

	REGULATORY DATA SHEET (RDS)	
	LIPOCIRE A PASTILLES / LIPOCIRE A PELLETS (Code: 5173)	Last update : 18 April 2013

REGULATORY DATA SHEET COSMETICS AND PERSONAL CARE USE

I. DEFINITION

DEFINITION
Triglycerides C10-18

DENOMINATION	
INCI NAME (PCPC - International Nomenclature of Cosmetic Ingredients)	NEW INCI name (approved): C10-18 Triglycerides Alternative INCI name (registered PCPC): Hydrogenated Palm Kernel Glycerides and Hydrogenated Palm Glycerides
EUROPEAN INVENTORY OF COSMETIC INGREDIENTS - COSING (European Commission database - COSING)	C10-18 Triglycerides

II. FIELD OF USE

FIELD OF USE	
This ingredient must be used according to appropriate regulations	
This product is a cosmetic ingredient. It is recommended for use in cosmetic formulations.	
SPECIAL APPLICATIONS	
Oral cosmetic applications	Yes
Paediatric cosmetic applications (children of less than 3 years old)	Yes
Use during Pregnancy and lactation (Breastfeeding)	Yes
<small>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.</small>	

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III. MANUFACTURING PROCESS AND COMPOSITION

MANUFACTURING PROCESS	
Interesterification reaction between hydrogenated Palm kernel oil (mainly containing Triglycerides of Lauric acid) and hydrogenated palm oil (containing Triglycerides of palmitostearic acid)	
COMPOSITION	
Triglycerides of saturated fatty acids (C10 - C18)	
FULL LABELING (KEY LETTERS SYSTEM)	
$75.0 \leq A_1$; $50.0 \leq A_2 < 75.0$; $25.0 \leq B < 50.0$; $10.0 \leq C < 25.0$; $5.0 \leq D < 10.0$; $1.0 \leq E < 5.0$; $0.1 \leq F < 1.0$; $G < 0.1$	
C10-18 Triglycerides	$A_1 : > 75.0$
OTHER CONSTITUENTS (INCIDENTAL INGREDIENTS)	
None	

IV. COSMETIC REGULATION

REGULATORY STATUS OF THE INGREDIENT FOR COSMETIC AND PERSONAL CARE APPLICATIONS (Non exhaustive list of countries, please contact us for additional information)	
EUROPE (European cosmetics Directive 76/768/EEC 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
JAPAN (Pharmaceutical Affairs Law - regulations for cosmetics)	Approved
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

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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)

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
<p>U.S.A.: Substances that are regulated under other federal regulations, including food additives, drug, cosmetics ... are not subject to TSCA including food additives, drug, cosmetics ... are not subject to TSCA regulation.</p> <p>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. In addition, substances not listed in DSL or NDSL, but listed in the "in-commerce list" (ICL) 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.</p> <p>Australia: Substances Introduced at 1% or less in cosmetics are exempted from AICS listing. Otherwise, substances not listed on AICS can be imported in Australia in quantities not exceeding 10 kg per 12-month period and per importer. In addition, in the Industrial Chemicals (Notification and Assessment) Act 1989 (the Act), an industrial chemical which meets the definition of 'a naturally-occurring chemical' is taken to be on the Australian Inventory of Chemical Substances (AICS), whether listed or not, and therefore does not require notification as a new chemical prior to manufacture or importation into Australia.</p>	

REGULATORY STATUS OF THE INGREDIENT FOR COSMETIC AND PERSONAL CARE APPLICATIONS
CHINA (Hygienic Standard for Cosmetics)
NORMAL AND SPECIAL COSMETICS

	Status ⁽¹⁾	Comments
C10-18 Triglycerides	APPROVED	Listed 2003/2007/2010/2012-04
CHINESE NAME (CCNCI)	C10-18 脂酸甘油三酯类	
⁽¹⁾ 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.		
2003 list: Inventory of existing cosmetic ingredients in China issued by MOH (IECIC 2003) 2007 list: Catalogue of Standard Chinese Name of International Cosmetic Ingredient (CCNCI) 2007 Ed issued by MOH (Based on PCPC dictionary 2004) 2010 list: Catalogue of Standard Chinese Name of International Cosmetic Ingredient (CCNCI) 2010 Ed issued by SFDA (Based on PCPC dictionary 2008) 2012-04(official 2013-02)/2012-07/2012-09... lists: Inventory of existing cosmetic ingredients in china (IECIC additional lists) issued by SFDA		

