

Tocomix L70-IP Organic CO

Product dossier – cosmetic
item ref.: 406422

1 Product and supplier identification

Trade name: Tocomix L70-IP Organic CO
Supplier name: IMCD Benelux B.V. or other IMCD affiliate
Manufacturing location: Product is made on the site of IMCD Benelux, Zandvoortstraat 49, 2800 Mechelen, Belgium.

2 Product details

2.1 General description

Antioxidant system, suitable for cosmetic purposes. Organic certified under Cosmos.

2.2 Product identity details of the ingredient

Ingredient name EU (2019/701): Tocopherol, Helianthus Annuus Seed Oil
INCI (US, PCPC): Tocopherol, Helianthus Annuus (Sunflower) Seed Oil

CAS / EC no:	Tocopherol:	1406-66-2 (tocopherols) / individual tocopherols: 200-412-2 (alpha) 240-747-1 (beta) 200-201-5 (gamma) 204-299-0 (delta)
	Helianthus Annuus Seed Oil:	8001-21-6 / 232-273-9
Function:	Tocopherol:	Antioxidant / skin conditioning
	Helianthus Annuus Seed Oil:	Emollient / skin conditioning
Chemical / common name:	Tocopherol:	individual tocopherols: alpha-tocopherol; [2R[2R*(4R*,8R*)]]-3,4-dihydro-2,5,8-trimethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol; [2R[2R*(4R*,8R*)]]-3,4-dihydro-2,7,8-trimethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol; [2R[2R*(4R*,8R*)]]-3,4-dihydro-2,8-dimethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol.

Helianthus Annuus Seed sunflower oil
Oil:

2.3 Composition

Compositional 100 % breakdown of the product into the ingredients: (EU ingredient names and concentrations)

Tocopherol (70 %), Helianthus Annuus Seed Oil (max. 30 %)

3 Registration status

3.1 Suitability for cosmetics

This product is suitable to be used as ingredient in cosmetic products within the framework of the Cosmetics Regulation (EC) 1223/2009, it is in compliance with the Regulation in relation to ingredients. As with all ingredients, the use is subject to relevant (national) legislation.

3.2 International registrations / legislation

(general, chemical) inventories, cosmetics listings:

Europe:	Tocopherol:	Regulation (EC) 1223/2009 Annex listing: Not Annex-listed, not applicable, not required. None of the substances listed in Annexes II through VI of the Regulation (EC) 1223/2009 is intentionally present, nor considered prone to be present. The ingredient is in compliance with e.g. Article 17 of the aforementioned Regulation.
	Helianthus Annuus Seed Oil:	Regulation (EC) 1223/2009 Annex listing: Not Annex-listed, not applicable, not required. None of the substances listed in Annexes II through VI of the Regulation (EC) 1223/2009 is intentionally present, nor considered prone to be present. The ingredient is in compliance with e.g. Article 17 of the aforementioned Regulation.
Japan (cosmetics):	Tocopherol:	No listed restriction found.
	Helianthus Annuus Seed Oil:	No listed restriction found.
Japan (quasi drugs, 2008):	Tocopherol:	List of quasi-drug additives/ingredients (2008): Please refer to listing 'Natural Vitamin E' component/standard code: 104457-51 (all 6 categories: marked 'O').
	Helianthus Annuus Seed Oil:	List of quasi-drug additives/ingredients (2008): name: 'Sunflower Seed Oil (1)', component/standard code: 520923-51. all 6 categories: marked 'O'.
Korea:	Tocopherol:	Max. 20 % for Vitamin E (tocopherol).

