Dermolife di Margonari Maria Franca
Via Don Emilio Perugini 14 - 38121 Vigo Meano TRENTO (IT)
Tel : +39 340 585 1384
Mail : info@dermolife.it
Web : www.dermolife.it
P.I. 02202500225
C.F. MRGMFR66A69L378D

Technical Information

SK-INFLUX® /SK-INFLUX® V MB

A skin-identical lipid concentrate for enhanced skin moisturization and protection

Intended use

Active for skin care

Benefits at a glance

- Restores the protective barrier function of the skin
- Ideal for aging skin, dry skin and sensitive skin
- Enhanced delivery and exchange of skin lipids
- SK-INFLUX® V MB is a new version of SK-INFLUX®, with non-animal based cholesterol (vegetal-derived, semi-synthetic cholesterol)
- SK-INFLUX® V MB is paraben-free

INCI (PCPC name)

Ceramide NP; Ceramide AP; Ceramide EOP; Phytosphingosine; Cholesterol; Sodium Lauroyl Lactylate; Carbomer; Xanthan Gum

For Chinese SFDA listed as:
Ceramide 3; Ceramide 6II; Ceramide 1; Phytosphingosine; Cholesterol; Sodium Lauroyl Lactylate; Carbomer; Xanthan Gum

Chemical and physical properties (not part of specifications)

Form	viscous liquid
Active matter	approx. 2.5%
Preservatives	Phenoxyethanol and Ethylhexylglycerin

Properties

- SK-INFLUX®/SK-INFLUX® V MB is a skin-identical lipid concentrate, which restores the protective barrier function of the skin.
- SK-INFLUX®/SK-INFLUX® V MB is a concentrated formulation, consisting of a multi-lamellar (membrane) system resembling the structure of the lipid barrier in the Stratum corneum
- A concentrated mix of different types of ceramides, cholesterol, free fatty acid and phytosphingosine makes it an ideal ingredient for personal care products with unique barrier restoring capabilities.
- Cholesterol is a key ingredient of SK-INFLUX®/SK-INFLUX® V MB and essential for the performance of the product. SK-INFLUX® V MB contains a vegetal-derived, semi-synthetic cholesterol that is chemically and physically indistinguishable from the animal-based product.
- Application of SK-INFLUX®/SK-INFLUX® V MB will result in an enhanced moisturization and protection, ultimately leading to less sensitive and less dry skin.
- Depending on the type of skin and desired effect, SK-INFLUX®/SK-INFLUX® V MB is used with concentrations varying from 1 - 15%.

  However, for typical applications such as aging and dry skin a dosage level of 3 -5 % is recommended.

Dermolife di Margonari Maria Franca
Via Don Emilio Perugini 14 - 38121 Vigo Meano TRENTO (IT)
Tel : +39 340 585 1384
Mail : info@dermolife.it
Web : www.dermolife.it
P.I. 02202500225
C.F. MRGMFR66A69L378D

Efficacy studies

Ex vivoincorporation study – Uptake of Ceramide into Stratum corneum

This study investigated the extent to which Ceramides can be incorporated into the natural lipid barrier of the Stratum corneum when topically applied in different types of formulations.

The study was performed by Prof. P.W. Wertz at the Dows Institute (University of Iowa, USA).

^{14}C-radiolabeled Ceramide VI was formulated in three different systems at a concentration of 0.5% (specific activity of 59 000 dpm/nmol):

System 1: Oil/water with ethoxylated sorbitan ester

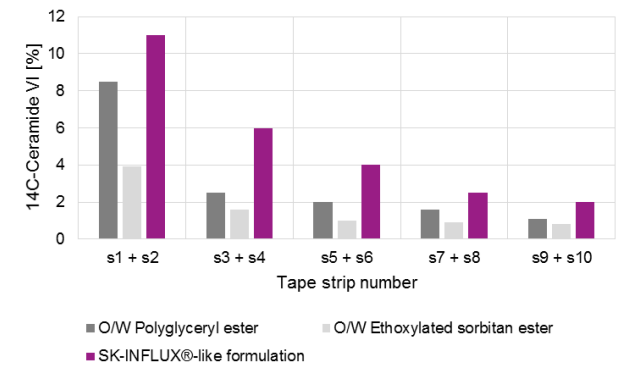
System 2: Oil/water with polyglyceryl ester

System 3: SK-INFLUX® system

Ceramide VI was chosen as a representative Ceramide for this study.

50 µl of each formulation were topically applied to isolated Stratum corneum(1.5 cm x 1.5 cm). After 1 hour, excess formulation was removed and new formulation (50 µl) was applied. This was repeated after the second hour. After 3 hours, excess formulation was removed from the surface. Ten layers of Stratum corneumwere removed by successive stripping with tape. Radioactivity in each strip was determined by liquid scintillation counting. The residual Stratum corneumwas excised to calculate the total amount of Ceramide incorporated (strips plus residue radioactivity).

