(台北)시 네이후(內湖)구 강첸(港墘)로 187호 8층
- ⑩ 제형: -
- ⑪ 성분: L-아스코르브산, 난소화성 말토덱스트린, 복합 비타민 C 분말 (이하 생략)

● Ministry of Food and Drug Safety



## Part II.



# 기능성 원료 안전성 확인 DB



## 미국

### [ Food, Herbs & Supplements ]

#### ● 개요

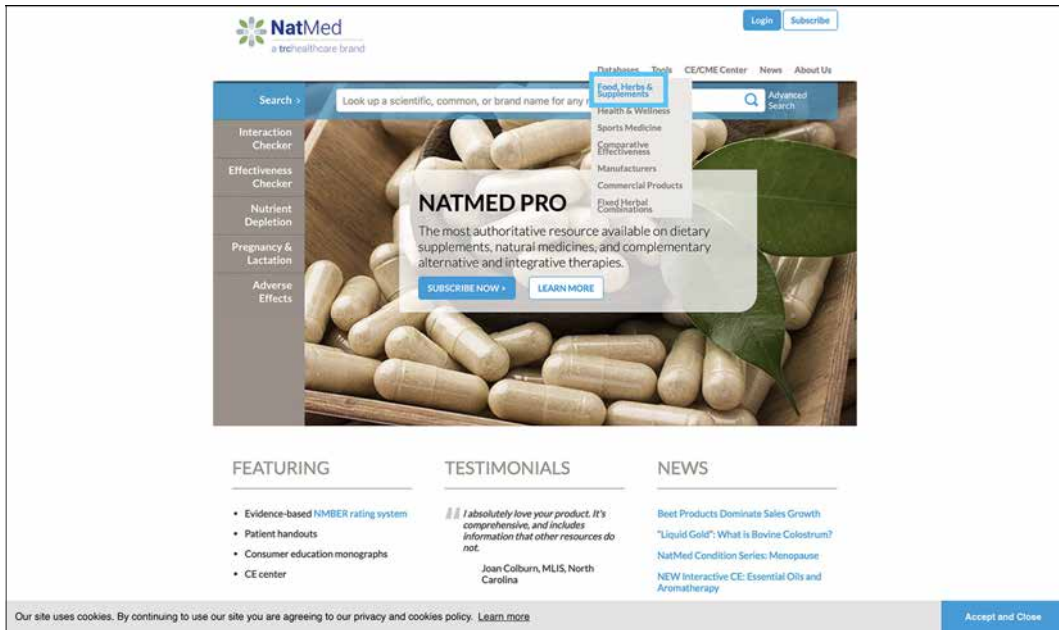
DB명	Food, Herbs & Supplements[Natural Medicines(NMCD)]
관리기관	Therapeutic Research Center
DB 내용	식품에 사용 가능한 원료, 안전성 미확인으로 사용 불가한 원료 정보를 제공하나 유료 회원 가입이 필요함
접속 주소	https://naturalmedicines.therapeuticresearch.com/databases/food,-herbs-supplements.aspx
정보 제공 건수	약 1,277건('24.11. 기준)

#### ● DB 접속 방법

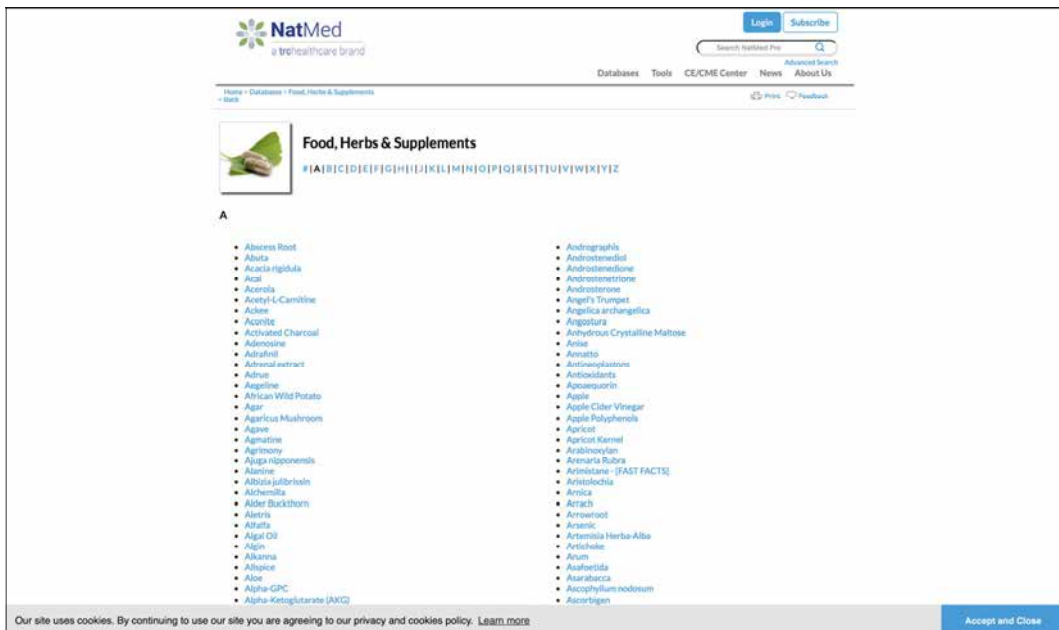
- 'NatMed a trchealthcare brand' 홈페이지에 접속 후 'Database' 클릭

The screenshot shows the NatMed website homepage. At the top, there is a search bar and navigation links for 'Databases', 'Tools', 'CE/CME Center', 'News', and 'About Us'. The main content area features a large banner for 'NATMED PRO' with the text 'The most authoritative resource available on dietary supplements, natural medicines, and complementary alternative and integrative therapies.' and a 'SUBSCRIBE NOW' button. Below the banner, there are three columns: 'FEATURING' (listing NMBER rating system, Patient handouts, Consumer education monographs, and CE center), 'TESTIMONIALS' (featuring a quote from Vincent T. DeVita Jr., MD), and 'NEWS' (listing articles like 'Beet Products Dominate Sales Growth' and 'Liquid Gold'). A footer contains a cookie consent message: 'Our site uses cookies. By continuing to use our site you are agreeing to our privacy and cookies policy. Learn more.' and an 'Accept and Close' button.

○ ‘Database’에서 ‘Food, Herbs & Supplements’ 클릭



○ ‘Food, Herbs & Supplements’에서 알파벳 순으로 탐색 가능



Part II.  
기초성 원료 안전성 확인 DB

## [ AHP(American Herbal Pharmacopoeia) – Order Monographs ]

### ● 개요

DB명	Order Monograph
관리기관	AHP(American Herbal Pharmacopoeia)
접속 주소	https://herbal-ahp.org/
기타	유료 회원 가입이 필요함

### ● DB 접속 방법

- ‘AHP’ 홈페이지에 접속 후 ‘PUBLICATIONS’ 클릭



- ‘PUBLICATIONS’ – ‘ORDER MONOGRAPHS’ 클릭 후 원료명을 알파벳 순으로 검색



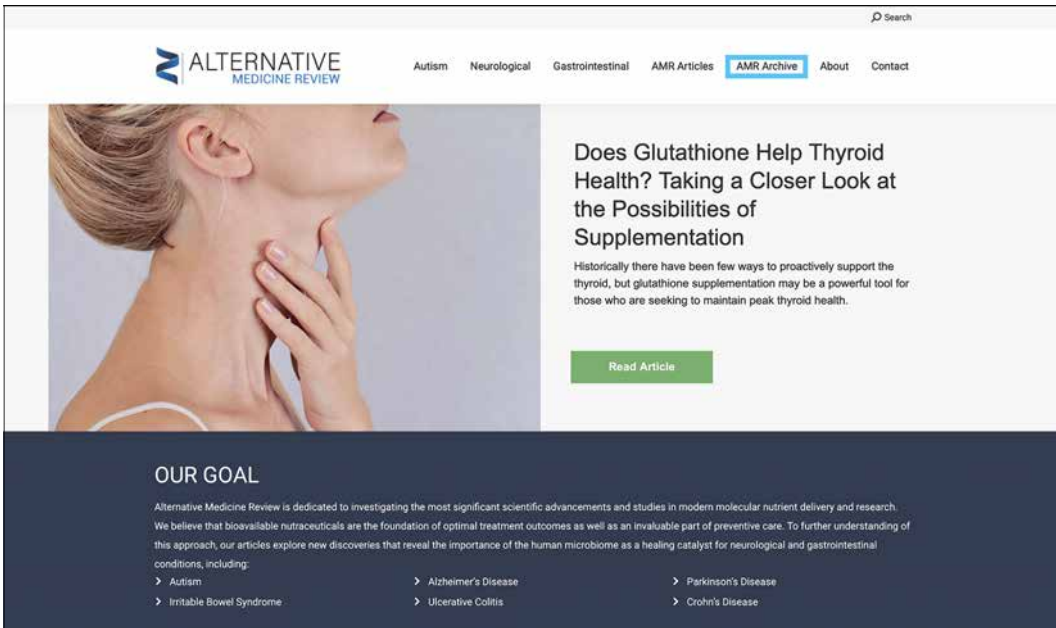
## [ AMR(Alternative Medicine Review) ARCHIVE ]

### ● 개요

DB명	AMR ARCHIVE
관리기관	Alternative Medicine Review
DB 내용	영양성분 소개 문헌 또는 영양성분에 대한 연구 논문 다운로드 가능
접속 주소	https://altmedrev.com/resources/
정보 제공 건수	111건('24.11. 기준)

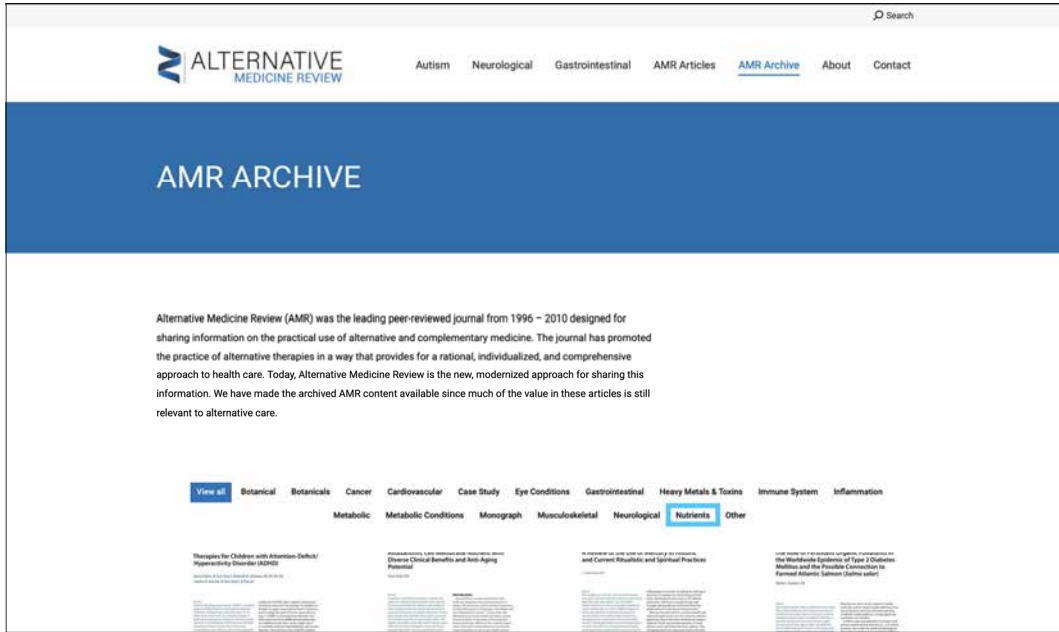
### ● DB 접속 방법

- 'Alternative Medicine Review' 홈페이지에서 'AMR Archive' 클릭

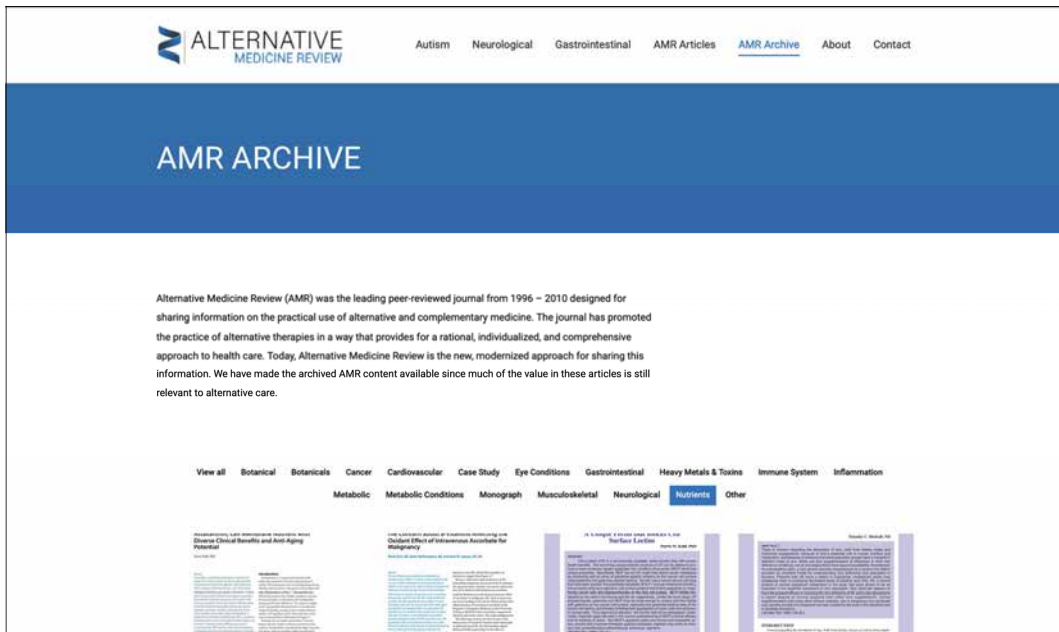


The screenshot shows the homepage of the Alternative Medicine Review website. The navigation menu includes 'Autism', 'Neurological', 'Gastrointestinal', 'AMR Articles', 'AMR Archive' (highlighted), 'About', and 'Contact'. The main content area features a large image of a woman's neck and a text box with the title 'Does Glutathione Help Thyroid Health? Taking a Closer Look at the Possibilities of Supplementation'. Below the title is a short paragraph and a 'Read Article' button. At the bottom, there is a dark blue section titled 'OUR GOAL' with a brief description of the website's mission and a list of conditions: Autism, Irritable Bowel Syndrome, Alzheimer's Disease, Ulcerative Colitis, Parkinson's Disease, and Crohn's Disease.

○ ‘AMR Archive’ 화면에서 ‘Nutrients’ 선택



○ ‘Nutrients’에서 원하는 원료명을 찾아서 클릭



Part II  
기능성 원료 안전성 확인 DB

- 원하는 원료에 대한 문헌을 클릭한 후 ‘Download’ 클릭

The screenshot shows the website 'ALTERNATIVE MEDICINE REVIEW'. The main article title is 'PROBIOTICS IN HEALTH MAINTENANCE AND DISEASE PREVENTION'. Below the title, there are social media sharing icons for Facebook, Twitter, and LinkedIn. The abstract text is visible, and a blue button labeled 'Download PDF' is positioned to the right of the abstract. The website header includes a search bar and a navigation menu with links for Autism, Neurological, Gastrointestinal, AMR Articles, AMR Archive, About, and Contact.

- 해당 원료의 상세 정보 확인

The screenshot shows the full article page. The title is 'Probiotics in Health Maintenance and Disease Prevention'. The authors listed are Jeanne A. Drisko, MD, CNS; Cheryl K. Giles, MD; and Bette J. Bischoff, RD. The page is categorized as a 'Review' and 'Probiotics'. The abstract text is provided, followed by an 'Introduction' section. The authors' contact information and affiliations are listed at the bottom of the page.

**Abstract**  
 Probiotic microflora display numerous health benefits beyond providing basic nutritional value. They cooperatively maintain a delicate balance between the gastrointestinal tract and immune system. When this balance is disrupted, disease and inflammation result. Inflammation and over stimulation of the immune system by pathogenic bacteria are competitively inhibited by mucosal adherence of normal beneficial microflora. A healthy gastrointestinal tract with adequate mucus production and appropriate bacterial colonization prevents the overgrowth of pathogenic bacteria, modulates disease processes, and prevents widespread inflammatory disorders. The understanding of the function of probiotics in the maintenance of health and their importance in preventing disease serves to enhance the overall health of patients. With increasing understanding that beneficial microbes are required for health maintenance and disease prevention, probiotics may be commonly used as a therapeutic tool by health care practitioners in the not-too-distant future. This article presents a review of probiotics in health maintenance and disease prevention. (Altern Med Rev 2003;8(2):143-155)

**Introduction**  
 In the late nineteenth century, microbiolo-

were termed probiotics. Probiotics, literally meaning "for life," are microorganisms proven to exert health-promoting influences in humans and animals.<sup>1</sup> For example, Metchnikoff discovered and promoted *Lactobacillus bulgaricus* as an aid in souring milk products to extend their shelf life. Tissier demonstrated that Bifidobacteria were helpful in treating infant diarrhea.<sup>2</sup>

Interest continues today as recent technological advances have enabled microorganisms to be isolated and colonized to determine their specific therapeutic properties.<sup>3,4</sup> Studies show these microflora are capable of providing numerous health benefits beyond basic nutritional value.<sup>5-15</sup>

In 1994, the World Health Organization deemed probiotics to be the next-most important immune defense system when commonly prescribed antibiotics are rendered useless by antibiotic resistance.<sup>6</sup> The use of probiotics in antibiotic resistance is termed microbial interference therapy. With increasing understanding that beneficial microbes are required for health, probiotics may become a common therapeutic tool used by health care practitioners in the not-too-distant future.