	Helianthus Annuus Seed Oil:	Not found on prohibited or restricted list.
	Tocomix L70-IP Organic CO:	Max. approx. 28 %, which is much higher than recommended use levels.
US:	Tocopherol:	<p>Cosmetic Ingredient Review (CIR) status: safe in the present practices of use and concentration described in the safety assessment (Final Amended Report, 2014), max. reported 5 % tocopherols.</p> <p>California: Product is not found on the Californian Proposition 65 list [3]. Some of the Proposition 65-listed substances are used as solvent (and are removed), but the first safe harbor level is reached at consuming over 1 kg of this product, using the upper limit of the detection limit. This product does not contribute significantly to the intake when compared to normal food. This does not pose a concern. Product / ingredients are not found on the California Reportable Ingredients List [4].</p>
	Helianthus Annuus Seed Oil:	<p>Cosmetic Ingredient Review (CIR) status: safe in the present practices of use and concentration described in the safety assessment (Final Report, Plant-Derived Fatty Acid Oils as Used in Cosmetics, 2011, 2017). Reported use up to 96 %.</p> <p>California: Product is not found on the Californian Proposition 65 list [3] and is not prone to contain Proposition 65-listed substances. Product is not found on the California Reportable Ingredients List [4].</p>
Australia:	Tocopherol:	<p>AICIS: AIC listed Ingredient not restricted and/or not found in the Poisons Standard [1].</p>
	Helianthus Annuus Seed Oil:	<p>AICIS: AIC listed Ingredient not restricted and/or not found in the Poisons Standard [1].</p>
Canada:	Tocopherol:	<p>DSL listed. Ingredient not found in Cosmetic Hotlist (List of Ingredients that are Prohibited / Restricted for Use in Cosmetic Products) [2].</p>
	Helianthus Annuus Seed Oil:	<p>DSL listed. Ingredient not found in Cosmetic Hotlist (List of Ingredients that are Prohibited / Restricted for Use in Cosmetic Products) [2].</p>

China:	Tocopherol:	Existing chemicals list: IECSC listed. Listed on Inventory of Existing Cosmetic Ingredients China (2015 Edition). TSSC 2015: The product is not found to be listed as prohibited or restricted in Table 1 through 3, and the product is not considered as prone to contain these substances.
	Helianthus Annuus Seed Oil:	Existing chemicals list: Listed as Existing Chemical. Listed on Inventory of Existing Cosmetic Ingredients China (2015 Edition). TSSC 2015: The product is not found to be listed as prohibited or restricted in Table 1 through 3, and the product is not considered as prone to contain these substances.

Listing on a (national) inventory or other list does not imply the product has been approved for use under local cosmetic legislation, approved for a particular application, or in compliance with certain specifications. It is up to the customer to ensure (legislative) suitability / compliance and to ensure the formulation is safe / compliant under relevant legislation.

4 Data on manufacture

4.1 Origin

Origin:	Plant.
Species:	<i>Glycine soja, Helianthus annuus.</i>
Endangered status:	Above species are not listed on the CITES Appendices.
Plant parts used:	Soja: beans, sunflower: seeds.
Animal origin involved?	No.

4.2 BSE / TSE status

Animal origin is not involved, BSE / TSE is not applicable to this product.

4.3 Genetically modified organisms (GMO)

Tocomix L70-IP Organic CO is not derived from genetically modified organisms (GMO).

Above product is manufactured in compliance with the FoodChain ID Certification NON-GMO Certification Standard under – in case of the tocopherols – an Identity Preserved (IP) regime. We are certified by FoodChain ID Certification (formerly known as Cert ID), and we operate in compliance with the above NON-GMO Standard.

The sunflower oil present (used to standardise the tocopherols to the target concentration) is not considered as a risk material with respect to GMO, and is organic certified.

4.4 Information on the manufacturing process – short description

Material coming from vegetable oil (soy) refining is subjected to separation techniques. (Multiple) purification steps are performed.

Organic sunflower oil is obtained by pressing and refining. Tocopherol and sunflower oil is blended to the required concentration.

4.5 Irradiation status

Product and its ingredients have not been subjected to irradiation treatment.

4.6 ISO 16128 natural status

Natural / organic indices according to ISO 16128-1 and 16128-2:

natural content: 100 %, natural origin content: 100 %, organic content: 26 %, organic origin content: 26 %

4.7 Impurities / contaminants / miscellaneous substances

This section contains information on contaminants that are typically requested. Listing does not necessarily imply a potential presence.

