

1. DEFINITION

DEFINITION

NaDES extract (Fructose/Glycerin/Water) of Chayote fruit (Sechium edule).

DENOMINATION

INCI NAME (PCPC - International Nomenclature of Cosmetic Ingredients)	Fructose (and) Glycerin (and) Water (and) Sechium Edule Fruit Extract
EUROPEAN INVENTORY OF COSMETIC INGREDIENTS - COSING (European Commission database - COSING)	Fructose (and) Glycerin (and) Aqua (and) Sechium Edule Fruit Extract
CHINA: NMPA NOTIFIED INCI NAME Please refer to Section 4 for more details	FRUCTOSE GLYCERIN WATER SECHIUM EDULE FRUIT EXTRACT SODIUM BENZOATE CITRIC ACID
ADDITIONAL INFORMATION ON THE DENOMINATION	Sechium edule is also known as chayote or chayotte or christophine

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	Yes
Pediatric cosmetic applications (children under 3 years old)	No data available
Use during pregnancy and lactation (breastfeeding)	No data available

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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.

3. MANUFACTURING PROCESS AND COMPOSITION

MANUFACTURING PROCESS

NaDES extraction

COMPOSITION

FULL LABELING (KEY LETTERS SYSTEM)

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

Fructose	$25.0\% \leq B < 50.0\%$
Glycerin	$10.0\% \leq C < 25.0\%$
Water	$10.0\% \leq C < 25.0\%$
Sechium Edule Fruit Extract	$5.0\% \leq D < 10.0\%$

MEDIAN VALUES

Median values are determined by taking the average of each key letter and adapting each result so that the total equals 100%.

Fructose	46.7%
Glycerin	23.0%
Water	23.0%
Sechium Edule Fruit Extract	7.0%

OTHER CONSTITUENTS (INCIDENTAL INGREDIENTS)

Sodium Benzoate: 0.15%

Citric Acid: 0.1%

Maximum added content.

ADDITIONAL INFORMATION

CITES: Not listed

4. 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



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

U.S.A. (FD&C Act— 21 CFR 700 to 740)	Approved
CANADA (Food and Drugs Act and Cosmetic Regulations)	Approved - our product can be imported in Canada in quantities not exceeding per 12-month period and per importer: 1428 kg
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
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
Gulf Cooperation Council (GCC) Official members: Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, UAE (United Arab Emirates)	Approved

CHINA - INVENTORY OF EXISTING INGREDIENTS (IECIC) - 2021

Overall status of the product for cosmetic use in China	Approved
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IECIC 2021 Status of Components

INCI Name (NMPA notified)	Chinese Name	Composition for NMPA cosmetics registration
FRUCTOSE	果糖	46.7%
GLYCERIN	甘油	23.0%
WATER	水	23.0%
SECHIUM EDULE FRUIT EXTRACT	佛手瓜 (SECHIUM EDULE) 果提取物	7.0%
SODIUM BENZOATE	苯甲酸钠	0.2%
CITRIC ACID	柠檬酸	0.1%

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5. BORDER-LINE REGULATIONS

AUSTRALIA - USE IN THERAPEUTIC GOODS

Status	TGA name	TGA reference number	Use	Restrictions
Not approved				Sechium edule is not approved

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/>

JAPAN - USE IN QUASI DRUGS

Status	Adopted Japanese name	MHW Code	Limitations
Not approved			Sechium edule is not approved

The Quasi-Drugs status is given for information only; it is based on the presence of the ingredient name in the List of Additives for Quasi-Drugs. It does not mean that the ingredient conforms with Quasi-Drugs requirements.

CANADA - USE IN NATURAL HEALTH PRODUCTS

Status	NHPID name	Route of administration/ Restrictions
Not approved		Sechium Edule Fruit Extract is not listed

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>

6. NATURAL & ORGANIC COSMETICS

STATUS OF THE INGREDIENT FOR ORGANIC/NATURAL COSMETIC FORMULATIONS

Body	Standard	Status	Evaluation conclusions
COSMOS			
Ecocert Greenlife	COSMOS-standard	Approved raw material	PPAI = 28,5% CPAI = 71,35% NNI = 0,15% PeMo = 0%

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STATUS OF THE INGREDIENT FOR ORGANIC/NATURAL COSMETIC FORMULATIONS

Body	Standard	Status	Evaluation conclusions
COSMOS: The following product has been evaluated by ECOCERT® Greenlife and complies with the COSMOS standard for ingredients to be used in COSMOS-Natural and COSMOS-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.			

