

1. DEFINITION

DEFINITION

Active texture agent, of 100% vegetable origin, based on a complex of vegetable waxes (jojoba and sunflower).

DENOMINATION

INCI NAME

(PCPC - International Nomenclature of Cosmetic Ingredients)

Jojoba Esters
Helianthus Annuus (Sunflower) Seed Wax
Polyglycerin-3

EUROPEAN INVENTORY OF COSMETIC INGREDIENTS - COSING

(European Commission database - [COSING](#))

Jojoba esters
Helianthus Annuus Seed Cera
Polyglycerin-3

2. FIELD OF USE

FIELD OF USE

This product is a cosmetic ingredient.
It is recommended for use in cosmetic formulations.

This ingredient must be used according to appropriate regulations. Use of the ingredient outside the fields of use recommended by Gattefossé is under the responsibility of the ingredient user.

Special applications

Oral cosmetic applications	No
Pediatric cosmetic applications (children under 3 years old)	No data available
Use during pregnancy and lactation (breastfeeding)	No data available
Other specific applications (eye products, intimate care...)	No data available

This information is based on our current knowledge. The status for our ingredient given in this section represents Gattefossé Regulatory Affairs department personal views on the subject matters. These views have not been adopted or in any way approved legally and should not be relied upon as a statement.

Please consult the document "Tox and safety overview" for additional information.

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DEFINICIRE (Code: 5938)

Last update: 23 April 2021

4. MANUFACTURING PROCESS AND COMPOSITION

MANUFACTURING PROCESS

Transesterification reactions of vegetable waxes (jojoba wax, sunflower wax) in presence of polyglycerol-3.

COMPOSITION

FULL LABELING (KEY LETTERS SYSTEM)

$75.0 \leq A_1$; $50.0 \leq A_2 < 75.0$; $25.0 \leq B < 50.0$; $10.0 \leq C < 25.0$; $5.0 \leq D < 10.0$; $1.0 \leq E < 5.0$; $0.1 \leq F < 1.0$; $G < 0.1$

Jojoba Esters	$50.0\% \leq A_2 < 75.0\%$
Helianthus Annuus (Sunflower) Seed Wax	$25.0\% \leq B < 50.0\%$
Polyglycerin-3	$1.0\% \leq E < 5.0\%$

OTHER CONSTITUENTS (INCIDENTAL INGREDIENTS)

Antioxidants: Tocopherols 200 ppm

Maximum added content.

5. COSMETIC REGULATIONS

REGULATORY STATUS OF THE INGREDIENT FOR COSMETIC AND PERSONAL CARE APPLICATIONS (Non-exhaustive list of countries, please contact us for additional information)

EUROPEAN UNION (European Cosmetic Regulation 1223/2009 and its amendments)	Approved
U.S.A. (FD&C Act— 21 CFR 700 to 740)	Approved
CANADA (Food and Drugs Act and Cosmetic Regulations)	Approved
MERCOSUR: Argentina, Brazil, Paraguay and Uruguay; with association agreements with Chile and Bolivia (Regulation for Personal Hygiene Products, Cosmetics & Perfumes)	Approved
AUSTRALIA (Notification & Assessment Act 1989, as amended—TGA)	Approved
NEW ZEALAND (Cosmetic Products Group Standard)	Approved
JAPAN (Pharmaceutical Affairs Law - regulations for cosmetics)	Approved
SOUTH KOREA (Cosmetics Law - Korea Food & Drug Administration KFDA)	Approved
TAIWAN	Approved
ASEAN: Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam (ASEAN Cosmetic Directive)	Approved

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INDIA (provisions of Indian Drug and Cosmetic Act)	Approved
Commonwealth of Independent States (CIS) Official members: Armenia, Azerbaijan, Belarus , Kazakhstan , Kyrgyzsta, Moldova, Russia, Tajikistan, Uzbekistan Unofficial associate members: Turkmenistan, Ukraine	Approved

REGULATORY STATUS OF THE INGREDIENT FOR COSMETIC AND PERSONAL CARE APPLICATIONS CHINA (Hygienic Standard for Cosmetics) Normal and Special cosmetics