Heavy metals:	Not considered as prone to contain heavy metals. A random batch gave the following results: Lead (Pb) < 0.05 mg/kg; Arsenic (As) < 0.02 mg/kg; Mercury (Hg) < 0.005 mg/kg; Cadmium (Cd) < 0.02 mg/kg.
Pesticides:	No atypically high levels of pesticides expected, based on available information on surveillance testing of the ingredients, and also on the organic status of the sunflower oil. Typical results is 'not detected' for a large range of pesticides as tested in the tocopherols.
Residual solvents / volatile organic compounds (VOCs):	With reference to ICH guideline Q3C (R7) on impurities (EMA/CHMP/ICH/82260/2006): guideline for residual solvents and the Swiss Ordinance on Incentive Taxes on Volatile Organic Compounds 814.018 (status January 2018): Solvents are used in the manufacturing process of the tocopherols. The solvents are removed during the manufacturing process, please note that vacuum processes / distillation is part of the manufacturing process. Please note that the use of this is not an obstacle in the Cosmos approval. The sunflower oil is obtained without solvents. Surveillance monitoring on solvent residues in the tocopherols yielded values much lower than the limits mentioned in e.g. ICH guideline Q3C on impurities: guideline for residual solvents (EMA/CHMP/ICH/82260/2006). Levels of hexane are considered as technically unavoidable.
Miscellaneous substances:	Acidity: In compliance with FCC on tocopherols (not more than 1.0 ml 0.1 N NaOH per g). Typical levels are much lower. The following substances are not expected / applicable based on product / process: 1,4-Dioxane Alkylphenols, Alkylphenol ethoxylates

Amines, nitrosamines
Ethylene oxide
Formaldehyde or formaldehyde donors
Glycol ethers
Palm (kernel) oil and its derivatives
Sulfates

4.8 CMR substances, with reference to Regulation (EC) 1223/2009 Article 15

None of the ingredients in this product is classified as CMR according to Regulation (EC) 1272/2008.

Legislative status of this product is not concerned by CMRs.

4.9 Allergens

Cosmetic allergens (no. 45, 67, 69–92 of Annex III of Regulation (EC) 1223/2009): None of these allergens are found in a random test on tocopherol concentrate (in general), these allergens were also not found in the refined oils tested. (A detection limit of 10 mg/kg should be taken into account in case of ref. no 45, 67, 69-90 in the Regulation).

Atranol, chloroatranol, hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC, Lyril) and vetiveryl acetate are, taken into account the source, considered as not applicable to this product.

Food allergens (Annex II, Regulation (EU) 1169/2011, i.e. cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame seeds, sulphur dioxide and sulphites, lupin, molluscs, and products thereof, as specified in the Annex): not present. Tocopherols are soy-derived, but tocopherols are exempted from allergen labelling.

4.10 Nanomaterials

Product is a liquid, it is not a nanomaterial in accordance with the definition in Regulation (EC) 1223/2009. Please note that, considering the fact it is a liquid, particle size considerations are not applicable to this product.

4.11 Microbiological quality

Considering the fact above product is anhydrous and lipophilic, microbial risk in above product is low. Microbial status is monitored on surveillance basis. Random results on a similar product:

Salmonella: absent / 25 g;

E. coli absent / 1 g.

Result on similar product (Tocomix L50-IP)

Aerobic count (30 °C): < 10 CFU/g;

Yeasts and moulds: < 100 CFU/g.

5 Toxicology

Typically, toxicological overviews in general contains information obtained from literature and public sources, we do not imply that we have performed / commissioned animal tests.

5.1 Toxicological summary

Tocopherol:

