

	<b>Regulatory data sheet (RDS)</b> <b>Cosmetic and Personal care applications</b>	
	ISOSTEARATE ISOSTEARYLE / ISOSTEARATE ISOSTEARYLE (Code: 5166)	Last update: 25 November 2015

## 1. DEFINITION

DEFINITION
Isostearyl Isostearate


DENOMINATION	
<b>INCI NAME</b> (PCPC - International Nomenclature of Cosmetic Ingredients)	Isostearyl Isostearate
<b>EUROPEAN INVENTORY OF COSMETIC INGREDIENTS - COSING</b> (European Commission database - <a href="#">COSING</a> )	Isostearyl Isostearate
<b>ADDITIONAL INFORMATION ON THE DENOMINATION</b>	Chemical name: Isooctadecyl isooctadecanoate

## 2. FIELD OF USE

FIELD OF USE	
This product is a cosmetic ingredient. It is recommended for use in cosmetic formulations.	
<b>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.</b>	
Special applications	
Oral cosmetic applications	No
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
Esterification reaction between Isostearyl Alcohol and Isostearic Acid.

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COMPOSITION	
Well defined multi-constituent substance composed of Isostearyl alcohol esters of Isostearic acid.	
FULL LABELING (KEY LETTERS SYSTEM)	
$75.0 \leq A_1$ ; $50.0 \leq A_2 < 75.0$ ; $25.0 \leq B < 50.0$ ; $10.0 \leq C < 25.0$ ; $5.0 \leq D < 10.0$ ; $1.0 \leq E < 5.0$ ; $0.1 \leq F < 1.0$ ; $G < 0.1$	
Isostearyl Isostearate	A1 : > 75.0
OTHER CONSTITUENTS (INCIDENTAL INGREDIENTS)	
None	

#### 4. COSMETIC REGULATION

REGULATORY STATUS OF THE INGREDIENT FOR COSMETIC AND PERSONAL CARE APPLICATIONS (Non exhaustive list of countries, please contact us for additional information)	
<b>EUROPE</b> (European Cosmetic Regulation 1223/2009 and its amendments)	Approved
<b>U.S.A.</b> (FD&C Act— 21 CFR 700 to 740)	Approved
<b>CANADA</b> (Food and Drugs Act and Cosmetic Regulations)	Approved
<b>MERCOSUR:</b> Argentina, Brazil, Paraguay and Uruguay; with association agreements with Chile and Bolivia (Regulation for Personal Hygiene Products, Cosmetics & Perfumes)	Approved
<b>AUSTRALIA</b> (Notification & Assessment Act 1989, as amended—TGA)	Approved
<b>JAPAN</b> (Pharmaceutical Affairs Law - regulations for cosmetics)	Approved
<b>KOREA</b> (Cosmetics Law - Korea Food & Drug Administration KFDA)	Approved
<b>TAIWAN</b>	Approved
<b>ASEAN:</b> Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, VietNam (ASEAN Cosmetic Directive)	Approved
<b>INDIA</b> (provisions of Indian Drug and Cosmetic Act)	Approved
<b>Commonwealth of Independent States (CIS)</b> Official members: Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Uzbekistan Unofficial associate members: Turkmenistan, Ukraine	Approved
<b>Gulf Cooperation Council (GCC)</b> Official members: Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, UAE (United Arab Emirates)	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.: 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.

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.

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.

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

	Status	Comments
Isostearyl Isostearate	Listed	Listed 2014-06
<b>CHINESE NAME</b> (IECIC)	异硬脂醇异硬脂酸酯	

2014-06 list: Inventory of existing cosmetic ingredients in China (IECIC) issued by CFDA on June 30<sup>th</sup>, 2014

**REGULATORY STATUS OF THE INGREDIENT FOR BORDER-LINE APPLICATIONS**

	Status	Denomination		Additional information
<b>AUSTRALIA</b> Therapeutic goods (TGA)	Not approved	/	/	/
<b>JAPAN</b> QUASI-DRUGS	Approved	Isostearyl Isostearate	511007-42	Limitations: /

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 homoeopathic products) or 'OTC medicines' and may be 'listed' (i.e. Sunscreens SPF4 and >4) or 'registered' in the ARTG.

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 ...)

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## 5. CHEMICAL REGULATION

CHEMICAL REGULATION			
	CAS #	EINECS #	Chemical name
Isostearyl Isostearate	41669-30-1	255-485-3	isooctadecyl isooctadecanoate

NATIONAL INVENTORIES					
	U.S.A. (TSCA)	Canada (DSL/NDSL)	Australia (AICS)	China (IECSC)	Other inventories
Isostearyl Isostearate	Listed	Listed	Listed	Listed	Isooctadecanoic acid, isooctadecyl ester (TSCA, DSL, AICS, ECL, ASIA-PAC, NZIoC)

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
Isostearyl Isostearate	Not exempted	Not exempted (Isostearyl Isostearate)

PRE-REGISTRATION		
Substance registration denomination	EU legal entity	Envisaged Tonnage band / registration date
isooctadecyl isooctadecanoate (INCI: Isostearyl Isostearate)	Gattefossé SAS	10 - 100T (2018)

### *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.