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 Correspondence address: 3901 Rainbow Blvd, Kansas City, Kansas 68150  
 E-mail: jdrisko@kumc.edu

Cheryl Giles, MD – Graduate of University of Kansas School of Medicine; residency at Northeast Iowa Family

● 정보 제공 범위

- 원료별 논문에서 원료의 효과와 검증된 연구 결과를 제공



예시 | 원료명: 프로바이오틱스

Review Probiotics

### Probiotics in Health Maintenance and Disease Prevention

Jeanne A. Drisko, MD, CNS;  
Cheryl K. Giles, MD; Bette J. Bischoff, RD

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**Abstract**  
Probiotic microflora display numerous health benefits beyond providing basic nutritional value. They cooperatively maintain a delicate balance between the gastrointestinal tract and immune system. When this balance is disrupted, disease and inflammation result. Inflammation and over stimulation of the immune system by pathogenic bacteria are competitively inhibited by mucosal adherence of normal beneficial microflora. A healthy gastrointestinal tract with adequate mucus production and appropriate bacterial colonization prevents the overgrowth of pathogenic bacteria, modulates disease processes, and prevents widespread inflammatory disorders. The understanding of the function of probiotics in the maintenance of health and their importance in preventing disease serves to enhance the overall health of patients. With increasing understanding that beneficial microbes are required for health maintenance and disease prevention, probiotics may be commonly used as a therapeutic tool by health care practitioners in the not-too-distant future. This article presents a review of probiotics in health maintenance and disease prevention.  
*(Altern Med Rev 2003;8(2):143-155)*

**1 Introduction**  
In the late nineteenth century, microbiologists identified microflora in the gastrointestinal tracts of healthy individuals that differed from those found in diseased individuals. The beneficial microflora found in the gastrointestinal tract

were termed probiotics. Probiotics, literally meaning "for life," are microorganisms proven to exert health-promoting influences in humans and animals.<sup>1</sup> For example, Metchnikoff discovered and promoted *Lactobacillus bulgaricus* as an aid in souring milk products to extend their shelf life. Tissier demonstrated that Bifidobacteria were helpful in treating infant diarrhea.<sup>2</sup>

Interest continues today as recent technological advances have enabled microorganisms to be isolated and colonized to determine their specific therapeutic properties.<sup>3,4</sup> Studies show these microflora are capable of providing numerous health benefits beyond basic nutritional value.<sup>5,11</sup>

In 1994, the World Health Organization deemed probiotics to be the next-most important immune defense system when commonly prescribed antibiotics are rendered useless by antibiotic resistance.<sup>7</sup> The use of probiotics in antibiotic resistance is termed microbial interference therapy. With increasing understanding that beneficial microbes are required for health, probiotics may become a common therapeutic tool used by health care practitioners in the not-too-distant future.

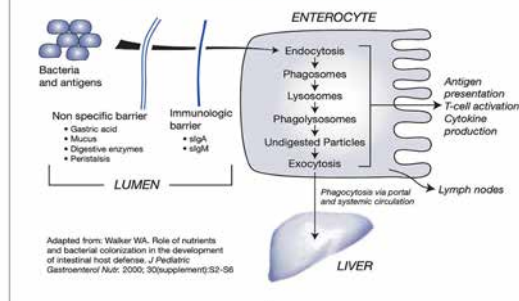
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Correspondence address: 3901 Rainbow Blvd, Kansas City, Kansas 66160.  
E-mail: jdrisko@kumc.edu

Cheryl Giles, MD – Graduate of University of Kansas School of Medicine, residency at Northeast Iowa Family Practice in Waterloo, Iowa.

Bette Bischoff, RD – Certified Diabetes Educator, research University of Kansas on irritable bowel syndrome.

Figure 1. Barriers to Antigenic Absorption in the Intestine



### 2 Colonization

The protective and immune barrier of the human gastrointestinal (GI) tract is diverse. It includes the epithelial layer, the mucous layer, the mechanics of peristalsis and desquamation, and actions of secretory IgA, all of which impact bacterial attachment (Figure 1).<sup>1</sup> After attachment, colonic bacteria are prevented from mixing with the host's eukaryotic cells by the epithelial layer, which acts as a vital barrier to invasion.<sup>16</sup> The barrier's healthy structure and proper functioning are essential for the health of the human host. In this complex system, the delicate balance between the gastrointestinal tract and the microflora is cooperatively maintained.

The GI tract is sterile until an infant ingests vaginal and fecal microflora at delivery.<sup>17</sup> The population of microflora in the infant GI tract is further enhanced by feeding. The breast-fed infant contains a colon population of 10<sup>11</sup> percent

Bifidobacteria with some Enterobacteriaceae and Enterococci present, but virtually no Bacteroides, Staphylococci, Lactobacilli, or Clostridia. In contrast, Bifidobacteria do not predominate in the bottle-fed infant. Breast-fed infants switched to cow's milk or solid foods colonize Bifidobacteria, Clostridia, Lactobacilli, Bacteroides, Streptococci, and enterics.<sup>17</sup>

The type and number of indigenous microflora increase distally along the length of the gastrointestinal tract.<sup>2,18</sup> The upper GI tract has relatively fewer bacteria secondary to saliva production and increased intestinal motility, which effectively move bacteria along the intestine and prevent large numbers from adhering to mucosal surfaces. In addition, gastric acid suppresses growth in the stomach. The relatively sparse flora of the upper intestine generally numbers less than 10<sup>8</sup> colony forming units (cfu) per milliliter (mL) of contents, until the mid ileum where the population increases to 10<sup>10</sup> cfu/mL of contents.

indicating a shift toward the flora that heavily populates the colon.<sup>2,18</sup>

Favorable characteristics found in probiotics colonizing the human gut are exhibited by *Lactobacillus plantarum*, *L. rhamnosus*, *L. reuteri*, and *L. agilis*.<sup>2</sup> However, these Lactobacilli species are scarce in people living in industrialized nations. *L. plantarum* is carried by 25 percent of the general population in the United States; whereas, nearly 100 percent of the population in Africa and Asia are colonized with favorable Lactobacilli species. The most significant reason is that a Western diet contains drastically decreased amounts of Lactobacilli.<sup>2</sup>

To qualify as a beneficial microflora, the following criteria must be met: (1) it must be acid and bile resistant; (2) it must be metabolically active in the GI tract; (3) it must be able to adhere to the GI tract; (4) it must possess antimicrobial activity toward pathogenic bacteria; and (5) it must reduce colon pH.<sup>2,9,19</sup> There are several species of Lactobacilli and Bifidobacteria within this milieu possessing complex enzymes and functions that have the potential to either benefit or harm the health of the host.<sup>20</sup> When there are alterations in the gastrointestinal barrier or in the composition of the microflora of the gut, there is opportunity for resultant malfunction and disease. For instance, overgrowth of one bacterial species can upset the ecosystem of the gut and result in derangement of beneficial characteristics.

Overgrowth of one bacterial species or imbalances in microflora resulting from a disturbed mucosal layer can alter digestive function, intestinal products, and/or immunological function.<sup>20</sup> In addition, a defective epithelial layer can allow bacteria to gain entry into the human host. This breach can arouse an inflammatory response in the host that has the potential to further alter normal function.

### 3 Function of the Gut

Colonization of the gut with appropriate microflora contributes to its ability to function normally. Commensal microflora byproducts contribute to the health of the intestinal tract and include short-chain fatty acids (SCFA), polyamines,

vitamins, antioxidants, and amino acids.<sup>1,20</sup> For example, the SCFA butyric acid, derived from carbohydrate fermentation, provides the main fuel for colonocytes in the large intestine. In addition, Lactobacillus species can prevent food decay, preserve antioxidants and vitamins, remove toxic food components, and prevent pathogenesis of Enterobacteriaceae, *S. aureus*, and Enterococci found in fermented foods.

Probiotics modulate not only the endogenous flora of the GI tract, but also the immune system.<sup>10,13,21</sup> Lactobacilli augment both cellular and humoral immunity.<sup>22</sup> Lactic acid-producing bacteria stimulate various aspects of the immune system, including phagocytic function of macrophages, natural killer cells, monocytes, and neutrophils.

Following a rotavirus vaccination, Lactobacillus GG induce IgM-secreting cells and improve IgA seroconversion, which enhances immunoglobulin response to vaccines.<sup>23</sup> In addition, IgA response to rotavirus is enhanced by administration of Lactobacillus GG.<sup>17</sup> These reports confirm the positive effects of probiotics on innate and acquired immune enhancement, most likely resulting from an ability to bind to gut epithelium. After binding, antibody production is stimulated and the complement and reticuloendothelial system is activated. The interaction between probiotics and epithelial cells has been termed bacterial-epithelial cross-talk.<sup>16</sup> In another study, Lactobacillus GG enhanced the antibody response in adults receiving a typhoid vaccination.<sup>22</sup>

Another example of a probiotic enhancing the immune response can be seen in the activation of the reticuloendothelial system and complement cascade by *Saccharomyces boulardii*.<sup>17</sup> Clearly, interaction of commensal gastrointestinal flora with the gut-associated immune system is an important key in maintaining normal immune function.

#### 4 The Effect of Probiotics on Pathogenic Bacteria

Probiotics reduce plasma levels of bacterial endotoxin concentrations, at least in part, by inhibiting translocation of bacteria across the GI lumen into the bloodstream.<sup>20</sup> Lactobacillus colonization in germ-free rats has been shown to decrease gut permeability to mannitol.<sup>11</sup> In addition, administration of Lactobacillus to interleukin-10 knockout mice decreased translocation of bacteria to extraintestinal sites and reduced myeloperoxidase concentrations, often associated with inflammation in the bowel.<sup>21</sup>

Decreases in translocation of bacteria may occur as a result of the ability of probiotics to tighten the mucosal barrier.<sup>18</sup> Although very little is known about specific molecular mechanisms by which indigenous flora tighten the mucosal barrier, this may be accomplished by bacterial-epithelial cross-talk and up-regulation of growth factors and receptor sites. Whatever the method of barrier to bacterial entry, the net effect is to modulate systemic intestinal allergy and inflammation. Allergy-induced intestinal inflammation mediated by fecal tumor necrosis factor- $\alpha$  is decreased by Lactobacillus GG. Lactobacillus GG also increases mucosal regeneration and reduces fecal urease production, a correlate of inflammation associated with chronic arthritis.<sup>17</sup>

There are several ways probiotic microflora can prevent pathogenic bacteria from adhering and colonizing gut mucosa. Probiotics disallow colonization by disease-provoking bacteria through competition for nutrients, immune system up-regulation, production of antitoxins,<sup>24</sup> and up-regulation of intestinal mucin genes.<sup>14</sup> Increased mucous production prevents adherence and colonization by competing microflora, thereby preventing imbalances.

Probiotics lower colon luminal pH and foster growth of non-pathogenic commensal bacteria by SCFA production.<sup>2</sup> One SCFA, acetic acid, has antimicrobial activity against molds, yeasts, and bacteria.<sup>25</sup> In addition, probiotics exert protective effects through production of hydrogen peroxide and benzoic acid, which inhibit many

Probiotics can also reduce the growth of *Clostridium difficile* and alter toxin receptors for *C. difficile* toxin-A through enzymatic actions on the receptor.<sup>17</sup>

The inhibition of pathogenic bacteria by probiotics is an orchestrated combination of structure and function. Interestingly, bacteriocins – antibacterial compounds produced by *L. acidophilus* – are antagonistic within a specific spectrum by inhibiting other strains of Lactobacilli. Therefore, the practice of combining probiotics needs to include beneficial bacteria that do not inhibit other included strains.<sup>26</sup>

Adherence of normal, beneficial flora competitively inhibits colonization of the mucosa by pathogenic bacteria and reduces over-stimulation of the immune system. A healthy colon with adequate mucus production and appropriate bacterial colonization prevents the adherence of pathogenic bacteria, modulates disease processes, and prevents widespread inflammatory disorders.

#### 5 Probiotics in Specific Disorders

Recent advances have been made in the understanding of when to use probiotics and how they impact specific pathological states. Increasing numbers of animal and human studies point to appropriate uses of probiotics as therapeutic agents in myriad conditions. Tables 1a and 1b summarize specific probiotics and their uses.

##### Inflammation/Arthritis

Probiotic supplementation has both direct and indirect effects. Probiotics exhibit direct effects locally in the GI tract, including modulation of resident bacterial colonies and vitamin production. There are also indirect effects exerted at sites outside the GI tract, including the joints, lungs, and skin. Indirect effects most likely result from an impact on immunity, via changes in inflammatory mediators such as cytokines. Modulation of inflammatory responses may be related to regulating or modulating the immune system both locally in the GI tract and systemically.

It is speculated that inflammation associated with rheumatoid arthritis may be modulated

probiotics appear to benefit viral diarrhea, possibly by increasing secretory IgA and decreasing viral shedding, suggesting an immunological mechanism. Although numerous strains of probiotics, doses, and different populations in these studies make generalizations difficult, it is clear probiotic agents are becoming an important tool in the treatment of gastrointestinal problems in infants and children.

Although gastroenteritis as the cause of acute diarrhea may heal spontaneously within a few days, it can be associated with morbidity and increased direct and indirect medical costs.<sup>24</sup> Acute diarrheal episodes can be related to viral, bacterial, or parasitic pathogens. Several studies have demonstrated improvement when acute diarrheal disorders, including rotavirus infection, traveler's diarrhea, and more serious bacterial infections such as *Clostridium difficile*, are treated with probiotics.<sup>7,22,24,30,41</sup> Importantly, studies using Lactobacillus species or *Saccharomyces boulardii* suggest a beneficial role during *C. difficile*-related infections.<sup>22,29,40,42-46</sup> In populations with small bowel bacterial overgrowth, and in particular those with short bowel syndrome, Lactobacillus species were shown to be efficacious in ameliorating the symptom complex.<sup>22,47</sup> However, in 10 patients during a seven-day, double-blind, randomized trial comparing antibiotic therapy to *Saccharomyces boulardii*, *S. boulardii* was ineffective in eliminating overgrowth of small bowel intestinal bacteria once it was established.<sup>24</sup>

*In vitro* studies demonstrate probiotic agents inhibit adherence of dysbiotic organisms to intestinal epithelial cells. This inhibition is hypothesized to be mediated through the ability to increase expression of MUC2 and MUC3 intestinal mucins.<sup>14</sup> Bacterial-to-epithelial cell binding is a multi-stage process, the first stage of which is characterized by an initial interaction of bacteria with the enterocyte layer. Probiotics increase intestinal mucin production, which prevents the attachment of enteropathogens. The attachment could be prevented by steric hindrance (a slight structural difference in the bacterial ligand interfering with proper attachment to the receptor) or through competitive inhibition for attachment sites

on mucins mimicking epithelial cell bacterial attachment sites. Enhancement of innate defense mechanisms in the gastrointestinal tract, such as mucin production, might be preventive or therapeutic, but this remains to be elucidated.

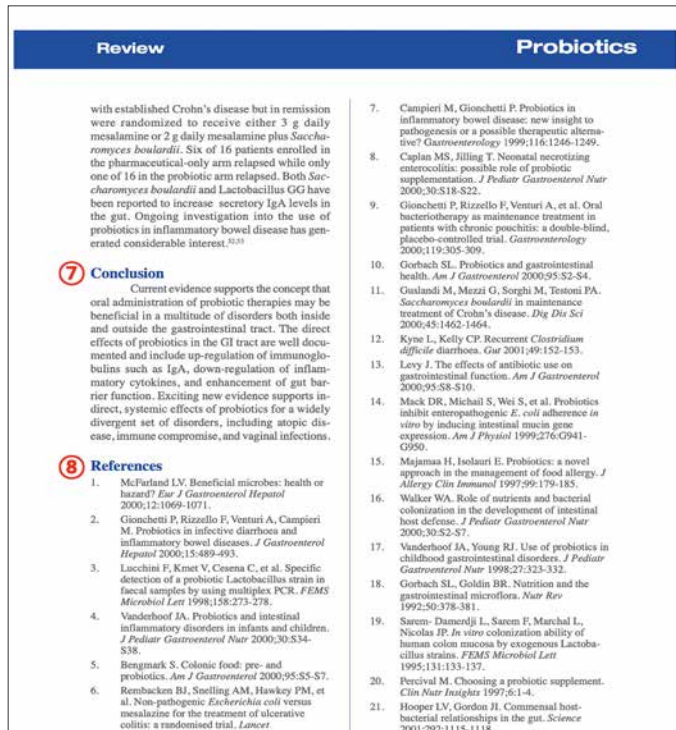
#### 6 Helicobacter pylori Infections

Evidence for the use of probiotics in the treatment of *Helicobacter pylori* infection has been conflicting. *H. pylori* may not always be eradicated with antibiotics and acquisition of resistance is often a serious problem. Aiba et al showed *Lactobacillus salivarius* capable of producing high amounts of lactic acid, which can inhibit the growth of *H. pylori* *in vitro*.<sup>23</sup> This was subsequently confirmed *in vivo* in a murine model. The authors concluded probiotics could be effective against *H. pylori*. It was found that the higher the level of lactic acid production by Lactobacillus, the more potent was the effect on reducing *H. pylori*'s urease activity. In addition, the number of *H. pylori* colonies decreased to an undetectable level with regression of inflammation in some of the treated mice.

When comparing *Lactobacillus acidophilus*, *L. casei*, and *L. salivarius*, *L. acidophilus* specifically was unable to suppress *H. pylori* *in vivo*, possibly due to a low level of lactic acid production resulting from poor colonization and growth in the stomach. *Lactobacillus salivarius* was found to be most effective. This is consistent with a human clinical trial that reported oral administration of *L. acidophilus* was unable to suppress *H. pylori* or reduce inflammation in patients with *H. pylori*-positive gastritis.<sup>48</sup> Identification of appropriate strains with increased adherence and lactic acid production is paramount in future studies.