Information on No Adverse Effect Level (NOAEL): (Tocopherol)	Please refer to long(er) term toxicological studies.
Acute toxicity: (Tocopherol)	Oral: 5 male mice were given a single dose of 10 ml/kg undiluted Tocopherol. Acute oral LD50 of undiluted Tocopherol of > 25 ml/kg was calculated by probit analysis. Oral LD50 of Tocopherol was > 4 g/kg for rats.
Longer term toxicity: (Tocopherol)	6 male rats were given 400 mg/kg Vitamin E in feed for 60 days. Tocopherol was not toxic. Compared to animals fed a high-fat diet, tocopherol vitamin E prevented increase in plasma lipid concentrations, decreased LDLc/HDLc ratio and lipid peroxide concentrations. In a 90-day study 7/10 rats dosed orally with 2000 mg/kg d-alpha-tocopherol died in 9 to 11 wks because of internal hemorrhage.
Skin irritation: (Tocopherol)	1.0 % Tocopherol in Paraffinum liquidum was applied to the backs of 8 male rabbits (backs of 4 were abraded) under an occlusive patch for 24 h. Primary irritation index, calculated according to Draize, was 0.13/8.0. Tocopherol, 0.1 %, was a weak primary irritant. 1.0 % Tocopherol in Paraffinum liquidum was applied to 3 male guinea pigs once daily for 3 consecutive days. Cumulative irritation index was 0.44 / 4.0. Tocopherol, 0.1 %, was a weak primary irritant. Cream with 5 % Tocopherol was not an irritant in a human RIPT using 113 subjects (semioclusive patch, 24 h, 3 times per week for a total of 10 applications. 1.0 % Tocopherol in Paraffinum liquidum was applied in 55 subjects. Test material was placed on human patch test plaster, for 24 h. Positive rate (percent rate of number of subjects with a positive reaction above score 2 (+1) (distinct erythema). Positive rate was 0/55. Tocopherol, 0.1 %, was not a primary skin irritant.
Eye irritation: (Tocopherol)	Tocopherol was instilled undiluted into the conjunctival sac of one of each of 3 male rabbits, eyes were not rinsed. Eyes were evaluated at 1 h, 4 h and 1, 2, 3, 6 and 7 days after instillation according to the Draize scoring system. Maximum score was 1 h after dosing, average total score at this time was 6.0 / 110. Tocopherol was a minimal eye irritant. 0.1 ml dl-alpha-tocopherol produced very slight irritation when instilled into rabbit eyes. Non-irritating to rabbit eyes.
Sensitisation: (Tocopherol)	Cream with 5 % Tocopherol was not a sensitiser in a human RIPT using 113 subjects (semioclusive patch, 24 h, 3 times per week for a total of 10 applications. Challenge applied after 2 week nontreatment. In guinea pigs, dl-alpha-tocopherol at 25 % induction with occlusive patch, 12.5 % at challenge (highest non-irritating concentration of tocopherol) was used. Some positive reactions noted.

Genotoxicity: (Tocopherol)	dl-alpha-tocopherol had moderate sensitisation potential in a local lymph node assay (LLNA). Mutagenicity: many studies on alpha-tocopherol, almost uniformly negative. Group of 15 male A/J mice were given chow containing 550 mg/kg Tocopherol. A/J mice are more susceptible to induction of spontaneous pulmonary tumorigenesis than ddY strain mice. A
Other toxicological data: (Tocopherol)	Please refer to protective effect of Tocopherol on tumor incidences. Oral administration of tocopherol, up to 75 mg /day in the diet, did not have reproductive or developmental effects in rats, Tocopherol had some effect on reducing the number of malformations observed in neonates from diabetic dams.
Remarks: (Tocopherol)	Unless specified, studies may be based on different kinds of tocopherol (mostly alpha-tocopherol) than used in this product. (*) with a similar tocopherol profile as in (high gamma+delta) Tocomix / Phytrox mixed tocopherols. Source: Cosmetic Ingredient R

Helianthus Annuus Seed Oil:

Information on No Adverse Effect Level (NOAEL): (Helianthus Annuus Seed Oil)	No data available. It should be noted that sunflower oil in general is an edible oil and is used at a large scale in food. In the CIR report from 2011 / 2017, sunflower oil has a very high reported number of uses.
Skin irritation: (Helianthus Annuus Seed Oil)	See sensitisation section.
Sensitisation: (Helianthus Annuus Seed Oil)	A massage oil containing 39.8 % sunflower oil, was tested. 9 induction applications (ca. 48 or 72 h) for 3 wks, 13 or 11 days for 5 volunteers rest period, 1 single challenge application (48 h), modified Marzulli and Maibach method, 109 (primary cutaneous irritation), 108 (cumulative irritation) or 107 (cutaneous sensitisation) subjects. – 0 % subjects with well visible to severe irritation during induction – mean irritation index (induction): 0 – 0 % sensitization reactions – 0 % reactions considered as serious adverse events linked to the investigational product. Test done in 2008. A face serum containing 20 % sunflower oil, was tested. 9 induction applications (ca. 48 or 72 h) for 3 wks, 13 d rest period, 1 single challenge application (24 or 48 h), 108 subjects, modified Marzulli and Maibach method: – 0 % subjects with well visible to severe irritation during induction – mean irritation index (induction): 0 – 0 % sensitization reactions – 0 % reactions considered as serious adverse events linked to the investigational product. Test done in 2008.