Overall status of the product	Approved	
IECIC Status of Components		
INCI Name	Status	Chinese Name
Jjoba Esters	Listed IECIC 2015	霍霍巴酯类
Helianthus Annuus (Sunflower) Seed Wax	Listed IECIC 2015	向日葵 (HELIANTHUS ANNUUS) 籽蜡
Polyglycerin-3	Listed IECIC 2015	聚甘油-3
IECIC 2015 list: Inventory of existing cosmetic ingredients in China (IECIC) issued by CFDA on December 23 rd , 2015		

6. BORDER-LINE REGULATIONS

USE IN THERAPEUTIC GOODS - AUSTRALIA

Status	TGA name & synonyms	TGA reference number	Use	Restrictions
Not approved	/	/	/	Not approved: Polyglycerin-3

Australia has a two-tiered system for the regulation of medicines, including complementary medicines:

Registered Medicines: higher risk medicines must be registered on the Australian Register of Therapeutic Goods (ARTG), which involves individually evaluating the quality, safety and effectiveness of the product.

Listed Medicines: lower risk medicines containing pre-approved, low-risk ingredients. Ingredients must be evaluated and included in the Therapeutic Goods (Permissible Ingredients) Determination before they can be used listed medicines.

The Australian Register of Therapeutic Goods (ARTG) is available at: <https://www.ebs.tga.gov.au/>

USE IN QUASI DRUGS - JAPAN

Status	Adopted Japanese name	Code	Limitations
Not approved	/	/	Not approved: jjoba esters

Quasi-drugs include Mouth wash products (for disinfection of the mouth); Deodorants; Talc powder (with active ingredient); Hair-growth products; Depilatories; Hair dyes (oxidative); Bath preparations (with active ingredients); Permanent wave products; Medicated cosmetics (including anti-dandruff shampoos and rinses, Leave-on acne products for prevention of acne, anti-chapping and anti-frostbite lotions, whitening products and anti-bacterial products); Medicated toothpastes ...)

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USE IN NATURAL HEALTH PRODUCTS - CANADA

Status	NHPID name	Route of administration/ Restrictions
Approved non-medicinal ingredient	Jojoba Esters Helianthus Annuus (Sunflower) Seed Wax Polyglycerin-3	Topical use

Under the Natural Health Products Regulations, which came into effect on January 1, 2004, natural health products (NHPs) are defined as: Probiotics; Herbal remedies; Vitamins and minerals; Homeopathic medicines; Traditional medicines such as traditional Chinese medicines; Other products like amino acids and essential fatty acids.

The Natural Health Products Ingredients Database (NHPID) lists acceptable medicinal and non-medicinal ingredients used in Natural Health Products. It is available at: <http://webprod.hc-sc.gc.ca/nhp-id-bdipsn/search-rechercheReq.do>

7. ORGANIC COSMETICS

STATUS OF THE INGREDIENT FOR ORGANIC COSMETIC FORMULATIONS

Body	Standard	Status	Evaluation conclusions
COSMOS			
Ecocert Greenlife	COSMOS-standard	Approved raw material	PPAI: 31,62 % CPAI: 68,38 % NNI: 0% PeMo: 0 %

COSMOS: The following product has been evaluated by ECOCERT® Greenlife and complies with the COSMOS® standard for ingredients to be used in Natural and Organic cosmetics. We would like to draw your attention to the fact that this product is not "Organic certified".

COSMOS Definitions: PPAI = Physically Processed Agro-Ingredient ; CPAI = Chemically Processed Agro-Ingredient ; PeMo = Petrochemical Moieties ; NNI : Non Natural Ingredients.

8. NATURALITY

CALCULATIONS ACCORDING TO ISO 16128 STANDARD

Guidelines on Technical Definitions and Criteria for Natural & Organic Cosmetic Ingredients

- Natural index (In): 0
- Natural origin index (Ion): 1
 - Organic index (IO): 0
- Organic origin index (IOO): 0

This has been determined based on the origin of the raw materials (including intentionally added additives, if any) and our manufacturing processes.