##### Conditions of the Genitourinary Tract

There is a developing role for the use of probiotics in the genitourinary (GU) system, especially for vaginitis, whether from bacterial or fungal etiology. A report on the use of *L. sporogenes* in non-specific vaginitis revealed symptomatic relief in the majority of women who



- ① 설명: 19세기 후반, 미생물학자들은 건강한 개인의 위장관에서 발견되는 미세 생물군이 질병이 있는 개인과 다르다는 것을 확인했다. (이하 생략)
- ② Colonization: 인간의 위장관(GI)에는 다양한 보호 및 면역 장벽이 존재한다. (이하 생략)
- ③ 장 기능: 적절한 미세 생물군의 장내 정착은 장이 정상적으로 기능하는 데 기여한다. (이하 생략)
- ④ 병원균에 대한 프로바이오틱스의 효과: 최근 프로바이오틱스를 언제 사용해야 하는지와 특정 병리 상태에 미치는 영향을 이해하는 데 많은 진전이 있었다. (이하 생략)
- ⑤ 특정 질환에서의 프로바이오틱스: 프로바이오틱 보충제는 직접적인 효과와 간접적인 효과를 모두 가지고 있다. (이하 생략)
- ⑥ 헬리코박터 파일로리 감염: 헬리코박터 파일로리 감염 치료에 있어 프로바이오틱스의 사용에 대한 증거는 상충되고 있다. (이하 생략)
- ⑦ 결론: 현재의 증거는 경구 프로바이오틱 치료가 위장관 내외의 다양한 질환에 유익할 수 있다는 개념을 지지한다. (이하 생략)
- ⑧ 참고문헌: (이하 생략)

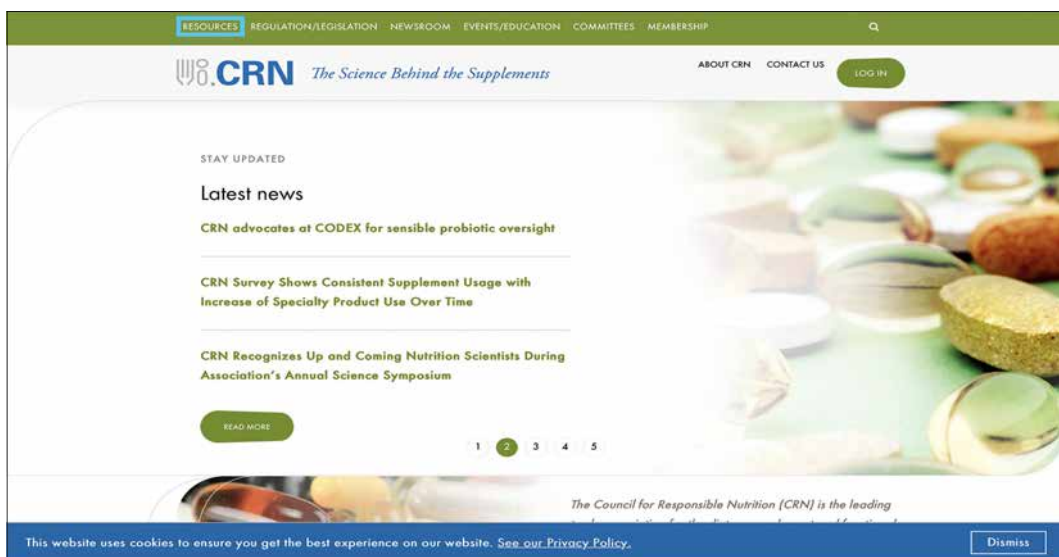
## [ Vitamin and Mineral Safety ]

### ● 개요

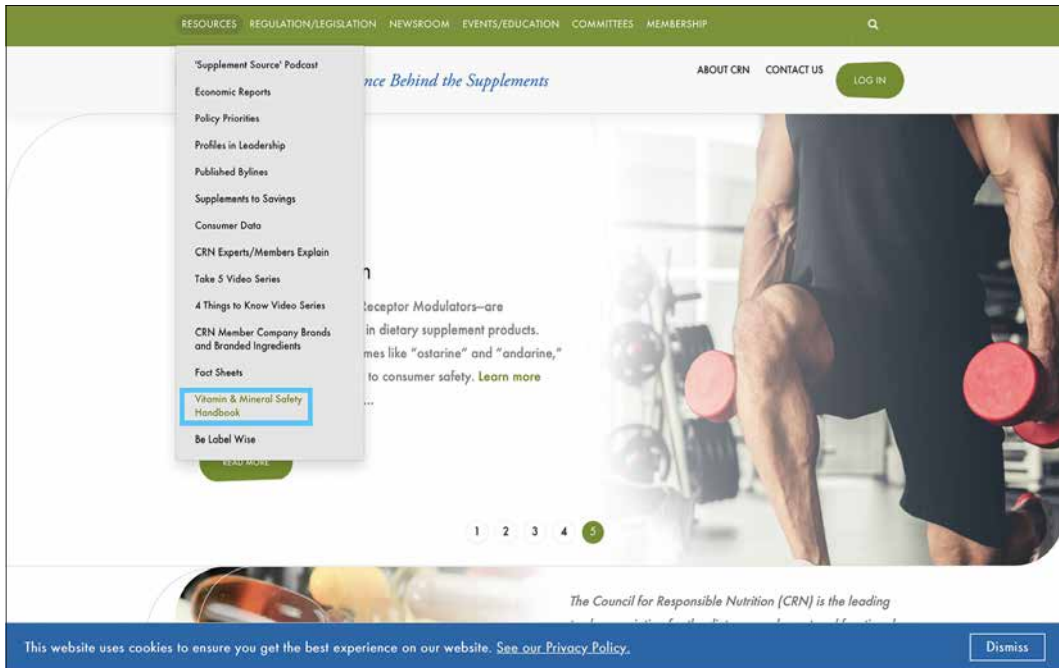
<b>DB명</b>	Vitamin and Mineral Safety(3rd Edition)
<b>관리기관</b>	Council for Responsible Nutrition(CRN)
<b>DB 내용</b>	원료에 대한 소개와 안전사항, CRN의 권장사항 등 효과와 섭취, 부작용에 대해서 설명하고 권고 사항을 적시함
<b>접속 주소</b>	<a href="https://www.crnusa.org/sites/default/files/files/resources/CRN-SafetyBook-3rdEdition-2014-fullbook.pdf">https://www.crnusa.org/sites/default/files/files/resources/CRN-SafetyBook-3rdEdition-2014-fullbook.pdf</a>
<b>정보 제공 건수</b>	28건('24.11. 기준) - 비타민: 14건, 미네랄: 4건, 미량 원소: 10건

### ● DB 접속 방법

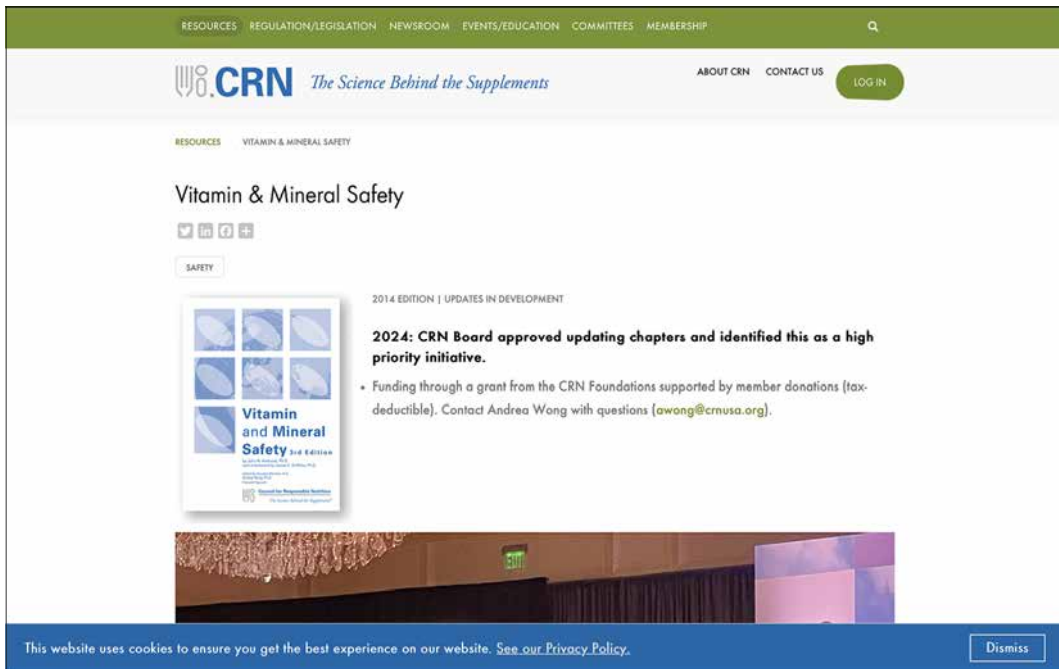
- 'Council for Responsible Nutrition' 홈페이지에 접속 후 화면 좌측 상단의 'RESOURCES' 선택




○ 아래의 선택지 중 하단의 ‘Vitamin & Mineral Safety Handbook’ 클릭



○ 보이는 화면 하단으로 스크롤



- ‘Download full book(2014 edition)’ 클릭 후 PDF 파일 다운로드



CRN SVP Scientific & Regulatory Affairs **Andrea Wong** discusses updates planned for the association's Vitamin and Mineral Safety book, under the direction of a committee of members of the Senior Scientific Advisory Council, Alex Eapen of Cargill, Andrew Shao of ChromaDex, Deshanie Rai of OmniActives, Eric Cioppio of Balchem, Karen Hecht of AstaReal and Michelle Stout of Amway.

**PAST INFORMATION**

This handbook provides valuable science-based recommendations for establishing Tolerable Upper Intake Levels [ULs] for supplemental sources of these nutrients—a trusted resource for dietary supplement and dietary ingredient manufacturers, as well as scientific bodies and regulatory policy makers worldwide. Read more in CRN's archived 2014 [press release](#).

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### Vitamin and Mineral Safety Chapters

INTRODUCTORY CONTENT:

- Abbreviations
- About CRN
- Foreword
- Methodology

VITAMINS:

- Vitamin A
- Beta-Carotene
- Vitamin D
- Vitamin E
- Vitamin K
- Vitamin C
- Vitamin B-1 (Thiamine)

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● 정보 제공 범위

- 원료별 페이지에서 소개, 안전 고려사항, 공식 연구, CRN 권장사항, 참고문헌 등을 제공



예시 | 원료명: 비타민 C

VITAMIN C

### Vitamin C

**1 Introduction**

Vitamin C, also known as ascorbic acid, is a water-soluble vitamin. It is required for the synthesis of collagen, which is a critically important structural component of blood vessels, tendons, ligaments, and bone. Also, vitamin C is necessary for the synthesis of carnitine, a small molecule that is essential for the transport of fat into cellular organelles such as mitochondria, where the majority of fat oxidation occurs.

Vitamin C is a highly effective antioxidant, especially in the acidic environment of the stomach. In this way, it may be important in blocking production of compounds such as nitrosamines, most of which are known carcinogens (Tricker and Preussmann 1991). This action is consistent with the lower rates of stomach cancer in persons with high vitamin C intakes (Scanlan 2000).

Unlike most mammals and other animals, humans do not have the ability to make their own vitamin C. Therefore it must be obtained from the diet (Higdon 2004). The intestinal absorption of vitamin C is regulated by at least one dose-dependent active transporter (National Institutes of Health [NIH] 2013). Cells accumulate vitamin C via a second specific transport mechanism. In vitro studies show that oxidized vitamin C (dehydroascorbic acid) enters cells via some facilitated glucose transport and is then reduced internally to ascorbic acid. The physiological importance of oxidized vitamin C uptake is unknown.

Overall vitamin C concentrations in the tissues and plasma are tightly controlled. At oral intakes above 1 g per day, vitamin C uptake falls off to less than 50 percent, and unmetabolized vitamin C is excreted in the urine (NIH 2013). It does not necessarily follow that unabsorbed vitamin C provides no benefit; for example, decreases in nitrosamine production may be beneficial in reducing stomach cancer risk.

**2 Safety Considerations**

Vitamin C has very low toxicity and is not believed to cause serious adverse effects at high intakes. The most common complaints after very high intakes of vitamin C are diarrhea, nausea, abdominal cramps, and other gastrointestinal effects related to the osmotic effect of unabsorbed vitamin C in the intestine (Institute of Medicine [IOM] 2000).

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**3 Official Reviews**

**IOM (2000).** The IOM found no credible reports of adverse effects other than gastrointestinal distress related to irritation and osmotic diarrhea from large doses. For these effects, the IOM identified a LOAEL of 3,000 mg per day but, because of the mild and transient nature of the effects, selected a UF of 1.5, thus deriving a UL of 2,000 mg per day.

**Expert Group on Vitamins and Minerals (EVM 2003).** The UK's EVM also found no credible reports of adverse effects other than mild gastrointestinal distress and diarrhea. The EVM applied a standard toxicological default UF of 3, setting a guidance level of 1,000 mg per day.

**European Food Safety Authority (EFSA 2004).** In April 2004, EFSA released a risk assessment for ascorbic acid that included some evidence of oxidative damage. Their report noted that genotoxicity was supported by oxidative damage that could occur in the presence of transition metal ion. However, EFSA theorized that such effects were countermanded by the antimutagenic effects in a variety of systems. Vitamin C would be expected to be antimutagenic because of its antioxidant properties, and there are several types of data consistent with this effect. EFSA concluded that the data are insufficient to establish a UL for vitamin C. It was noted, however, that doses of vitamin C up to about 1 g in addition to normal dietary intakes are not associated with adverse gastrointestinal effects, but that such effects may occur at higher intakes (3 to 4 g per day). There are no data on the gastrointestinal absorption or tolerability of esterified forms of vitamin C.

**4 CRN Recommendations**

Vitamin C has an extremely low potential for toxicity. Multigram supplements have been widely used for decades, with only mild and transient gastrointestinal effects such as irritation, bloating, and diarrhea. The adverse gastrointestinal effects of very high intakes justify the establishment of a UL at 2,000 mg per day.

CRN also identified a LOAEL of approximately 3,000 mg. Given the mild, transient, and self-correcting nature of the adverse effects, CRN considers an uncertainty factor of 1.5, as identified by the IOM, to be ample.

The IOM and the EVM set their ULs at 1,000 mg per day, but neither considered in detail the role of individual dosages versus total intake. CRN recommends a UL of 2,000 mg

per day but spread out into at least two doses. Single doses should not exceed 1,000 mg in order to avoid undesirable gastrointestinal effects.

**5 Quantitative Summary for Vitamin C**

CRN UL, supplemental intake	2,000 mg/day
IOM UL, total intake	2,000 mg/day
EFSA UL, total intake	Not determined
EC, supplement maximum	Not determined
EVM, guidance level, supplemental intake	1,000 mg/day

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- ① 소개: 비타민 C에 대한 화학적 설명 및 필요성 소개
  - ② 안전 고려사항: 비타민 C는 고용량에서도 매우 낮은 독성을 가지며, 일반적으로 심각한 부작용을 초래하지 않음. 그러나 고용량 섭취 후에는 설사, 메스꺼움, 복부 경련 등의 일반적인 위장 문제를 경험할 수 있음
  - ③ 공식 연구: IOM (2000): IOM은 대량 투여로 인한 자극 및 삼투성 설사와 관련된 위장관 불편을 제외하고는 신뢰할 수 있는 부작용 보고가 없다고 판단했다.  
(이하 생략)
  - ④ CRN 권장사항: 비타민 C는 독성 잠재력이 매우 낮다. (이하 생략)
  - ⑤ 비타민 C에 대한 정량적 요약: CRN UL (보충제 섭취): 2,000 mg/일 등
  - ⑥ 참고문헌: (이하 생략)

## ■ 캐나다

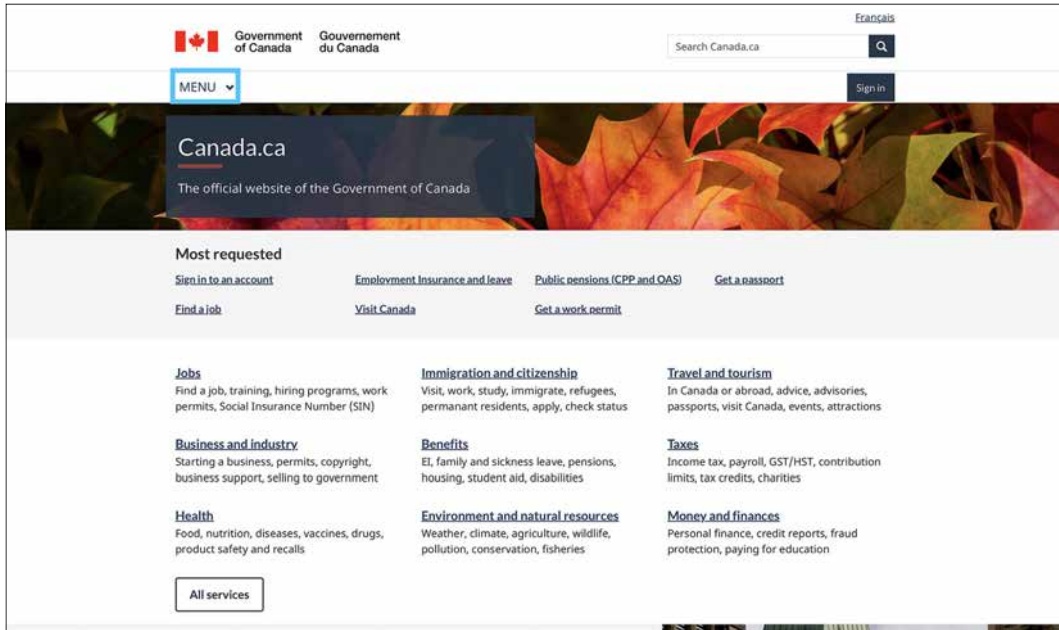
### [ Pre-Cleared information ]

#### ● 개요

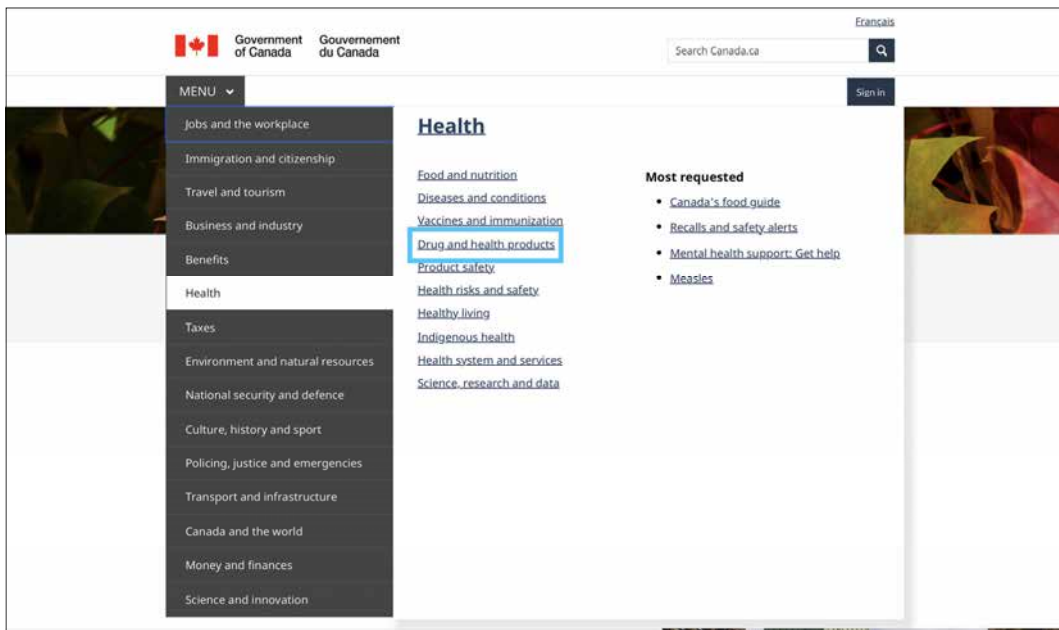
DB명	Pre-Cleared information
관리기관	캐나다 보건부(Health Canada)
DB 내용	NNHPD(Natural and Non-prescription Health Products Directorate)가 검토하여 안전성, 효능, 품질을 지원하는 것으로 판단한 의약 성분 또는 자연 건강 제품 관련 정보를 제공함
접속 주소	<a href="https://webprod.hc-sc.gc.ca/nhpid-bdipsn/monosReq">https://webprod.hc-sc.gc.ca/nhpid-bdipsn/monosReq</a>
정보 제공 건수	259건('24.11. 기준) - 단일 성분에 대한 자료: 215건 - 제품에 대한 자료: 44건