A skin cream, containing 6 % sunflower oil, was tested. 9 induction applications (ca. 48 or 72 h), 13 d rest period, 1 single application on 2 sites for ca. 48 h.) Modified Marzulli and Maibach method, 108 (primary cutaneous irritation), 106 (cumulative irritation), or 106 (cutaneous sensitisation) subjects.

- 0 % subjects with well visible to severe irritation during induction
- mean irritation index (induction): 0.00 – 0.01
- 0 % sensitization reactions
- 0 % reactions considered as serious adverse events linked to the investigational product.

Test done in 2010.

More data available.

6 Additional information

6.1 Information on hazardous ingredients (with reference to Regulation (EC) 1223/2009 Article 21)

Product does not contain hazardous ingredients according to Regulation (EC) 1272/2008.

6.2 Statement on animal testing

IMCD Benelux B.V. (or Jan Dekker International) has not performed nor commissioned any animal test on above product (or its ingredients).

6.3 Suitability for vegans

Animal origin is not involved, IMCD Benelux B.V. did not perform or commission any animal tests on this product or its ingredients, and the product is not obtained from GMO sources. The product is therefore considered suitable for vegans.

6.4 Relevant certifications

ISO 9001, ISO 14001, (and in practical sense FSSC 22000)

6.5 Product-specific approvals / certifications

Organic certified for cosmetics, under Cosmos (26 % organic)

non-GMO Identity Preserved certified

Halal certified

6.6 REACH registration / exemption status

Tocopherol: REACH-registered. Registration number: 01-2120087841-49-XXXX

Helianthus Annuus Seed Oil: Exempted from registration. It is listed in Annex V, heading 9.

6.7 Substances of Very High Concern (SVHC)

No ingredients are intentionally present appearing (at time of writing) on Annex XIV or on the Candidate List of Substances of Very High Concern for Authorisation in the framework of REACH (Regulation (EC) No 1907/2006).

Furthermore, considering the nature of this product and the manufacturing process, the presence of an impurity appearing on the aforementioned Annex XIV or Candidate List is not expected in a concentration of 0.1 % or greater.

Henk de Jager, Technical Manager, IMCD Benelux B.V.

Abbreviations / meanings:

- Animal: In line with e.g. The Vegan Society, in this document 'animal' refers to the entire Animal Kingdom, that is all vertebrates and all multi-cellular invertebrates.
- BSE: Bovine Spongiform Encephalopathy / TSE: Transmissible Spongiform Encephalopathy.
- CMR: Classified as carcinogenic, mutagenic or toxic for reproduction according to Annex VI part 3 of Regulation (EC) 1272/2008 (CLP).
- Ingredient name EU: the common ingredient name for use in the labelling of cosmetic products, with reference to Regulation (EC) 1223/2009, as listed in the glossary established in Decision (EU) 2019/701. The names are to be applied, for the purpose of labelling cosmetic products placed on the EU market, at the latest at 8 May 2020.
- INCI (US, PCPC): According to the International Cosmetic Ingredient Dictionary and Handbook, Personal Care Products Council.
- REACH: Regulation (EC) No 1907/2006.

Legislative references (last known version at time of writing):

- [1] Australia: Poison standard February 2021.
- [2] Canada: Cosmetic Ingredient Hotlist: 0.
- [3] US, California: Safe Drinking Water and Toxic Enforcement Act of 1986, Chemicals Known to the State to Cause Cancer or Reproductive Toxicity (State of California, Environmental Protection Agency, Office of Environmental Health Hazard Assessment) (Proposition 65), December 18, 2020.
- [4] US, California: California Department of Public Health Occupational Health Branch California Safe Cosmetics Program, Reportable Ingredients List, July 2019.

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