CALCULATIONS ACCORDING TO ISO 16128 STANDARD

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

- Natural content (CN): 76.7%
- Natural origin content (Cno): 99.8%
 - Organic content (CO): 0%
 - Organic origin content (COO): 0%

The indexes/ contents displayed above are based on Median Value Composition.

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).

7. RSPO CERTIFICATION

ROUNDTABLE ON SUSTAINABLE PALM OIL

<http://www.rspo.org/certification>

Product status	Gattefossé RSPO certification number
Product certified RSPO Mass Balance. More information on: www.RSPO.org	Supply Chain Certificate (SCC) number: BVC-RSPO-1-1106949778.

8. CHEMICAL REGULATIONS

CHEMICAL REGULATIONS

INCI name	CAS #	EC #	Chemical name
Fructose	57-48-7	200-333-3	D-Fructose
Glycerin	56-81-5	200-289-5	1,2,3-Propanetriol or Glycerol or Glycerin
Water	7732-18-5	231-791-2	Water
Sechium Edule Fruit Extract	223748-59-2	None	Sechium edule, ext.

NATIONAL INVENTORIES

INCI name	U.S.A. (TSCA)	Canada (DSL/NDL)	Australia (AIIC)	China (IECSC)	Inventory names
Fructose	Listed	DSL listed	Listed	Listed	D-Fructose (AIIC, AREC, DSL, ECL, EINECS, ENCS, IECSC, INSQ, NZIoC, PICCS, TCSI, TSCA, VNECI)

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NATIONAL INVENTORIES

INCI name	U.S.A. (TSCA)	Canada (DSL/NDSL)	Australia (AIC)	China (IECSC)	Inventory names
Glycerin	Listed	DSL listed	Listed	Listed	1,2,3-Propanetriol (AIC, DSL, INSQ, NZIoC, PICCS, TCSI, TSCA)/ Glycerol (AREC, DSL, ECL, EINECS, PICCS, REACH, VNECI)/ Glycerin (ENCS, IECSC, PICCS)
Water	Listed	DSL listed	Listed	Listed	Water (AIC, AREC, DSL, ECL, EINECS, ENCS, IECSC, INSQ, NZIoC, PICCS, REACH, TCSI, TDCA, TSCA, VNECI)
Sechium Edule Fruit Extract	Not listed	Not listed (ICL listed)	Not listed	Registered*	Sechium edule fruit extract (TCSI)

U.S.A.: Substances used in the following product categories are excluded from TSCA authority: foods, food additives, drugs, cosmetics.

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 to 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 (AIC) since July 2020. Chemicals listed on the AIC 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 AIC listing.
Chemicals not listed on the AIC must be assessed before importation.

*China: if your company intends to import our ingredient as chemical entities in China, please consult us.

Australia: AIC - Canada: DLS/NDSL - China: IECSC - European Union: EINECS, REACH - Japan: ENCS - Mexico: INSQ - New Zealand: NZIoC - Philippines: PICCS - South Korea: ECL, AREC - Switzerland: SWISS - Taiwan: TCSI - Thailand: TDCA - USA: TSCA - Vietnam: VNECI

INCIDENTAL INGREDIENTS

Name	CAS #	EC #	Chemical inventories
Citric Acid	5949-29-1	201-069-1	Citric acid, monohydrate: AIC, DSL, IECSC, NZIoC, PICCS, TCSI, VNECI
Sodium Benzoate	532-32-1	208-534-8	Sodium benzoate: AIC, AREC, DSL, ECL, EINECS, ENCS, IECSC, INSQ, NZIoC, PICCS, TCSI, TSCA, VNECI

Australia: AIC - Canada: DLS/NDSL - China: IECSC - European Union: EINECS, REACH - Japan: ENCS - Mexico: INSQ - New Zealand: NZIoC - Philippines: PICCS - South Korea: ECL, AREC - Switzerland: SWISS - Taiwan: TCSI - Thailand: TDCA - USA: TSCA - Vietnam: VNECI

REACH REGULATION

(REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS)

Overall status of the product

Please refer to Safety Data Sheet



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Liability clause

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