● DB 접속 방법

○ ‘Government of Canada’ 접속 후 ‘MENU’ 클릭



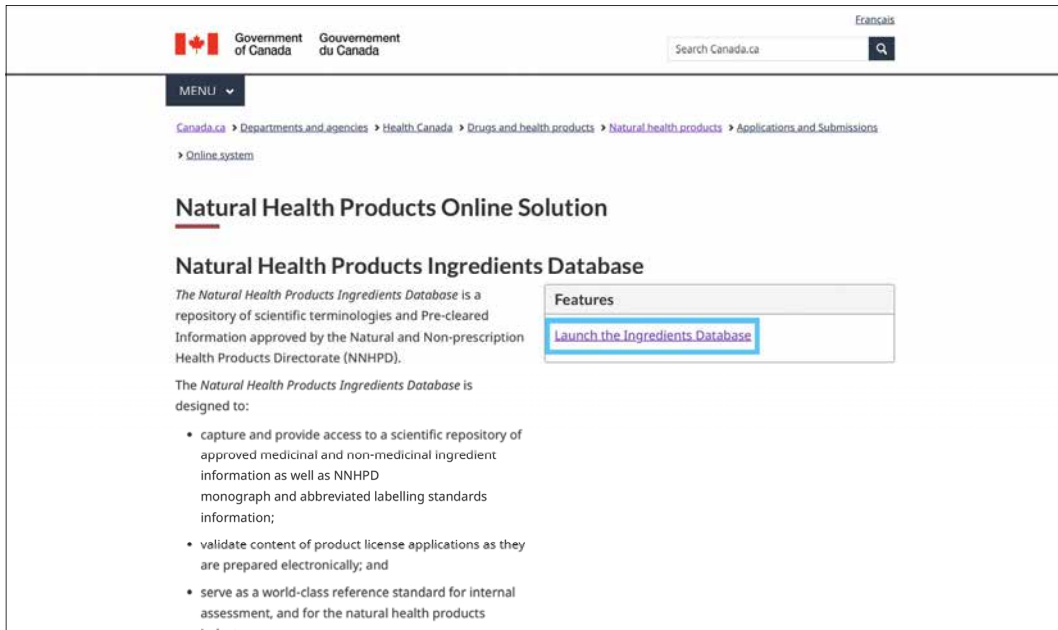
○ ‘MENU’의 ‘Health’에서 ‘Drug and health products’ 클릭



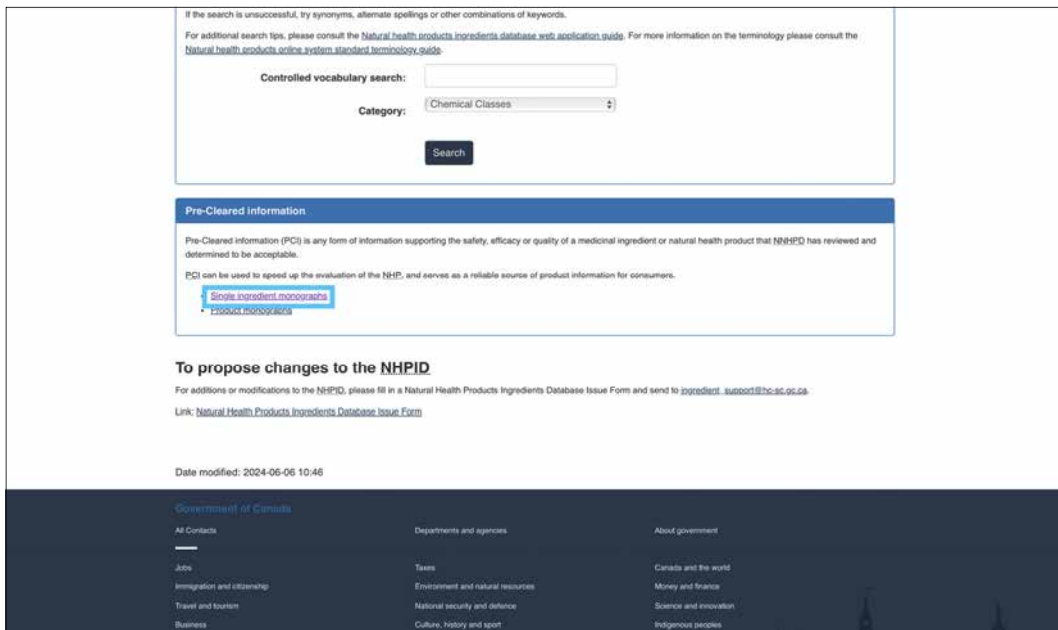
- ‘Drug and health products’ 화면에서 Natural and non-prescription health products 클릭

- 화면을 아래로 스크롤하여 ‘For Consumers’에서 ‘Natural Health Products Ingredients Database’ 클릭

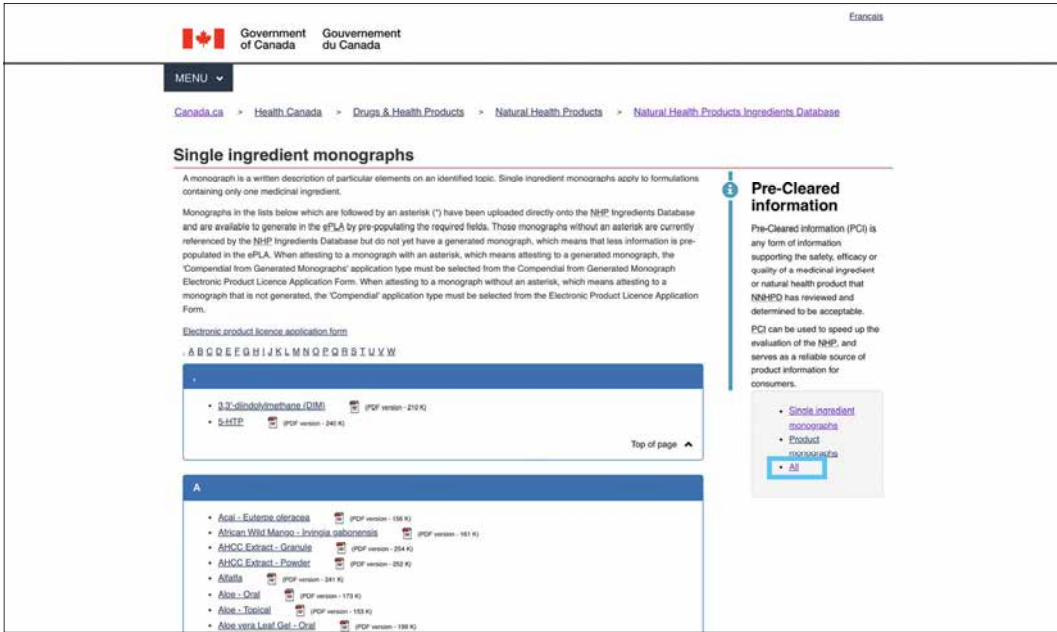
○ 화면 우측 'Features'의 'Launch the Ingredients Database' 클릭



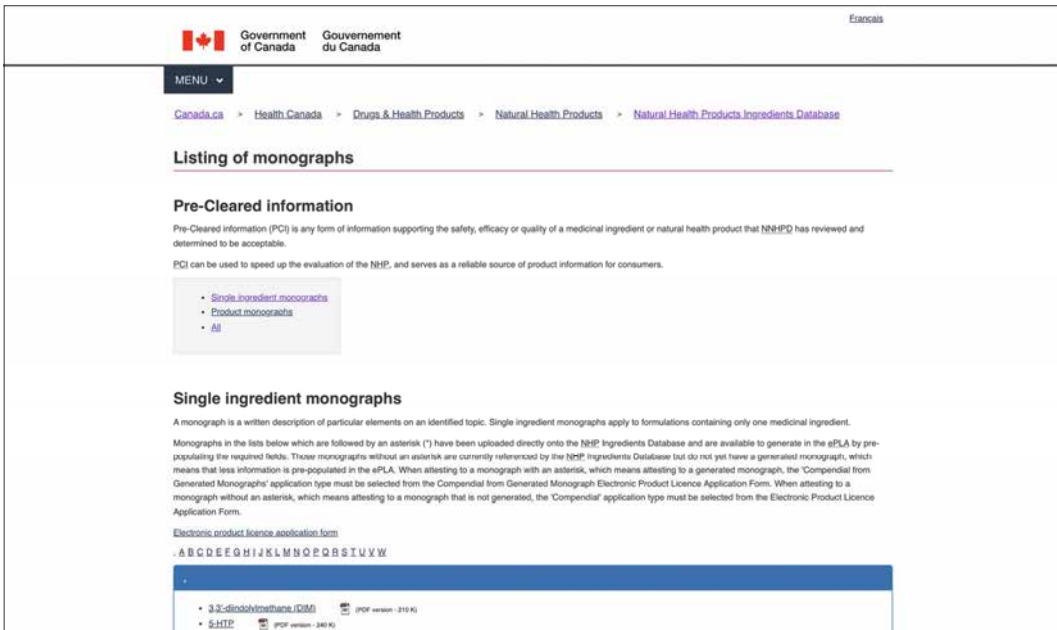
○ 화면 하단으로 이동하여 'Single ingredient monographs' 클릭




○ 화면 우측 ‘All’ 클릭



○ 열람하고자 하는 원료를 알파벳 순으로 나열된 페이지에서 찾아서 이름을 클릭



○ 해당 원료의 상세 정보 확인



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MENU ▾

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## Probiotics

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the [alternate format help](#) section.

 PDF Version - 224 KB

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

**Notes**

- By submitting a PLA referencing this monograph, the applicant is attesting that the product will comply fully with the recommended conditions of use and specifications section outlined in this monograph. These include species identification, strain characterization, quantification in colony forming units (CFU), and a complete assessment of virulence properties (including but not limited to: antibiotic resistance profile, virulence factor production, and toxigenic activity).
- Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.
- Any non-viable form of the medicinal ingredients found in Tables 1.2 and 3 (e.g. heat-killed, thermostabilised) is excluded from this monograph and the compendial application process.
- All of the microorganisms found in Appendix I (Table 6) are excluded from this monograph and the compendial application process.

**Date**

January 27, 2023

**Proper name(s), Common name(s), Source information, Strain(s)**

**Note**

Refer to Appendix I, Table 6 for medicinal ingredients that are excluded from this monograph.

**Table 1. Proper name(s), Common name(s), Source information, Strain(s) - BACTERIA**

Proper name(s)	Common name(s)	Source Information <sup>1</sup>	
		Part(s)	Strain(s) <sup>2</sup>
<i>Bifidobacterium adolescentis</i>	<i>Bifidobacterium adolescentis</i>	Whole cell	Strain designation
		Whole	Strain



Table 3. Proper name(s), Common name(s), Source information, Strain(s) – FUNGI

Proper name(s)	Common name(s)	Source information <sup>1</sup>	
		Part(s)	Strain(s) <sup>2</sup>
<i>Debaryomyces hansenii</i>	<i>Debaryomyces hansenii</i>	Whole cell	Strain designation
<i>Kluyveromyces lactis</i>	<i>Kluyveromyces lactis</i>	Whole cell	Strain designation
<i>Kluyveromyces marxianus</i>	<i>Candida pseudotropicalis</i>	Whole cell	Strain designation
<i>Saccharomyces bayanus</i>	<i>Saccharomyces bayanus</i>	Whole cell	Strain designation
<i>Saccharomyces boulardii</i>	<i>Saccharomyces boulardii</i>	Whole cell	Strain designation
<i>Saccharomyces cerevisiae</i>	► Baker's Yeast ► Brewer's Yeast ► Brewers yeast fungus	Whole cell	Strain designation
<i>Saccharomyces pastorianus</i>	<i>Saccharomyces pastorianus</i>	Whole cell	Strain designation
<i>Schizosaccharomyces pombe</i>	<i>Schizosaccharomyces pombe</i>	Whole cell	Strain designation
<i>Xanthophyllomyces dendrorhous</i>	<i>Xanthophyllomyces dendrorhous</i>	Whole cell	Strain designation

<sup>1</sup>The source material should be the same as the proper name.

<sup>2</sup>The PLA and label must identify the strain designation as the source material for each microorganism (e.g. *Saccharomyces cerevisiae* ABC123 where "ABC123" is the strain designation).

References: Golubev 1995, van der Walt 1971, Lodder 1952, Saccardo 1895, Lindner 1893, Meyen ex E. C. Hansen 1883, Rees 1870.

**3 Route of administration**

Oral

**4 Dosage form(s)**

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

**Acceptable dosage forms by age group:**

**Children 1-2 years:** The acceptable pharmaceutical dosage forms are limited to emulsion/suspension and solution/liquid preparations (Giacioia et al. 2008; EMEA/CHMP 2006).

**Children 3-5 years:** The acceptable pharmaceutical dosage forms are limited to chewables, emulsion/suspension, powders and solution/liquid preparations (Giacioia et al. 2008; EMEA/CHMP 2006).

**Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older:** Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compensial applications.

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**5 Use(s) or Purpose(s)**

Medicinal ingredients from Tables 1, 2, and 3

Source of probiotics.

Medicinal ingredients from Tables 1, 2, and 3 except *Lactobacillus crispatus* and *Lactobacillus gallinarum*

- Helps support intestinal/gastrointestinal health (Alonso and Guarner 2013; DuPont and DuPont 2011; WGOGG 2011; Rolfe 2000).
- Could promote a favorable gut flora (Bezkorovainy 2001; Morelli 2000; Collins et al. 1998).

Table 4. Medicinal ingredients from Table 2 with specific use(s) or purpose(s)

Medicinal ingredients	Strains	Uses or Purposes
<i>Lactocaseibacillus rhamnosus</i>	GG	Helps to manage acute infectious diarrhoea
		Helps to manage and/or reduce the risk of antibiotic-associated diarrhoea
<i>Lactobacillus johnsonii</i>	► La 1 ► I,j1 ► NCC 533	An adjunct to physician-supervised antibiotic therapy in patients with <i>Helicobacter pylori</i> infections
► <i>Saccharomyces boulardii</i> ► <i>Saccharomyces cerevisiae</i>	All	Helps to reduce the risk of antibiotic-associated diarrhoea

References: Canani et al. 2007, Bergonzelli et al. 2006, Kotowska et al. 2005, Can et al. 2006, Cruchet et al. 2003, Pantoflickova et al. 2003, Cremonini et al. 2002, Armuzzi et al. 2001, Felley et al. 2001, Guandalini et al. 2000, Vanderhoof et al. 1999, Guarino et al. 1997, McFarland et al. 1995, Surawicz et al. 1989.

**6 Dose(s)**

**Subpopulation(s)**

Children 1 to 11 years, Adolescents 12 to 17 years and Adults 18 years and older (Gill and Prasad 2008; Lenoir-Wijnkoop et al. 2007; Hawrelak 2006; Picard et al. 2005; Reid et al. 2003).

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(i.e., blends) are not included in this monograph.  
 ▶ Gravimetric or volumetric amounts (e.g. g, mL) are not acceptable.

**Direction(s) for use**

*All medicinal ingredients found in Tables 1 and 2 except Saccharomyces cerevisiae and S. boulardii*

Take at least 2-3 hours before or after antibiotics (NIH 2011; APhA 2006; Biradar et al. 2005).

*All medicinal ingredients found in Table 3*

Take at least 2-3 hours before or after taking antifungal medications (NIH 2011; APhA 2006; Biradar et al. 2005).

**7 Duration(s) of use**

No statement required.

**8 Risk information**

**Caution(s) and warning(s)**

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have fever, vomiting, bloody diarrhoea or severe abdominal pain (APhA 2006; WHO 2005; CPhA 2002).
- ▶ Stop use and consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms of digestive upset (e.g. diarrhea) occur, worsen and/or persists beyond 3 days (APhA 2006; WHO 2005).

**Contraindication(s)**

Do not use this product if you have an immune-compromised condition (e.g. AIDS, lymphoma, patients undergoing long-term corticosteroid treatment) (APhA 2006; Cukovic-Cavka et al. 2006; Ledoux et al. 2006; Riquelme et al. 2003; Lherm et al. 2002).

**Known adverse reaction(s)**

No statement required.

**9 Non-medicinal ingredients**

Must be chosen from the current Natural Health Products Ingredient Database (NHPID) and must meet the limitations outlined in the database.

**Note**

Cryoprotectants: All ingredients that are intentionally added during the manufacturing process of a live microorganism to preserve its stability/viability need to be disclosed as non-medicinal ingredients.

**10 Storage condition(s)**

*Liquid products*

Store in refrigerator in a tightly closed, light-resistant container.

**Note**

This requirement does not apply to shelf-stable liquid dosage form preparations (i.e. oil suspensions and emulsions indicated in the Compendium of Monographs Guidance Document).

*Non-liquid products (optional)*

Store in refrigerator in a tightly closed container (Liu 2009; Juarez Thomas 2004; Shillinger 1999).

**11 Specifications**

- ▶ The medicinal ingredients must comply with the requirements outlined in the NHPID and the following requirements are expected to be met by each live microorganism attesting to this monograph:
  - The species Latin binomial identification must be up to date and validated.
  - Survivability of the microorganisms in the human gut must be demonstrated. In-vitro gastric acid and bile resistance testing is considered acceptable.
  - The microorganism must be identified by phenotype and genotype:
    - Phenotyping must be assessed based on characteristics routinely used to distinguish the species from others. This includes a series of testing for sufficient confirmation of observable traits of the species.
    - Genotyping must be assessed as follows:
      - Species identification by comparison of genome sequence homology in percentage, to both "identical" and "closely related" type strains – obtained from an internationally recognized culture collection;
      - AND
      - Strain characterization through an up to date complete/whole genome sequencing method.
  - Absence of virulence of each live microorganism must be established through the following:
    - Comparison of antibiotic/antifungal resistance profile to typical species resistance – as published by an internationally recognized panel;
    - AND

**Note**

Information on the manufacturing process, including but not limited to the above, must be maintained by the applicant or the manufacturer and provided to Health Canada upon request.