REGULATORY STATUS OF THE INGREDIENT FOR BORDER-LINE APPLICATIONS

	Status	Denomination		Additional information
AUSTRALIA Therapeutic goods (TGA)	Approved	Hard fat	53866	Limitations: /
JAPAN QUASI-DRUGS	Approved	Saturated Fatty Acid Glycerides	520983-42	Limitations: /
<p>AUSTRALIA: Therapeutic goods are divided into 'medicines' and 'medical devices'. Some 'medicines' are limited to prescription-only while others are available without a prescription. Non-prescription medicines may be 'complementary medicines' (i.e. vitamin, mineral, herbal, aromatherapy, and homeopathic products) or 'OTC medicines' and may be 'listed' (i.e. Sunscreens SPF4 and >4) or 'registered' in the ARTG.</p> <p>JAPAN: 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 ...)</p>				

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V. ORGANIC COSMETICS

STATUS OF THE INGREDIENT FOR ORGANIC COSMETIC FORMULATIONS

Body	Standard	Status	Evaluation conclusions
ECOCERT			
ECOCERT® Greenlife	ECOCERT® standard for ingredients to be used in Ecological and Organic cosmetics.	Evaluated Cosmetic ingredient	On the total of ingredients: 100% ingredients of Natural origin
COSMOS			
ECOCERT® Greenlife	COSMOS® standard for ingredients to be used in Natural and Organic cosmetics.	Evaluated Cosmetic ingredient	PPAI: % CPAI: 100 % SyMo: 0 %
NPA - Natural Products Association			
NPA	Natural Products Association Standard and certification program for Personal care products	Certified	/
ECOCERT Definition: PI = Plant Ingredient ; SYN = Synthetic Origin ; COSMOS Definition: PPAI = Physically Processed Agro-Ingredient ; CPAI = Chemically Processed Agro-Ingredient ; SyMo = Synthetic Moieties ECOCERT: The following product has been evaluated by ECOCERT® Greenlife and complies with the ECOCERT® standards for ingredients to be used in Ecological and Organic cosmetics. We would like to draw your attention on the fact that this product is not "Organic certified". COSMOS: The following product has been evaluated by ECOCERT® Greenlife and complies with the COSMOS® standards for ingredients to be used in Ecological and Organic cosmetics. We would like to draw your attention on the fact that this product is not "Organic certified".			

VI. CHEMICAL REGULATION

CHEMICAL REGULATION			
	CAS #	EINECS #	Chemical name
C10-18 Triglycerides	85665-33-4 (or 67701-26-2)	288-123-8 (or 266-944-2)	Glycerides, C10-18 (Glycerides, C12-18)

NATIONAL INVENTORIES					
	U.S.A. (TSCA)	Canada (DSL/NDSL)	Australia (AICS)	China (IECSC)	Other inventories
C10-18 Triglycerides	Listed	Listed	Listed	Listed	Glycerides, C10-18 (DSL, EINECS, AICS, PICCS, ASIA-PAC, NZIoC, ECL) Glycerides, C12-18 (TSCA, DSL, EINECS, AICS, PICCS, ASIA-PAC, NZIoC, ECL)

U.S.A.: Substances that are regulated under other federal regulations, including food additives, drug, cosmetics ... are not subject to TSCA regulation.
 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. 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.
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**REACH REGULATION
(REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS)**

	Status of the product	Status per substance
C10-18 Triglycerides	Exempted	Exempted Annex IV (Glycerides, C10-18 ; CAS: 85665-33-4)

PRE-REGISTRATION

Substance registration denomination	EU legal entity	Tonnage band / registration date
Not applicable	/	/

Liability clause

The information contained in this statement is based on our knowledge of the related product on the date indicated, but does not amount to a guarantee in respect of the product's properties and does not give rise to any contractual legal tie. This information is given in utmost good faith. It cannot substitute for indispensable preliminary tests that must be conducted to ensure product suitability for each intended use. Nothing herein shall be construed as a recommendation or license to use any information that conflicts with any patent or trademark of our company or others. We make no representations or warranties, express or implied that any use of this information will not infringe any such patent or trademark. The user's attention is also drawn to the possible risks incurred if a product is used for a purpose other than its designed purpose. This statement does not under any circumstance replace knowledge and application by the user of all laws and regulations relevant to his own operations. The user shall be solely liable for the precautions taken relevant to the use made of the products. This information does not exempt the user from ensuring that he may possibly come under other obligations pursuant to laws or regulations other than those indicated relating to the possession and manipulation of the product for which he shall be solely liable.