This is based on our current knowledge and understanding of the available texts (ISO 16128-1 and ISO 16128-2).



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10. CHEMICAL REGULATIONS

CHEMICAL REGULATIONS			
INCI name	CAS #	EC #	Chemical name
Jojoba Esters	61789-91-1	612-381-6	Waxes and Waxy substances, jojoba
Helianthus Annuus (Sunflower) Seed Wax	8001-21-6	232-273-9	Sunflower oil
Polyglycerin-3	25618-55-7	607-759-2	1,2,3-Propanetriol, homopolymer

NATIONAL INVENTORIES					
INCI name	U.S.A. (TSCA)	Canada (DSL/NDSL)	Australia (AIC)	China (IECSC)	Other inventories
Jojoba Esters	Listed	DSL listed	Listed	Listed	Waxes and Waxy substances, jojoba (TSCA, DSL, AICS, PICCS, ASIA-PAC, NZIoC)
Helianthus Annuus (Sunflower) Seed Wax	Listed	DSL listed	Listed	Listed	Sunflower oil (TSCA, DSL, EINECS, AICS, ECL, SWISS, PICCS, ASIA-PAC, NZIoC)
Polyglycerin-3	Listed	DSL listed	Listed	Listed	1,2,3-Propanetriol, homopolymer (TSCA, DSL, AICS, PICCS, ASIA-PAC, NZIoC, ENCS, ECL)

U.S.A.: Substances that are regulated under other federal regulations, including food additives, drug, cosmetics... are not subject to TSCA regulation. "Naturally occurring substances" are not subject to Premanufacture Notice reporting.

Canada: Substances not listed on DSL or NDSL can be imported in Canada in quantities not exceeding 100 kg per 12-month period and per importer. Substances listed on NDSL only can be imported in Canada in quantities not exceeding 1000 kg per 12-month period and per importer. Please contact us if you go beyond these volumes. In addition, substances not listed in DSL or NDSL, but listed in the "in-commerce list" can be freely used in Products Regulated Under the Food and Drugs Act (F&DA). In addition, substances considered as "Natural" according Health Canada's definition are exempted from New Substances regulation.

Australia: The Australian Inventory of Chemical Substances (AICS) has been replaced by the Australian Inventory of Industrial Chemicals (AIIC) since July 2020. Chemicals listed on the AIIC are available for industrial use in Australia; however, importers must register with Australian authorities before importing the chemical in Australia. Some chemicals require specific information to be provided to Australian authorities.

Naturally occurring chemicals are exempted from AIIC listing.

Chemicals not listed on the AIIC must be assessed before importation.

INCIDENTAL INGREDIENTS			
Name	CAS #	EC #	Chemical inventories
Tocopherols	59-02-9	200-412-2	α -Tocopherol (DSL, EINECS, PICCS, ECL)/ 2H-1-Benzopyran-6-ol, 3,4-dihydro-2,5,7,8-tetramethyl-2-[(4R,8R)-4,8,12-trimethyltridecyl]-, (2R)- (INSQ, NZIoC, PICCS, TCSI, TDCA, TSCA, AIIC, ENCS)



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REACH REGULATION

(REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS)

Overall status of the product

Please refer to Safety Data Sheet

Liability clause

The information contained in this document is based on our knowledge of the related product(s) at the date indicated herein, and is provided in good faith. Notwithstanding the foregoing, no guarantee is made in respect of the product's(s') properties or efficacy, or the continued exactitude and completeness of the information herein. No contractual tie is formed by the provision of this information. This document does not relieve the user from conducting all tests and verifications to ensure the product's(s') suitability for each intended use. Nothing herein shall be construed as a recommendation or licence to use any information that does or may conflict with any intellectual property. We make no representation or warranty, express or implied, that use of this information will not infringe any intellectual property of Gattefossé or any third party. The user assumes all risks and liability incurred if a product is used other than for the purpose designated by Gattefossé. This statement does not relieve the user from verifying its conformity with all current applicable laws and regulations, and the user shall remain solely liable for ensuring its continued conformity therewith.