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from: [http://www.who.int/entity/child\\_adolescent\\_health/documents/9241593180/en/](http://www.who.int/entity/child_adolescent_health/documents/9241593180/en/)

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- ① 작성일: 2023년 1월 27일
- ② 학명, 통용명, 유래 정보, 균주 정보: 박테리아
- ③ 투약 경로: 경구
- ④ 복용 형태: 나이대로 구분
- ⑤ 사용 목적: 장/위 건강에 도움을 줄 수 있음, 장내 유익균 군집을 촉진할 수 있음
- ⑥ 권장량: 하루에  $1.0 \times 10^7$  이상의 총 균체 형성 단위(CFU)를 제공 등
- ⑦ 사용 기간: 별도 표시 없음
- ⑧ 위험 정보: 주의사항, 금기사항, 부작용
- ⑨ 비의약 정보: 냉동보호제
- ⑩ 보관 조건: 어둡고 서늘한 곳에 보관
- ⑪ 사양: 의약품 성분은 NHPID에 명시된 요건을 준수해야 하며, 이 모노그래프를 증명하는 각 살아있는 미생물은 다음 요건을 충족해야 한다. (이하 생략)
- ⑫ 참고 사이트: (이하 생략)
- ⑬ 참고 자료: (이하 생략)

## ■ 유럽연합

### [ ESCOP Monographs ]

#### ● 개요

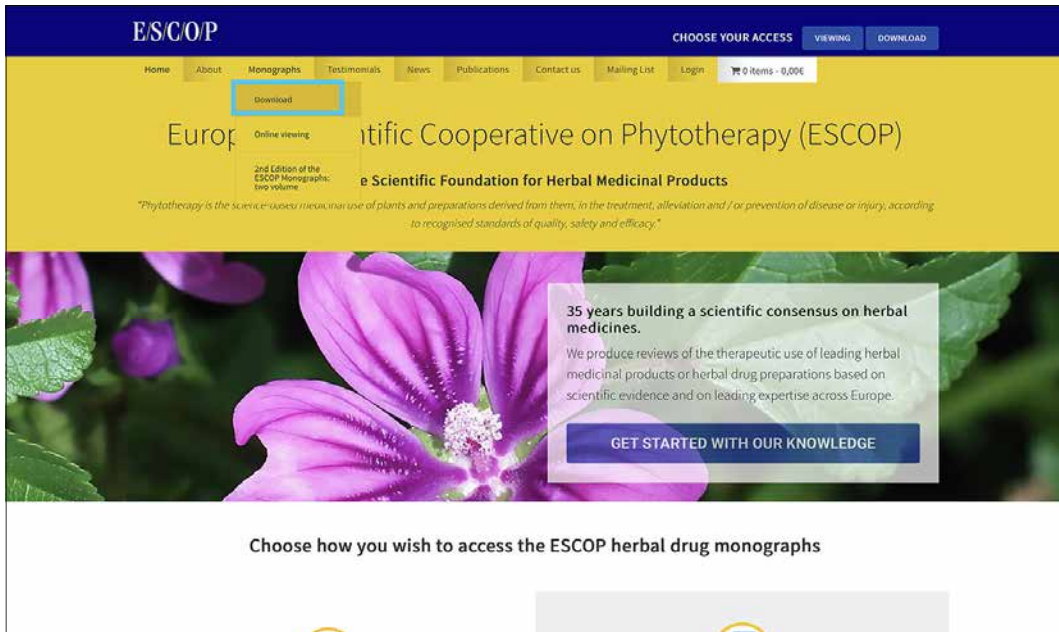
DB명	ESCOP Monographs – List of online Monographs
관리기관	European Scientific Cooperative on Phytotherapy(ESCOP)
DB 내용	자료 열람 불가
접속 주소	<a href="https://www.escop.com/escop-products/online-monographs/">https://www.escop.com/escop-products/online-monographs/</a>
정보 제공 건수	87건('24.11. 기준)
기타	유료 결제가 필요하며, 협회 회원만 회원 가입 가능

#### ● DB 접속 방법

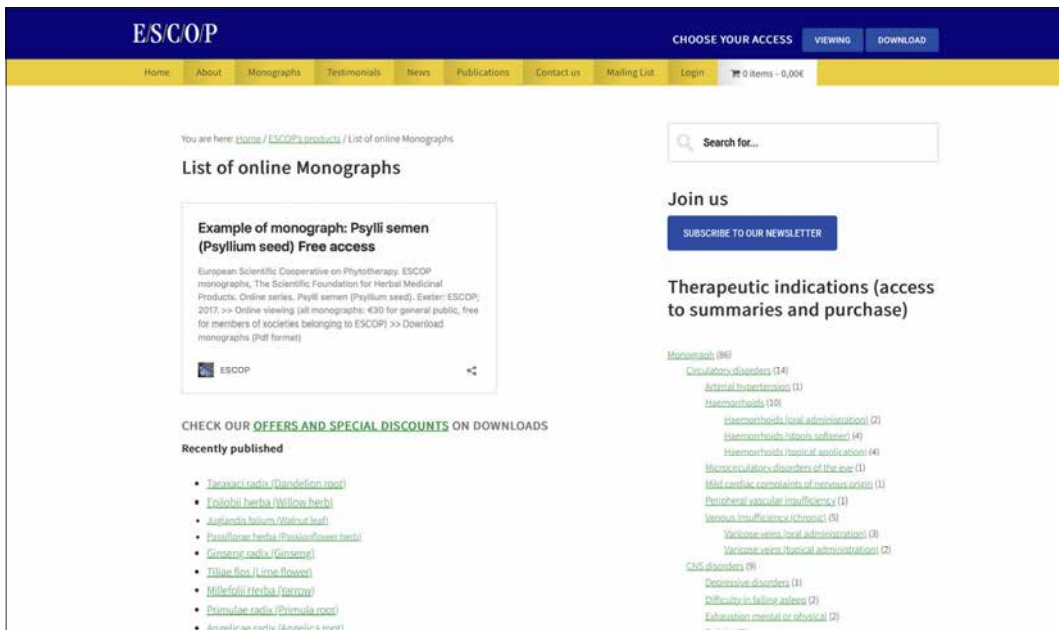
##### ○ 'ESCOP' 홈페이지 메뉴 중 'Monographs' 선택

The screenshot shows the ESCOP website homepage. The top navigation bar includes 'Home', 'About', 'Monographs', 'Testimonials', 'News', 'Publications', 'Contact us', 'Mailing List', and 'Login'. A shopping cart icon shows '0 items - 0,00€'. The main header features the ESCOP logo and the text 'European Scientific Cooperative on Phytotherapy (ESCOP)'. Below this is the tagline 'The Scientific Foundation for Herbal Medicinal Products' and a quote: 'Phytotherapy is the science-based medicinal use of plants and preparations derived from them, in the treatment, alleviation and / or prevention of disease or injury, according to recognised standards of quality, safety and efficacy.' A large image of purple flowers is displayed, with a text box overlay that reads: '35 years building a scientific consensus on herbal medicines. We produce reviews of the therapeutic use of leading herbal medicinal products or herbal drug preparations based on scientific evidence and on leading expertise across Europe. GET STARTED WITH OUR KNOWLEDGE'. At the bottom, there is a section titled 'Choose how you wish to access the ESCOP herbal drug monographs'.

○ ‘Monographs’ 하단 ‘Download’ 클릭



○ 이동한 화면에서 아래로 스크롤 후 알파벳 순의 자료를 열람



Part II  
기능성 약물 안전성 확인 DB

## ■ 영국

### [ Safe Upper Levels for Vitamins and Minerals ]

#### ● 개요

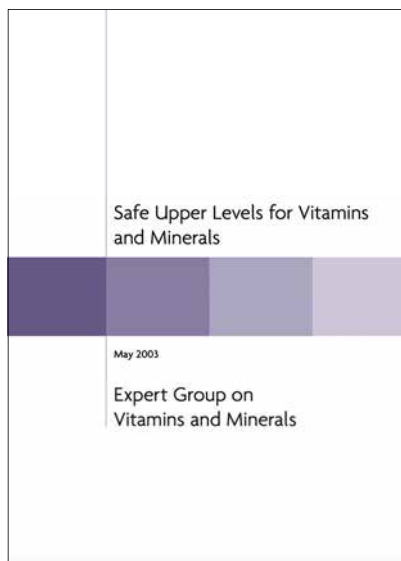
DB명	Safe Upper Levels for Vitamins and Minerals
관리기관	Expert Group on Vitamins and Minerals(EVM)
DB 내용	수용성 비타민, 지용성 비타민, 미량 원소, 미네랄로 대분류하여, 각 원료들의 특성과 화학 성질, 섭취량 등을 정리함 - 비타민과 미네랄의 안전한 섭취 수준을 연구하므로서 영양소의 안전성과 식품 섭취 가이드라인 제공
접속 주소	<a href="https://cot.food.gov.uk/sites/default/files/vitmin2003.pdf">https://cot.food.gov.uk/sites/default/files/vitmin2003.pdf</a>
정보 제공 건수	36건('24.11. 기준) - 수용성 비타민 : 9건, 지용성 비타민 : 5건, 미량 원소 : 13건, 미네랄 : 9건

#### ● DB 접속 방법

##### ○ 접속 주소로 접속



- PDF파일 표지에서 아래로 스크롤



- 목차에서 원하는 원료를 찾고 페이지 이동

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● 정보 제공 범위

- 원료별 페이지에서 원료의 일반정보, 독성, 위험평가에서 중요한 연구, 노출 평가 등의 자료를 제공



예시 | 원료명: 비타민 C

Risk Assessment	Vitamin C
<b>① General information</b>	
<b>Chemistry</b> Vitamin C is a six-carbon compound structurally related to glucose, consisting of two inter-convertible compounds: L-ascorbic acid, which is a strong reducing agent, and its oxidised derivative, L-dehydroascorbic acid.	
<b>Natural occurrence</b> Most animals are able to synthesise vitamin C from glucose and galactose. However, primates and guinea pigs are unable to do so.	
<b>Occurrence in foods, food supplements and medicines</b> Food of plant origin, particularly citrus and soft fruits and leafy green vegetables, are major sources of vitamin C. Kidney and liver are good animal-derived sources of vitamin C. Vitamin C is readily lost during cooking, due to oxidation. Ascorbic acid is a permitted anti-oxidant in food with no specified limits on the level of fortification. Vitamin C is present in numerous dietary supplements and in licensed medicines at doses of up to 3000 mg.	
<b>Recommended amounts</b> In 1991, COMA recommended a RNI for ascorbic acid of 40 mg/day for adults, with an increase in pregnancy to 50 mg/day, and during lactation to 70 mg/day (COMA, 1991).	
<b>Analysis of tissue levels and vitamin C status</b> Plasma and urinary vitamin C levels may be measured but reflect recent dietary intake rather than the level of vitamin C in body stores. Leucocytes contain higher concentrations of vitamin C than plasma, whole blood or serum but measurement of leucocyte vitamin C is technically more difficult than estimation of plasma or urinary levels. A leucocyte vitamin C level below 0.01 mg per 10 <sup>6</sup> cells is generally regarded as deficient.	
<b>Brief overview of claimed non-nutritional beneficial effects</b> It has been claimed that vitamin C protects against the common cold. Beneficial effects on conditions such as cancer, vascular disease, cataracts, diabetes, asthma, arthritis, Parkinson's disease, autism and depression have also been suggested.	
<b>② Toxicity</b>	
<b>Human data</b> Gastrointestinal effects are the most common adverse clinical events associated with acute, high doses of vitamin C given over a short period of time.	

### ③ Studies of particular importance in the risk assessment

(For full review see <http://www.food.gov.uk/science/ouradvisors/vitamins/evmpapers> or the enclosed CD)

Cameron and Campbell, 1974

In a stepped study, healthy human volunteers were given vitamin C with the dose increasing each week by 1000 mg. Abdominal distention, flatulence, diarrhoea and transient colic were described as 'fairly frequent' effects at supplemental dose levels of 3000-4000 mg daily. No other details were provided.

Cook et al., 1984

Seventeen adult volunteers were given 2000 mg vitamin C/day with meals for 16 weeks in a study examining the effect of dietary iron absorption and assimilation on body iron status. Nine subjects continued in the study, taking these doses of vitamin C for 24 months. No subjective side effects were reported. Although vitamin C enhances absorption of non-haem iron, no increase in serum ferritin levels was found, despite wide variation in initial iron status between the volunteers. The authors concluded that supplemental vitamin C had a negligible effect on iron stores. Vitamin C supplementation continued for a further 20 months in 4 iron-deficient and 4 iron-replete subjects. No effect of vitamin C on body iron reserves (as measured by serum ferritin levels) was apparent and no intestinal adaptation to the enhancing effect of the vitamin had occurred. The authors considered several possible explanations for their findings. No adverse effects were reported in this study of large supplemental doses of vitamin C but the authors noted that the study did not exclude possible adverse effects in individuals who are heterozygous for the haemochromatosis gene (approximately 10% of the population). The study involved small numbers of participants with variable iron status and was not blinded, though compliance was checked.

### ④ Exposure assessment

Total exposure/intake:

Food Mean: 64 mg/day  
95th percentile: 160 mg/day (from 1986/87 NDNS)

Supplements up to 3000 mg/day (Annex 4)

Estimated maximum daily intake: 160 + 3000 = 3160 mg

Vegetarians are a potential high intake group.

#### ① 일반정보

- 화학 : 비타민 C는 포도당과 구조적으로 관련된 6탄소 화합물로, 두 가지 상호 전환 가능한 화합물로 구성된다: 강력한 환원제인 L-아스코르브산과 그 산화 유도체인 L-디하이드로아스코르브산이다. (이하 생략)

#### ② 독성

- 인간 데이터 : 위장관 효과는 단기간에 고용량의 비타민 C를 투여했을 때 가장 일반적으로 발생하는 부작용이다. (이하 생략)

#### ③ 위험 평가에서 특히 중요한 연구

- Cameron과 Campbell, 1974, 단계적 연구에서 건강한 인간 자원자들에게 비타민 C가 주어졌으며, 매주 1000 mg씩 용량이 증가했다. (이하 생략)

#### ④ 노출 평가: 총 노출/섭취량, 어린이 노출 평가, 위험 관리 (이하 생략)

## WHO

### [ WHO monographs on selected medicinal plants ]

#### ● 개요

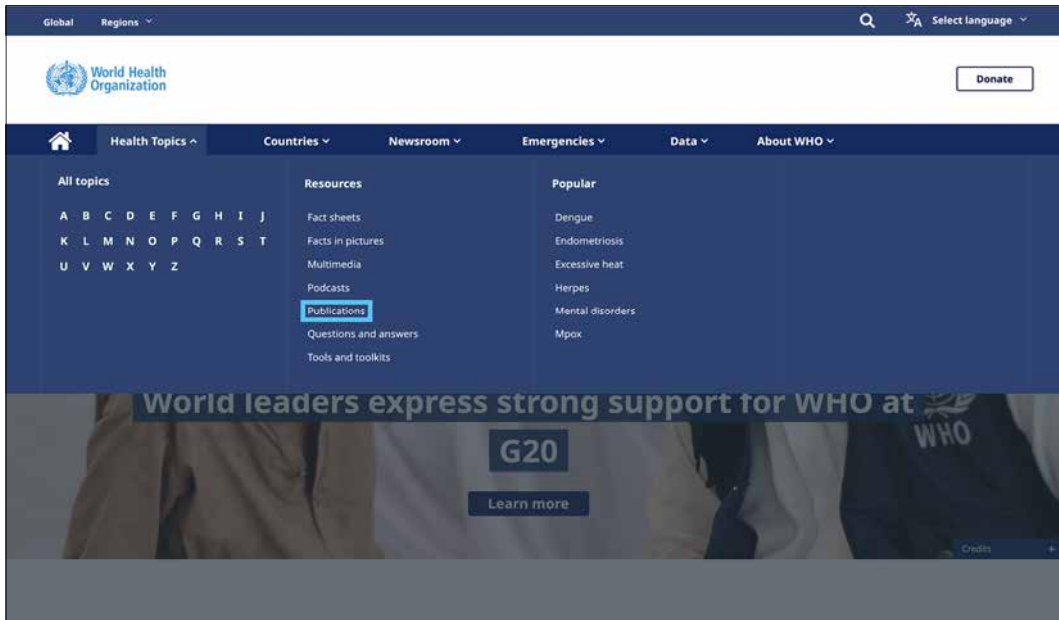
DB명	WHO monographs on selected medicinal plants
관리기관	World Health Organization
DB 내용	세계보건기구(WHO)에서 발표한 여러 약용 식물에 대한 정보 및 과학적 데이터를 제공함. 주로, 안전성과 효과에 대한 근거를 바탕으로 약용 식물을 정리함
접속 주소	<a href="https://www.who.int/publications/i/item/9241545178">https://www.who.int/publications/i/item/9241545178</a>
정보 제공 건수	28건('24.11. 기준) - WHO에서 특정한 약용 식물 : 28건

#### ● DB 접속 방법

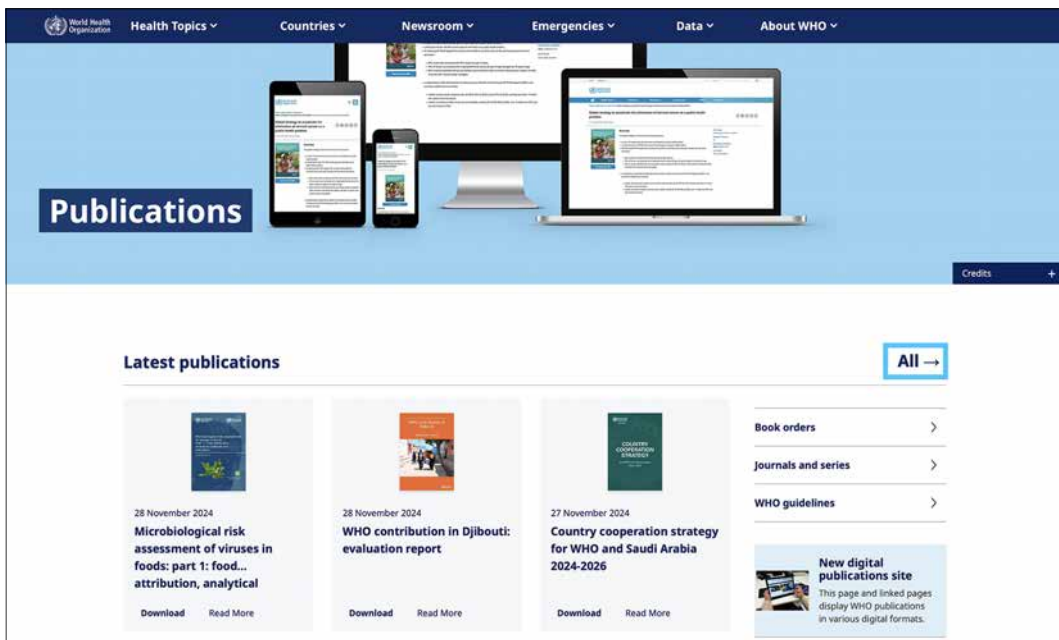
- 'WHO' 홈페이지 접속 후 'Health Topic' 클릭



○ 화면에서 'Publications' 클릭

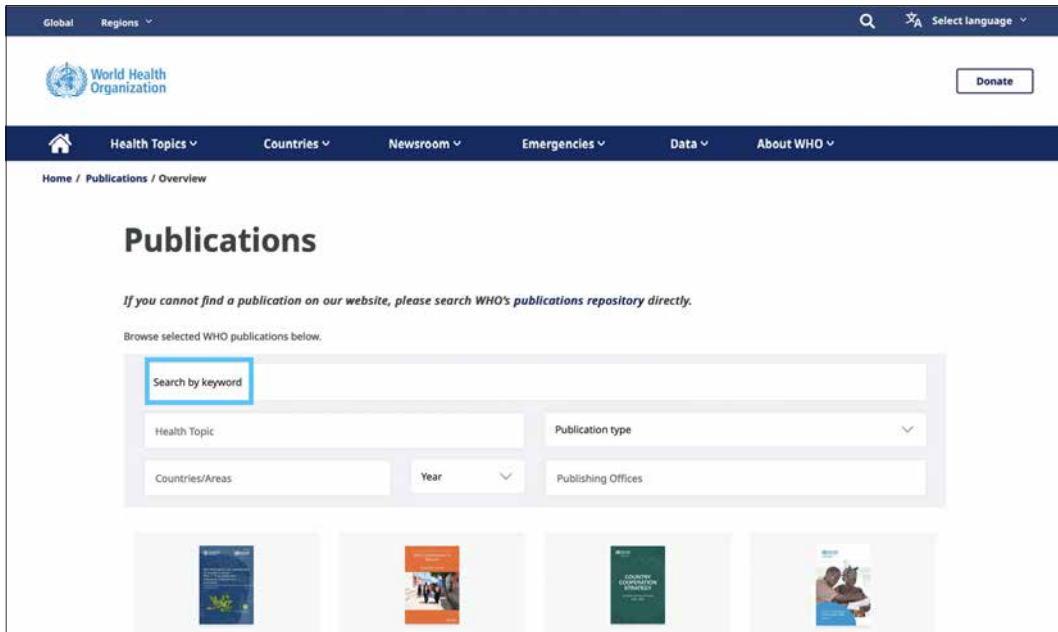


○ 화면 아래로 스크롤 후 우측의 'All' 클릭

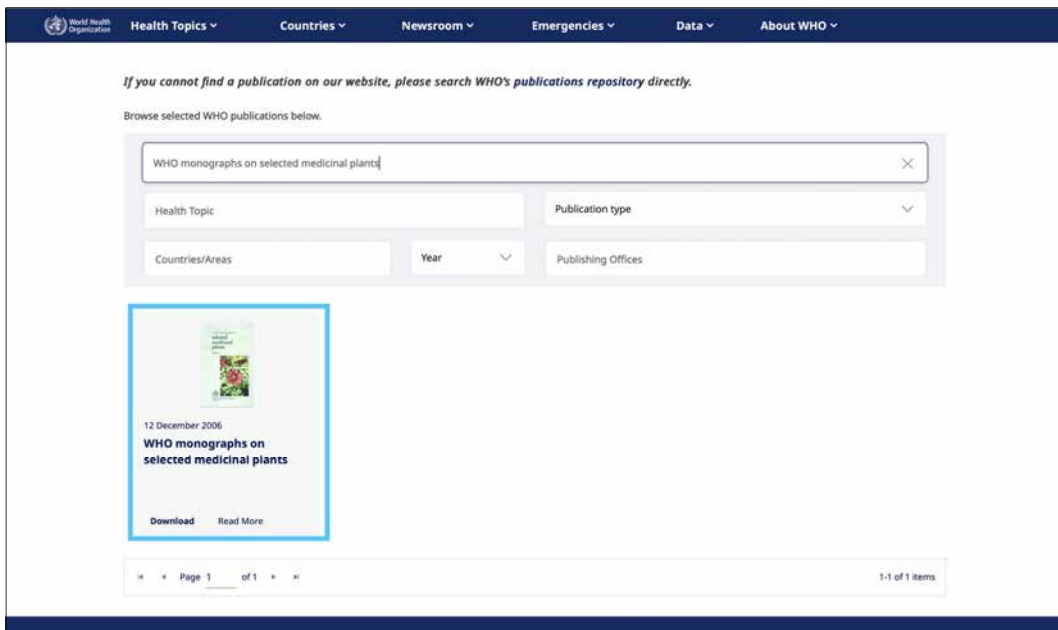


Part II  
기능성 원료 안전성 확인 DB

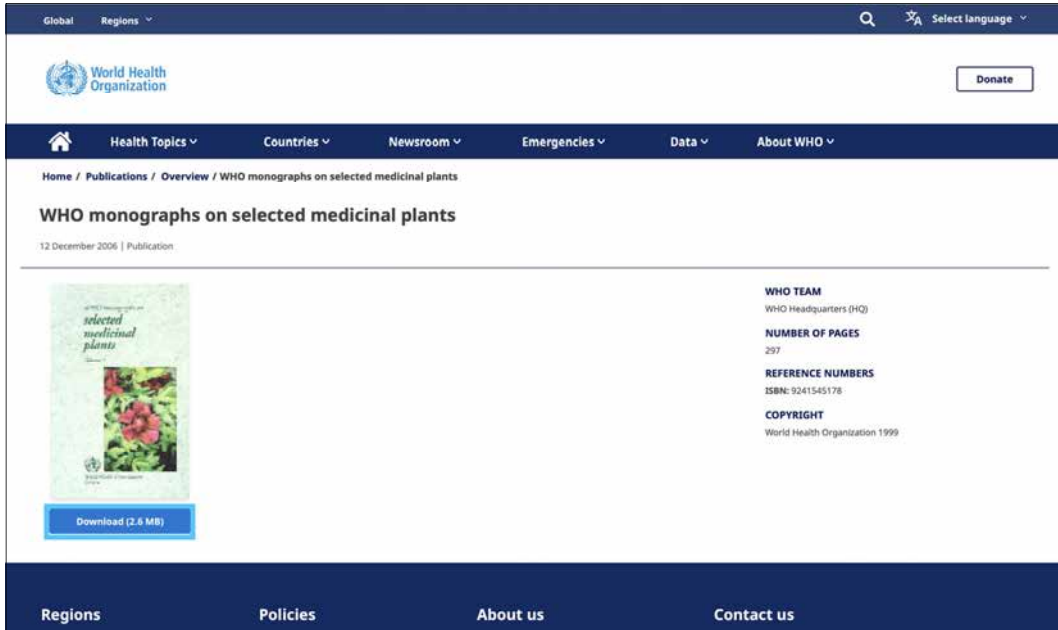
- ‘Publications’ 하단 ‘Search by keywords’ 클릭



- ‘WHO monographs on selected medicinal plants’ 검색 후 하단 표지 선택



○ 표지 선택 후 'Download' 클릭



● 정보 제공 범위

- 약초별 상세 정보에서 해당 약초의 정의, 명칭, 학명, 생김새, 화학성분 등의 정보 제공



예시 | 원료명: 알로에

## Aloe

### ① Definition

Aloe is the dried juice of the leaves of *Aloe vera* (L.) Burm. f. or of *A. ferox* Mill. and its hybrids with *A. africana* Mill. and *A. spicata* Baker (Liliaceae) (1-6).

### ② Synonyms

#### *Aloe vera* (L.) Burm. f.

*Aloe barbadensis* Mill., *Aloe chinensis* Bak., *A. elongata* Murray, *A. indica* Royle, *A. officinalis* Forsk., *A. perfoliata* L., *A. rubescens* DC, *A. vera* L. var. *littoralis* König ex Bak., *A. vera* L. var. *chinensis* Berger, *A. vulgaris* Lam. (7).

In most formularies and reference books, *Aloe barbadensis* Mill. is regarded as the correct species name, and *Aloe vera* (L.) Burm. f. is considered a synonym. However, according to the International Rules of Botanical Nomenclature, *Aloe vera* (L.) Burm. f. is the legitimate name for this species (8-10). The genus *Aloe* has also been placed taxonomically in a family called Aloaceae.

#### *Aloe ferox* Mill.

*Aloe horrida* Haw., *A. perfoliata* Thunberg., *A. pseudoferox* Salm. Dyck, *A. socotrina* Masson., *A. supralaevis* Haw., *Pachydendron ferox* Humb. & Bonpl., *P. supralaeve* Haw. (7).

### ③ Selected vernacular names

Aloe capensis, aloe curacao, aloe vera, aloes, aloès, aloès du Cape, aloès féroce, aloes vrai, aloès vulgaire, alovis, Barbadoes aloe, Barbadoes aloes, Barbados aloe, Bergaalwyn, Bitteraalwyn, Cape aloe, chirukattali, Curacao aloe, Curacao aloes, Curacao alos, Echte Aloe, ghai kunwar, ghai kunwar, gheekuar, ghikanvar, ghikuar, ghikumar, ghikumari, ghikwar, ghiu kumari, ghrita kumari, ghritakumari, grahakanya, gwar-patha, haang takhe, hlaba, Indian aloe, jadam, korphad, kumari, kumaro, kunvar pata, kunwar, laloi, laluwe, lo-hoei, lo-hoi, lou-houey, lu wei, luchuy, manjikattali, Mediterranean aloe, murr sbarr, musabar, rokai, sabbara, saber, sábila, sabilla, sabr, saibr, savila, savilla, semper vivum, shubiri, sibr, siang-tan, star cactus, tuna, umhlaba, waan haang charakhe, wan-hangchorakhe, yaa dam, yadam, zábila, zambila (1, 7, 11).

**4 Description*****Aloe vera* (L.) Burm. f.**

Succulent, almost sessile perennial herb; leaves 30–50 cm long and 10 cm broad at the base; colour pea-green (when young spotted with white); bright yellow tubular flowers 25–35 cm in length arranged in a slender loose spike; stamens frequently project beyond the perianth tube (12).

***Aloe ferox* Mill.**

Arborescent perennial shrub with a single stem of 2–3 m in height, crowned by a large rosette of numerous leaves which are glaucous, oval-lanceolate, 40–60 cm in length, thorny on the ridge and the edges; inflorescence an erect raceme 60 cm in height; flowers with perianth 2.5 cm in length, red, yellow, or orange (2).

**5 Plant material of interest: dried juice**

Solidified juice originating in the cells of the pericycle and adjacent leaf parenchyma, and flowing spontaneously from the cut leaf, allowed to dry with or without the aid of heat.

It is not to be confused with Aloe Vera Gel, which is the colourless mucilaginous gel obtained from the parenchymatous cells in the leaves of *Aloe vera* (L.) Burm. f. (13).

**General appearance****Curacao or Barbados Aloe, derived from *Aloe vera* (L.) Burm. f.**

The dried juice occurs in dark chocolate-brown usually opaque masses; fracture, dull waxy, uneven, and frequently conchoidal (2, 6).

**Cape Aloe, derived from *A. ferox* Mill. and its hybrids with *A. africana* Mill. and *A. spicata* Baker**

The dried juice occurs in dark brown or greenish brown glassy masses, often covered with a yellowish powder; in thin fragments it is transparent and exhibits a yellowish, reddish brown or greenish tinge; fracture, smooth, even, and glassy (2, 6).

**Organoleptic properties**

Aloe is marketed as opaque masses that range from reddish black to brownish black to dark brown in colour. Odour, characteristic and disagreeable; taste, somewhat sour, nauseating and very bitter (2, 7, 12).

**Microscopic characteristics**

See "Powdered plant material" below.

**Powdered plant material**

Powdered aloes are yellowish brown to dark reddish brown. Microscopically, Cape Aloe appears as transparent brown or greenish brown irregular and angular fragments; Curacao Aloe shows fragments with numerous minute acicular crystals embedded in an amorphous matrix (1–3, 12, 14).

**6 Geographical distribution**

Native to southern and eastern Africa, and subsequently introduced into northern Africa, the Arabian peninsula, China, Gibraltar, the Mediterranean countries, and the West Indies (15). It is commercially cultivated in Aruba, Bonaire, Haiti, India, South Africa, the United States of America, and Venezuela (2, 7, 12, 14, 15).

**7 General identity tests**

Macroscopic and microscopic examinations (1–3, 7, 12, 14); solvent solubility (hot alcohol, boiling water, and ether) determination (2, 4–6); chemical reactions (1–6, 8, 12–14); and thin-layer chromatographic analysis employing barbaloin as the reference standard (4–7).

**8 Purity tests****Microbiology**

The test for *Salmonella* spp. in aloe products should be negative. The maximum acceptable limits of other microorganisms are as follows (16–18). For preparation of decoction: aerobic bacteria—not more than  $10^7$ /g; fungi—not more than  $10^6$ /g; *Escherichia coli*—not more than  $10^2$ /g. Preparations for internal use: aerobic bacteria—not more than  $10^7$ /g or ml; fungi—not more than  $10^6$ /g or ml; enterobacteria and certain Gram-negative bacteria—not more than  $10^6$ /g or ml; *Escherichia coli*—0/g or ml.

**Foreign organic matter**

Adulterants: Aloe in commerce may sometimes be adulterated with black catechu, pieces of iron, and stones. These can be detected by examining alcohol-soluble extracts under ultraviolet light which gives a deep brown colour with aloe and a black colour with catechu (14).

**Total ash**

Not more than 2% (3–5).

**Water-soluble extracts**

Not less than 50% (1, 2, 14).

**Alcohol-insoluble extracts**

Not more than 10% (1-3, 14).

**Moisture**

Not more than 10% for Cape Aloe (6), and not more than 12% for Curacao or Barbados Aloe (2-6, 14).

**Pesticide residues**

To be established in accordance with national requirements. Normally, the maximum residue limit of aldrin and dieldrin for Aloe is not more than 0.05 mg/kg (18). For other pesticides, see the WHO guidelines on quality control methods for medicinal plants (16) and guidelines for predicting dietary intake of pesticide residues (19).

**Heavy metals**

Recommended lead and cadmium levels are not more than 10 and 0.3mg/kg, respectively, in the final dosage form of the plant material (16).

**Radioactive residues**

For analysis of strontium-90, iodine-131, caesium-134, caesium-137, and plutonium-239, see WHO guidelines on quality control methods for medicinal plants (16).

**Other tests**

Acid-insoluble ash and chemical tests to be established in accordance with national requirements.

**9 Chemical assays**

Thin-layer chromatography and microchemical analyses are employed for the qualitative analysis for the presence of anthracene glycosides (1-7, 12, 14). Quantitative analysis of total anthracene glycosides, calculated as barbaloin, is performed by spectrophotometry (4, 5).

**Curacao or Barbados Aloe, derived from *Aloe vera* (L.) Burm. f.**

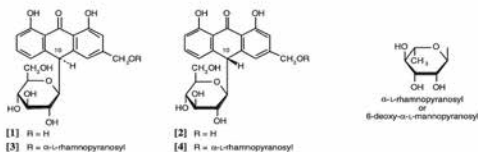
Contains not less than 28% of hydroxyanthracene derivatives, expressed as barbaloin (4-6).

**Cape Aloe, derived from *A. ferox* Miller and its hybrids with *A. africana* Mill. and *A. spicata* Baker**

Contains not less than 18% of hydroxyanthracene derivatives, expressed as barbaloin (4, 5).

**10 Major chemical constituents**

Aloe contains as its major and active principles hydroxyanthrone derivatives, mainly of the aloe-emodin-anthrone 10-C-glycoside type. The major constituent is known as barbaloin (aloin) (15-40%) (8, 13). It also contains hydroxyaloin (about 3%). Barbaloin (=aloin) is in fact a mixture of aloin A (105) [1] and B (10R) [2]. *A. ferox* also contains aloinoside A [3] and B [4]. Aloin A and B interconvert through the anthranol form as do aloinoside A and B (13).

**11 Dosage forms**

Powdered, dried juice and preparations thereof for oral use.

**12 Medicinal uses****Uses supported by clinical data**

Short-term treatment of occasional constipation (2, 12, 13, 15).

**Uses described in pharmacopoeias and in traditional systems of medicine**

None.

**Uses described in folk medicine, not supported by experimental or clinical data**

Treatment of seborrhoeic dermatitis, peptic ulcers, tuberculosis, and fungal infections, and for reduction of blood sugar (glucose) levels (11, 20).

**13 Pharmacology****Experimental pharmacology**

As shown for senna, Aloe's mechanism of action is twofold. It stimulates colonic motility, augmenting propulsion and accelerating colonic transit, which reduces fluid absorption from the faecal mass. It also increases paracellular permeability across the colonic mucosa probably owing to an inhibition of Na<sup>+</sup>, K<sup>+</sup>-adenosine triphosphatase or to an inhibition of chloride channels (8, 21, 22), which results in an increase in the water content in the large intestine (24).

**Clinical pharmacology**

The laxative effects of Aloe are due primarily to the 1, 8-dihydroxyanthracene glycosides, aloin A and B (formerly designated barbaloin) (23, 24). After oral administration aloin A and B, which are not absorbed in the upper intestine, are hydrolysed in the colon by intestinal bacteria and then reduced to the active metabolites (the main active metabolite is aloemodin-9-anthrone) (25, 26), which like senna acts as a stimulant and irritant to the gastrointestinal tract (27). The laxative effect of Aloe is not generally observed before 6 hours after oral administration, and sometimes not until 24 or more hours after.

**Toxicity**

The major symptoms of overdose are griping and severe diarrhoea with consequent losses of fluid and electrolytes. Treatment should be supportive with generous amounts of fluid. Electrolytes, particularly potassium, should be monitored in all recipients, especially in children and the elderly (28).

**14 Contraindications**

As with other stimulant laxatives, products containing Aloe should not be used in patients with intestinal obstruction or stenosis, atony, severe dehydration with electrolyte depletion, or chronic constipation (28). Aloe should not be administered to patients with inflammatory intestinal diseases, such as appendicitis, Crohn disease, ulcerative colitis, irritable bowel syndrome, or diverticulitis, or to children under 10 years of age. Aloe should not be used during pregnancy or lactation except under medical supervision after evaluating benefits and risks. Aloe is also contraindicated in patients with cramps, colic, haemorrhoids, nephritis, or any undiagnosed abdominal symptoms such as pain, nausea, or vomiting (28, 29).

**15 Warnings**

Aloe-containing products should be used only if no effect can be obtained through a change of diet or use of bulk-forming products. Stimulant laxative products should not be used when abdominal pain, nausea, or vomiting are present. Rectal bleeding or failure to have a bowel movement within 24 hours

after use of a laxative may indicate a serious condition. Chronic use may cause dependence and need for increased dosages, disturbances of water and electrolyte balance (e.g. hypokalaemia), and an atonic colon with impaired function (28).

The use of stimulant laxatives for more than 2 weeks requires medical supervision.

Chronic abuse with diarrhoea and consequent fluid and electrolyte losses (mainly hypokalaemia) may cause albuminuria and haematuria, and may result in cardiac and neuromuscular dysfunction, the latter particularly in the case of concomitant use of cardiac glycosides (digoxin), diuretics, corticosteroids, or liquorice root (see Precautions below).

**16 Precautions****General**

Laxatives containing anthraquinone glycosides should not be used continuously for longer than 1–2 weeks, owing to the danger of electrolyte imbalance.

**Drug interactions**

Decreased intestinal transit time may reduce absorption of orally administered drugs (30).

Existing hypokalaemia resulting from long-term laxative abuse can potentiate the effects of cardiotonic glycosides (digitalis, strophanthus) and anti-arrhythmic drugs such as quinidine (30). The induction of hypokalaemia by drugs such as thiazide diuretics, adrenocorticosteroids, and liquorice root may be enhanced, and electrolyte imbalance may be aggravated (31).

**Drug and laboratory test interactions**

Standard methods may not detect anthranoid metabolites, so measurements of faecal excretion may not be reliable (26).

Urinary excretion of certain anthranoid metabolites may discolour the urine, which is not clinically relevant but which may cause false positive results for urinary urobilinogen, and for estrogens when measured by the Kober procedure (30).

**Carcinogenesis, mutagenesis, impairment of fertility**

Data on the carcinogenicity of Aloe are not available. While chronic abuse of anthranoid-containing laxatives was hypothesized to play a role in colorectal cancer, no causal relationship between anthranoid laxative abuse and colorectal cancer has been demonstrated (32–35).

*In vitro* (gene mutation and chromosome aberration tests) and *in vivo* (micro-nucleus test in murine bone marrow) genotoxicity studies, as well as human and animal pharmacokinetic data, indicate no genotoxic risk from Cape Aloe (36–38).

#### **Pregnancy: teratogenic effects**

No teratogenic or fetotoxic effects were seen in rats after oral treatment with aloe extract (up to 1000 mg/kg) or aloin A (up to 200 mg/kg) (39).

#### **Pregnancy: non-teratogenic effects**

Aloe should not be used during pregnancy except under medical supervision after benefits and risks have been evaluated (40).

#### **Nursing mothers**

Anthranoic acid metabolites appear in breast milk. Aloe should not be used during lactation except under medical supervision, as there are insufficient data available to assess the potential for pharmacological effects in the breast-fed infant (30, 40).

#### **Paediatric use**

Oral use of Aloe in children under 10 years old is contraindicated.

### **17 Adverse reactions**

Abdominal spasms and pain may occur after even a single dose. Overdose can lead to colicky abdominal spasms and pain, as well as the formation of thin, watery stools (28).

Chronic abuse of anthraquinone stimulant laxatives can lead to hepatitis (41). Long-term laxative abuse may lead to electrolyte disturbances (hypokalaemia, hypocalcaemia), metabolic acidosis, malabsorption, weight loss, albuminuria, and haematuria (30, 42, 43). Weakness and orthostatic hypotension may be exacerbated in elderly patients when stimulant laxatives are repeatedly used (31). Secondary aldosteronism may occur owing to renal tubular damage after aggravated use. Steatorrhoea and protein-losing gastroenteropathy with hypoalbuminaemia have also been observed, as have excessive excretion of calcium in the stools and osteomalacia of the vertebral column (44, 45). Melanotic pigmentation of the colonic mucosa (pseudomelanosis coli) has been observed in individuals taking anthraquinone laxatives for extended time periods (29, 42). The pigmentation is clinically harmless and usually reversible within 4 to 12 months after the drug is discontinued (29, 42). Conflicting data exist on other toxic effects such as intestinal-neuronal damage after long-term use (42, 46).

### **18 Posology**

The correct individual dose is the smallest amount required to produce a soft-formed stool (26). As a laxative for adults and children over 10 years old, 0.04–0.11 g (Curacao or Barbados Aloe) or 0.06–0.17 g (Cape Aloe) of the dried juice (6, 14), corresponding to 10–30 mg hydroxyanthraquinones per day, or 0.1 g as a single dose in the evening.

Aloe

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- ① 정의: 알로에는 알로에 베라(L.) Burm. f. 또는 A. 페록스 밀의 잎과 A. 아프리카나 밀 및 A. 스피카타 베이커와의 교배종에서 나옴
- ② 동의어: Aloe vera (L.) Burm. f. 등
- ③ 통용명: Aloe capensis, aloe curacao, aloe vera 등
- ④ 설명: (이하 생략)
- ⑤ 주요 재료: 건조된 즙
- ⑥ 지리적 분포: 아프리카 남부 및 동부, 아라비아 반도, 중국 (이하 생략)
- ⑦ 일반 확인 검사: 거시적 및 미세적 검사, 용매 용해도 시험(뜨거운 알코올, 끓는 물, 에테르) (이하 생략)
- ⑧ 순도 검사: 미생물, 불순물, 수분 용해 추출물 (이하 생략)
- ⑨ 화학 분석: 얇은 층 크로마토그래피와 미세 화학 분석은 안트라센 글리코사이드의 존재를 확인하기 위한 정성 분석에 사용된다. (이하 생략)
- ⑩ 주요 화학 성분: 알로에는 주요 및 활성 성분으로 하이드록시안트론 유도체를 포함하고 있으며, 주로 알로에 에모딘 안트론 10-C-글루코사이드 유형이다. (이하 생략)
- ⑪ 복용법: 분말, 건조 주스, 그리고 그에 따른 제조물은 경구용으로 사용됨
- ⑫ 약용 용도: 임상 데이터에 의해 뒷받침되는 용도, 가끔 발생하는 변비의 단기 치료 (이하 생략)
- ⑬ 약리학: 실험적 약리학, 임상 약리학, 독성
- ⑭ 금기 사항: 폐색, 위장관 질환이 있는 환자에게는 사용 금지
- ⑮ 경고: 복용 후 효과가 없는 경우, 다른 형태의 완하제를 사용할 것을 권장
- ⑯ 주의사항: 일반주의사항, 약물 상호작용, 약물 및 실험실 검사 상호작용 등
- ⑰ 부작용: 과다 복용 시 복통이나 경련이 발생할 수 있으며, 설사를 유발할 수 있음 (이하 생략)
- ⑱ 용법 및 용량: 정확한 용량은 건강한 대변을 생성하는 데 필요한 최소한의 양이다.
- ⑲ 참고문헌: (이하 생략)

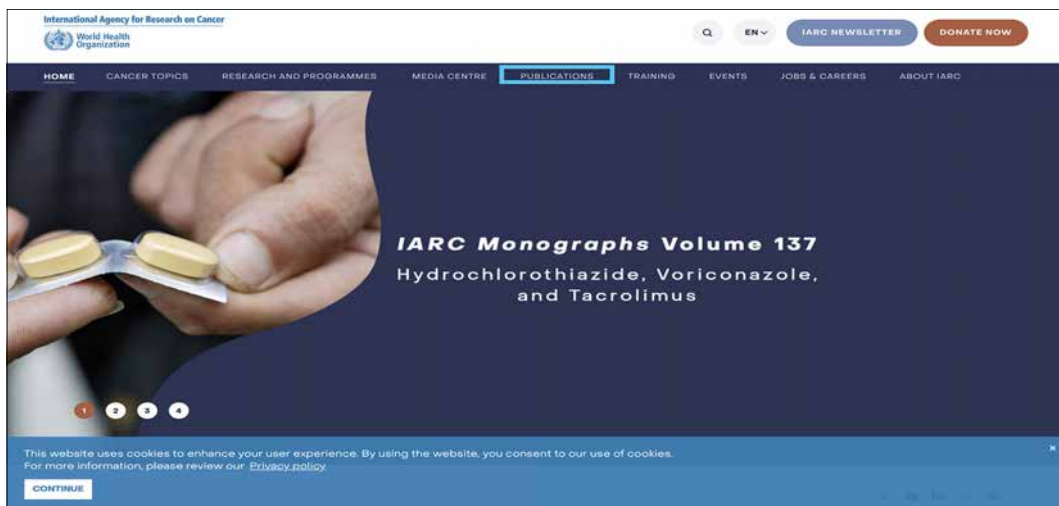
## [ SOME DRUGS AND HERBAL PRODUCTS VOLUME 108 ]

### ● 개요

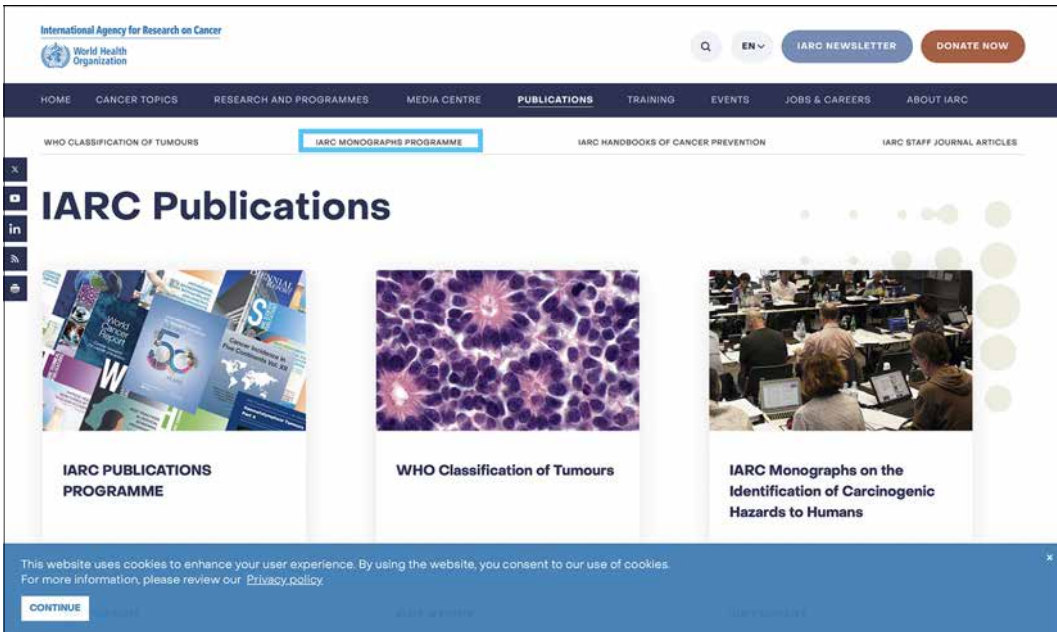
<b>DB명</b>	SOME DRUGS AND HERBAL PRODUCTS VOLUME 108
<b>관리기관</b>	WHO 산하 International Agency for Research on Cancer(IARC)
<b>DB 내용</b>	약용 식물과 일부 영양소들의 유해성과 관련된 데이터 및 연구 결과를 제공하고, 건강과 환경에 미치는 영향을 제시함
<b>접속 주소</b>	<a href="https://monographs.iarc.who.int/cards_page/publications-monographs/">https://monographs.iarc.who.int/cards_page/publications-monographs/</a>
<b>정보 제공 건수</b>	13건('24.11. 기준) - 약용 식물: 4건 - 화학물질: 9건

### ● DB 접속 방법

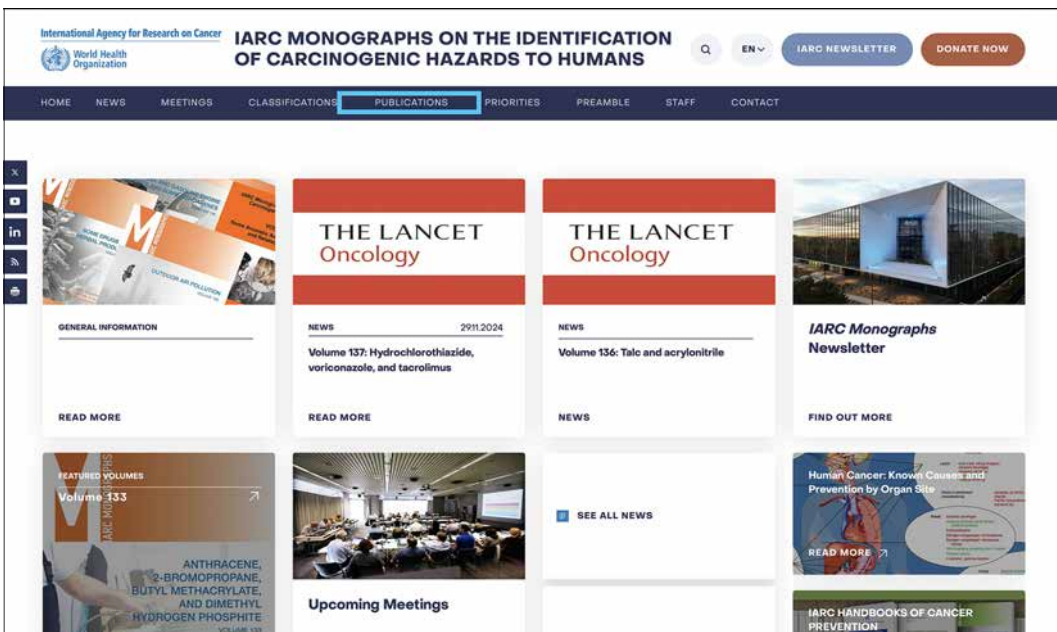
- 'International Agency for Research on Cancer' 홈페이지에 접속 후 상단 메뉴의 'PUBLICATIONS' 클릭



- 클릭 후 화면에서 'PUBLICATIONS' 아래의 'IARC MONOGRAPHS PROGRAMME' 클릭

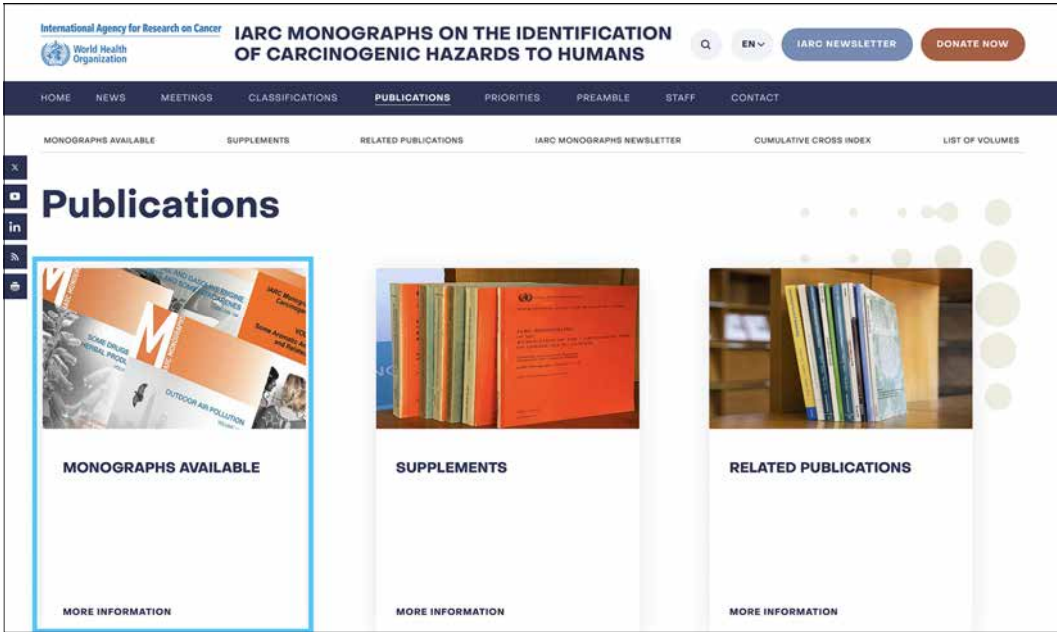


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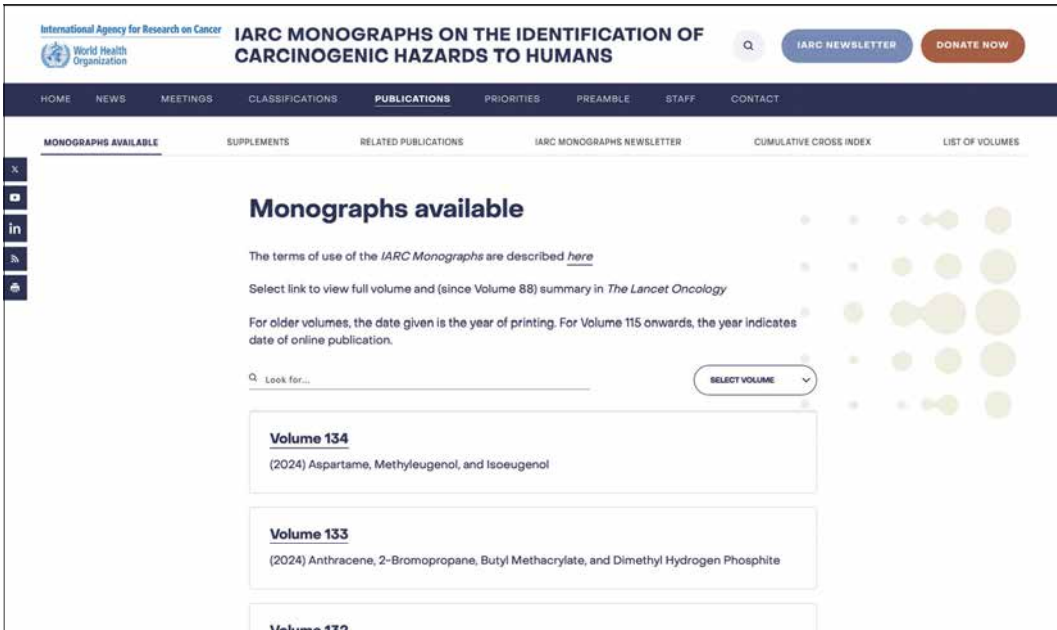


Part II.  
기능성 원료 안전성 확인 DB

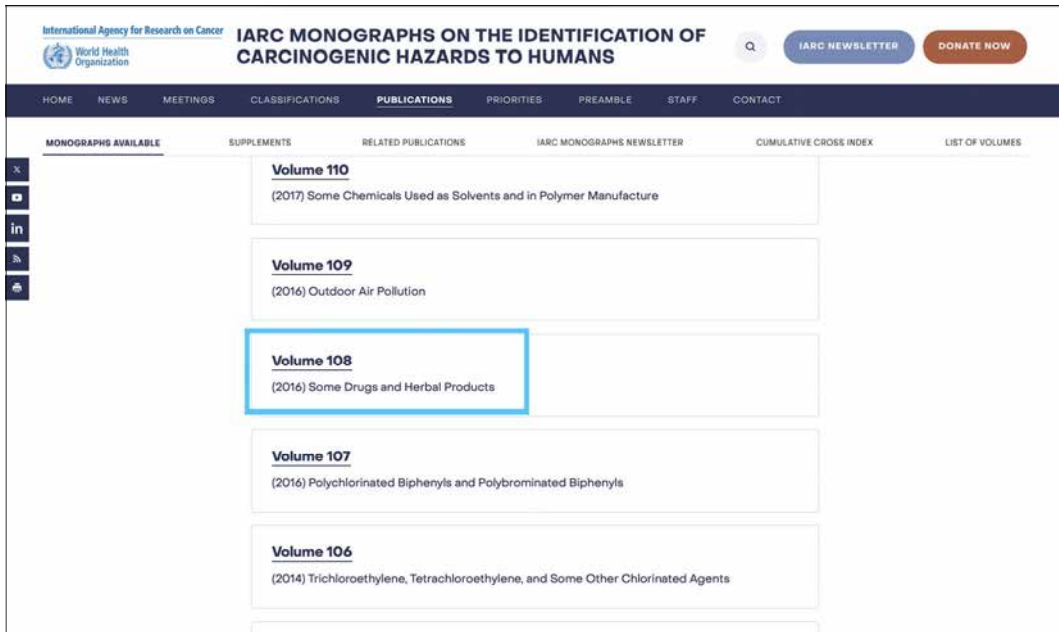
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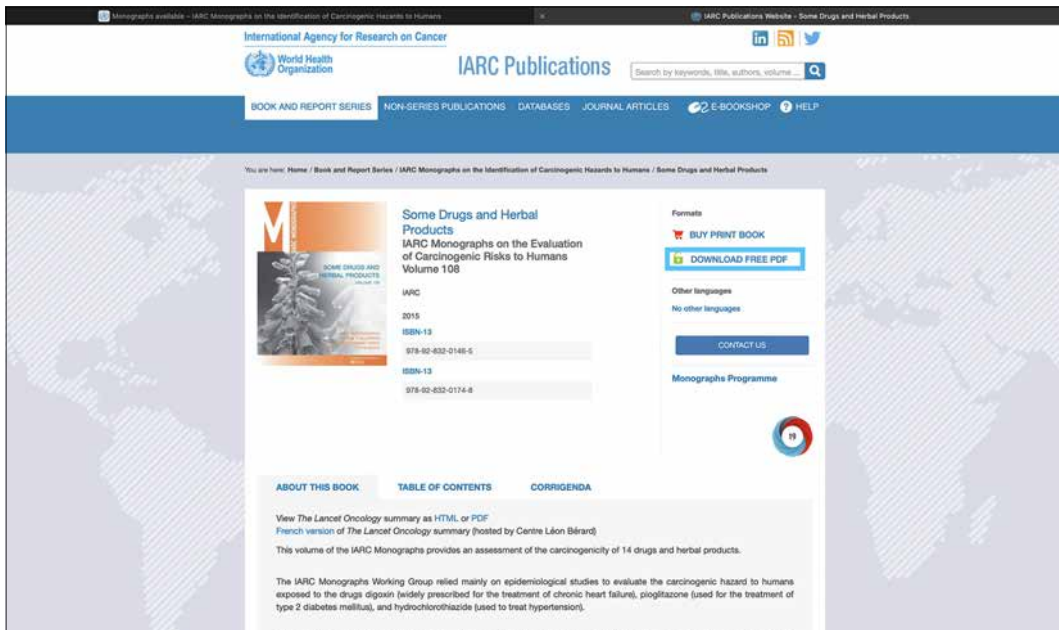
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○ ‘Volume 108’을 클릭



○ 이후 화면의 우측의 ‘DOWNLOAD FREE PDF’ 클릭 후 다운로드



Part II  
기능성 원료 안전성 확인 DB

● 정보 제공 범위

- 원료별 페이지에서 알려진 정보, 인간과 동물을 구분하여 암 유발 가능성 판단, 유관 데이터, 데이터 요약, 평가 등을 제공



예시 | 원료명: 알로에 베라

**ALOE VERA**

**1. Exposure Data**

The first record of human use of *Aloe vera* is in Sumerian hieroglyphics engraved on clay tablets during the Mesopotamia civilization circa 2200 BC, in which it is described as a laxative. Use of aloe in ancient times is also documented in Egypt, Greece, and China. *Aloe vera* was cultivated on the islands of Barbados and Curacao in the Caribbean by Spain and the Netherlands, and was sold in various parts of Europe during the 17th century (Park & Jo, 2006). Commercial cultivation of *Aloe vera* in the USA began in the 1920s in Florida (Grindlay & Reynolds, 1986). Although *Aloe vera* originated in the warm, dry climates of Africa, the plant is readily adaptable and grows worldwide (Steenkamp & Stewart, 2007).

Use of *Aloe vera* gel extracts in health foods and beverages, and moisturizing cosmetics, began during the 1970s, starting in the USA and parts of Europe (Park & Jo, 2006). Historically, *Aloe vera* was used topically to heal wounds and for various skin conditions, and orally as a laxative (Steenkamp & Stewart, 2007). The dried latex of other *Aloe* species, such as *Aloe ferox* Miller (Cape aloe or bitter aloe) has also been used as a laxative (EMA, 2006). Today, *Aloe vera* is also used as a folk or traditional remedy for a variety of conditions and is found in some dietary supplements and food products. *Aloe vera* gel can be found in hundreds of skin products, including lotions and sunblocks (NCCAM, 2012).

A glossary of commonly used terms for *Aloe vera* products is provided in Table 1.1.

**1.1 Identification of the agent**

**1.1.1 Botanical data**

(a) Nomenclature

For details on botanical nomenclature, see Newton (2004).

Chem. Abstr. Serv. Reg. No.: 8001-97-6  
Chem. Abstr. Name: *Aloe barbadensis*  
Botanical name: *Aloe vera* (L.) Burm. f. (synonym, *Aloe barbadensis*, *Aloe humilis* Blanco, *Aloe indica* Royle, nomen nudum, *Aloe perfoliata* var. *vera* L., *Aloe vulgaris* Lam.) (GRIN, 2013).  
Family: Xanthorrhoeaceae  
Genus: *Aloe*  
Plant part: Leaf  
Common names: *Aloe vera*; *Aloe vera* Linné; True aloe; *Aloe barbadensis*; Barbados aloe; Curaçao aloe; Mediterranean aloe; Ghritakumari; Lu Hui; Luhui, etc.  
From WHO (1999), Ear. Ph. (2008), O’Neil et al. (2006), SciFinder (2013), IASC (2013a), Boudreau et al. (2013a).

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of *Aloe vera* has been reported in 8.5–13.8% of people in predominantly Hispanic populations in the southern USA; according to surveys, it is also used frequently by 10.8%, 10.3%, and 7.6% of adults in Australia, Italy, and Jamaica, respectively (Nsgo *et al.*, 2010).

#### 1.5 Occupational exposure

No specific studies on occupational exposure were identified. It can be assumed that workers in the production of *Aloe vera* may be exposed, as well as workers in pharmaceutical, cosmetic, and food industries that use *Aloe vera* as an ingredient.

#### 1.6 Regulations and guidelines

Products made with various components of *Aloe vera* (aloin, aloe-emodin, and barbaloin) were at one time regulated by the FDA as oral over-the-counter (OTC) laxatives (NCCAM, 2012). In 2002, the FDA promulgated a regulation stating that the stimulant laxative ingredient *Aloe vera* in over the counter (OTC) drug products is not "generally recognized as safe and effective" or is misbranded (FDA, 2002). Because the companies that manufactured such products did not provide the necessary safety data, the FDA required that all OTC *Aloe vera* laxative products be removed from the USA market or reformulated (NCCAM, 2012). [The Working Group noted that currently no medicinal OTC *Aloe vera* products are available in the USA, unlike Europe where some medicinal *Aloe vera* products are still available.]

According to FDA regulations, *Aloe vera* may be safely used as a flavouring in foods as defined in 21CFR172.510. The Environmental Protection Agency (EPA) classified *Aloe vera* gel as a List 3 substance (level of unknown toxicity), and also listed *Aloe vera* gel as an inert ingredient of pesticide products (SciFinder, 2013).

A published tabulation of acceptable levels of natural flavourings by the Flavor and Extract Manufacturers' Association indicates that an acceptable level of *Aloe vera* extract is 5–2000 ppm. No distinction is given for the part of the plant or type of plant extract used to produce the extract used as a flavouring additive (Duke & Beckstrom-Sternberg, 1994).

For cosmetic uses, many of the manufacturers of *Aloe vera* gel take care to supply an ingredient containing anthraquinones at no more than 50 ppm (Committee of Experts on Cosmetic Products, 2008). This maximum level was also demanded in a safety assessment of the cosmetic industry (Cosmetic Ingredient Review Expert Panel, 2007).

*Aloe vera* is specified in several official pharmacopoeias, and an industry quality standard of the International Aloe Science Council is also available (Table 1.4). An American Herbal Pharmacopoeia on "Aloe vera leaf, Aloe vera leaf juice, Aloe vera inner leaf juice" was provided (AHP, 2012).

②

## 2. Cancer in Humans

No data were available to the Working Group.

## 3. Cancer in Experimental Animals

### 3.1 Studies of carcinogenicity

Whole leaf extract of *Aloe barbadensis* Miller [*Aloe vera*] was tested for carcinogenicity by oral administration (drinking-water) in one study in mice and one study in rats.

#### 3.1.1 Mouse

In a 2-year study of carcinogenicity, groups of 48 male and 48 female B6C3F<sub>1</sub> mice (age, 6–7 weeks) were given drinking-water containing 0 (controls), 1.0%, 2.0%, or 3.0% (wt/wt) whole leaf extract of *Aloe barbadensis* Miller [*Aloe vera*]

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## ④ 4. Mechanistic and Other Relevant Data

In reviewing studies relevant to the possible carcinogenicity of *Aloe vera*, the Working Group noted that attributing appropriate weight to individual studies was complicated by the consideration that, despite the terminology used, the material tested may not have been identical across various studies and/or may not have been identical to the material that was studied in experimental animals, as described in Section 3 of this Monograph.

### 4.1 Absorption, distribution, metabolism, and excretion

#### 4.1.1 Humans

There were no reports of studies to determine the absorption, distribution, metabolism, or excretion of topically applied *Aloe vera* gel, whole leaf extract or decolorized whole leaf extract in experimental animals or humans.

*Aloe vera* whole leaf extract is composed of gel and latex. *Aloe vera* gel contains non-starch polysaccharides of high molecular weight (the major one being acemannan) that are composed of sugar moieties linked by  $\beta$ -1,4-glycosyl bonds (Fig. 1.3 in Section 1). *Aloe vera* latex contains the anthrone C-glycosides aloin A (barbaloin) and aloin B (isobarbaloin) that are linked by  $\beta$ -glycosyl bonds to D-glucopyranose. Other C-glycosides found in *Aloe vera* latex include aloesin (aloeresin B) and aloeresin A in which

#### (a) Components of *Aloe vera* gel: metabolism *ex vivo*

Incubation of acemannan (aloemannan; molecular weight > 400 kDa) labelled with fluoresceinyl isothiocyanate (FITC) with a suspension of fresh human faeces for 5 days gave two metabolites, with molecular weights of 10 and 30 kDa, in 1% yield, meaning that aloemannan is catabolized by human intestinal bacteria (Yagi *et al.*, 1999).

#### (b) Components of *Aloe vera* latex

Orally ingested anthrone C-glycosides (*i.e.* aloin A and aloin B) pass intact through the upper portion of the gastrointestinal tract and upon reaching the lower gastrointestinal tract are cleaved to aloe-emodin-9-anthrone by human *Eubacterium* sp. BAR given to germ-free rats (Che *et al.*, 1991; Hattori *et al.*, 1993; Akao *et al.*, 1996). The free aglycone is then absorbed, undergoes oxidation, and is excreted in the urine as rhein, as was shown in three volunteers receiving *Aloe vera* or barbaloin (Vyith & Kamp, 1979; Fig. 4.1).

#### 4.1.2 Experimental systems

##### (a) Components of *Aloe vera* gel

In beagle dogs, the oral administration of radiolabelled acemannan at a dose of 20 mg/kg body weight (bw) per day for 3 months resulted in peak blood concentrations at 4–6 hours and a half-life of > 48 hours (Fogleman *et al.*, 1992).

Male ddY mice were given FITC-labelled acemannan (aloemannan; molecular weight,

undergoes sequential oxidation to aloe-emodin and rhein (Fig. 4.1). Likewise, intestinal microflora metabolize acemannan to smaller compounds by cleavage of the  $\beta$ -1 $\rightarrow$ 4 linkages.

The oral administration of *Aloe vera* whole leaf preparation induces hyperplasia of the large intestine in mice and rats, and adenomas and carcinomas of the large intestine in rats. Rats dosed orally with acemannan for up to 6 months did not display any treatment-related pathological changes. Likewise, rats given *Aloe vera* gel orally, and mice and rats given charcoal-treated *Aloe vera* gel did not show any treatment-related non-neoplastic or neoplastic lesions.

*Aloe vera* preparations, acemannan, and aloin A do not display genotoxic activity in bacterial assays for mutagenesis and/or other assays for genotoxicity. In contrast, aloe-emodin is mutagenic in *Salmonella typhimurium* reversion assays, induces unscheduled DNA synthesis, gene mutations, micronucleus formation, and chromosomal aberrations, inhibits topoisomerase II, and gives positive results in comet assays. These data suggest that the neoplastic response observed with *Aloe vera* is a consequence of the conversion of the anthrone C-glycosides to aloe-emodin, which by itself or in combination with other *Aloe vera* components is responsible for the development of adenomas and carcinomas in the large intestine.

In the 2-year bioassays with *Aloe vera* whole leaf preparations, mice were exposed to nearly 10 times more test material (on a per kg bw basis) than rats. In spite of this higher exposure, the mice did not develop adenoma or carcinoma of the large intestine, which may be due to the fact that the intestinal bacteria in mice are less efficient than the intestinal bacteria of rats in converting aloin A and aloin B to aloe-emodin anthrone and subsequently aloe-emodin. In addition, mice have shorter gastrointestinal tracts and faster gastrointestinal transit times than rats, which could contribute to the lack of a tumour response in mice.

Although the carcinogenicity of *Aloe vera* appears to be dependent upon the presence of the anthraquinone fraction, in particular aloe-emodin, the mechanism by which this fraction causes intestinal tumours is presently unknown. The administration of *Aloe vera* whole leaf preparations to rats induced non-neoplastic lesions (i.e. goblet cell hyperplasia) that are not observed with other *Aloe vera* preparations (e.g. *Aloe vera* gel, decolorized gel, or decolorized whole leaf). These non-neoplastic changes may result in the formation of ROS that could promote neoplastic progression. Aloe-emodin has been shown to generate ROS after incubation with human cells in vitro, probably as a result of its anthraquinone structure. Aloe-emodin also contains a benzylic hydroxy moiety that has the potential to undergo esterification (e.g. sulfation) to a reactive electrophile that could bind to DNA. This pathway does not appear to have been investigated. The incubation of *Aloe vera* whole leaf preparations with human intestinal microflora results in an increased production of short-chain fatty acids. The impact of this increased production is presently not clear. Although the mechanism by which *Aloe vera* whole leaf preparations induce intestinal neoplasms in rats is not fully understood, it is clear that the molecular pathways observed in the intestinal neoplasms induced in rats by *Aloe vera* whole leaf preparations are also observed in human colorectal cancers.

## 5. Summary of Data Reported

### 5.1 Exposure data

*Aloe vera*, also known as *Aloe barbadensis*, is a perennial succulent plant with green fleshy leaves. The leaves contain two types of liquids: a yellow bitter latex under the skin, and a viscous gel in the inner section. Commercial products are made from processed leaves. Four major types of processed products were identified: whole leaf

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extract; decolorized whole leaf extract; inner-leaf gel; and dried bitter latex. Decolorization removes pigments and anthraquinones from the whole leaf extract. The dried latex has medicinal uses as a laxative. The other forms are used in foods, dietary supplements, beverages, and cosmetic products. Exposure data, where they exist, do not identify the nature of products containing *Aloe vera* used by consumers.

### 5.2 Human carcinogenicity data

No data were available to the Working Group.

### 5.3 Animal carcinogenicity data

Whole leaf extract of *Aloe vera* was tested for carcinogenicity after oral administration in one 2-year study in mice, and one 2-year study in rats.

In male and female rats, drinking-water containing whole leaf extract of *Aloe vera* caused significantly increased incidences of adenoma of the large intestine (colon and caecum) and carcinoma of the large intestine (colon and caecum), tumours rarely developed spontaneously in rats.

In the 2-year study in mice, there was no significantly increased incidence of any type of tumours in males or females given drinking-water containing whole leaf extract of *Aloe vera*.

In a study of photo-co-carcinogenesis with simulated sunlight, four articles were studied by skin application in hairless mice: three test articles containing *Aloe vera* that included gel, whole leaf extract, and decolorized whole leaf extract; and an aloe-emodin preparation. Almost all mice exposed to simulated sunlight developed skin neoplasms. No increase in the incidence of skin neoplasms was observed in the groups receiving any of the four test articles applied as a cream followed by simulated sunlight when compared with the group receiving control cream followed by simulated sunlight. There was a significant

enhancing effect of *Aloe vera* gel cream or aloe-emodin cream on the photocarcinogenic activity of simulated sunlight in female mice based on an increase in the multiplicity of squamous cell papilloma, carcinoma or carcinoma in situ (combined). There was a significant enhancing effect of the whole leaf extract cream or decolorized whole leaf extract cream on the photocarcinogenic activity of simulated sunlight in both male and female mice, based on an increase in the multiplicity of squamous cell papilloma, carcinoma or carcinoma in situ (combined).

### 5.4 Mechanistic and other relevant data

The C-glycosides aloin A and aloin B, which are components of *Aloe vera* latex, are converted to aloe-emodin-9-anthrone by bacteria present in the gastrointestinal tract of rats and humans. Aloe-emodin-9-anthrone undergoes sequential oxidation to aloe-emodin and rhein. Preparations of *Aloe vera*, acemannan, and aloin A, do not display genotoxic activity in assays for mutagenesis in bacteria and/or other assays for genotoxicity. In contrast, aloe-emodin has genotoxic activity. These data suggest that the neoplastic response observed with *Aloe vera* is a consequence of the conversion of the anthrone C-glycosides to aloe-emodin, which by itself or in combination with other components of *Aloe vera* is responsible for the adenomas and carcinomas in the large intestine of rats.

## 6. Evaluation

### 6.1 Cancer in humans

There is inadequate evidence in humans for the carcinogenicity of *Aloe vera*.

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## 6.2 Cancer in experimental animals

There is sufficient evidence in experimental animals for the carcinogenicity of whole leaf extract of *Aloe vera*.

## 6.3 Overall evaluation

Whole leaf extract of *Aloe vera* is possibly carcinogenic to humans (Group 2B).

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- ① 알려진 정보: Aloe Vera는 젤, 분말 등 다양한 형태로 제공되며, 식품, 음료 및 화장품에 사용됨
- ② 인간에서의 암: 작업 그룹에 제공된 데이터는 없음
- ③ 실험 동물에서의 암: 알로에 바르바덴시스 밀러(*Aloe vera*)의 전체 잎 추출물이 쥐와 쥐를 대상으로 경구로 발암성을 테스트한 연구가 각각 하나씩 진행되었다. (이하 생략)
- ④ 기타 관련 데이터: 알로에 베라의 가능성 있는 발암성에 관련된 연구를 검토하는 과정에서, 작업 그룹은 개별 연구에 적절한 비중을 부여하는 것이 복잡하다는 점을 지적했다. (이하 생략)
- ⑤ 보고된 데이터 요약: 알로에 베라(*Aloe barbadensis*)는 녹색의 육즙이 많은 잎을 가진 다년생 다육 식물이다. (이하 생략)
- ⑥ 평가: 알로에 베라의 발암성에 대한 인간의 증거는 불충분하다. (이하 생략)
- ⑦ 참고문헌: (이하 생략)

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## 기능성 원료 안전성 확인을 위한 국가별 원료 정보 검색 가이드

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발 행 일 2025년 7월

발 행 인 식품의약품안전평가원장 강석연

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