The graph shows the amount of Ceramide VI incorporated in the layers of the Stratum corneum S1-S10 refer to ten sequential tape strips (fig. 1).



The largest amount of Ceramide VI, thus the best incorporation, can be found with the SK-INFLUX® system. The lower layers of the Stratum corneum showed decreasing amounts of incorporated Ceramide VI.

Total amounts of incorporated Ceramide VI (strips plus residue) were 20, 31 and 44 µg/cm² for systems 1 to 3, respectively.

Conclusion:

It was demonstrated that Ceramides are effectively incorporated into the lipid barrier of the Stratum Corneum when topically applied. Furthermore, the SK-INFLUX® formulation increased the bioavailability of Ceramide VI by more than 38% compared to the other oil/water emulsions.

Effect on barrier repair

In this study the ability of SK-INFLUX® to accelerate the Stratum Corneum barrier repair was investigated.

Methods: The study was performed using a porcine ear skin permeation model described by de Lange et al. (1992, JPM 27: 71-77). The skin was exposed to multiple acetone applications. Before application (baseline) and 2 hours post irritant exposure, transepidermal water loss (TEWL) was measured to determine the degree of damage after Stratum Corneum disruption. The damaged areas were treated with the test formulations. The aqueous formulations used in this study were:

Vehicle:	Sodium lauroyl lactylate (SLL) membrane system without ceramides (control)
System 1:	0.5 % Ceramide III in 4.5% SLL membrane system
System 2:	0.5 % Ceramide III/IIIB (60:40), 0.5% cholesterol, 0.5% free fatty acids, 2% SLL membrane system (SK-INFLUX®-like system)

Fig. 1: Ex vivoincorporation study with^{14}C-radio-labeled Ceramide VI

Dermolife di Margonari Maria Franca
Via Don Emilio Perugini 14 - 38121 Vigo Meano TRENTO (IT)
Tel : +39 340 585 1384
Mail : info@dermolife.it
Web : www.dermolife.it
P.I. 02202500225
C.F. MRGMFR66A69L378D

At 2 and 20 hours post application, TEWL was measured to study the effects of repair. TEWL at 2 and 20 hours after treatment were expressed as a percentage of the value obtained directly after exposure to the irritant.

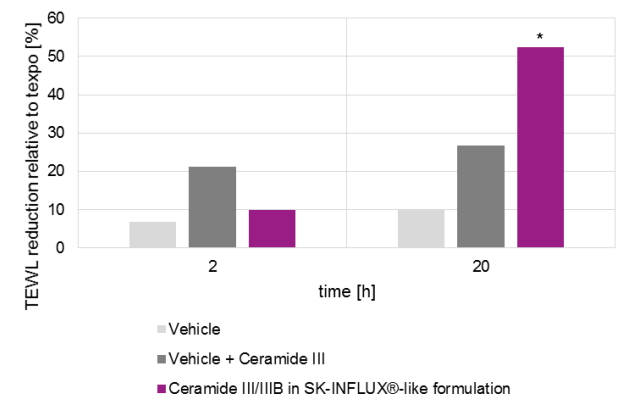


Fig. 2: Effect of a SK-INFLUX®-like formulation on barrier repair: reduction of the transepidermal water loss after acetone exposure

Results: The graph shows the percentage barrier repair after acetone exposure. A statistically significant decrease in TEWL, implying improved Stratum Corneum barrier repair, was found 20 hours after application of the SK-INFLUX®-like system.

Clinical multi center study

A formulation with Ceramide III, cholesterol and fatty acid was applied in a multi center study. The patients suffer from Allergic Contact Dermatitis (35 patients), Irritant Contact Dermatitis (123 patients) and Atopic Dermatitis (24 patients). They applied the test formulation for maximum 8 weeks 1-2 times a day. The symptoms were evaluated randomly by a dermatologist at day 0, week 4 and week 8. The following symptoms were evaluated: dryness, desquamation, erythema, puritis and fissuring. For rating the following scale was used:
0 = none; 1 = mild; 2 = moderate; 3 = severe.

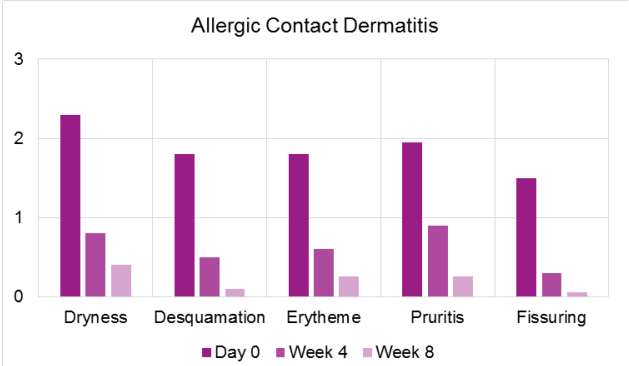


Fig. 3: Effect of the test formulation on the symptoms of patients suffering from Allergic Contact Dermatitis

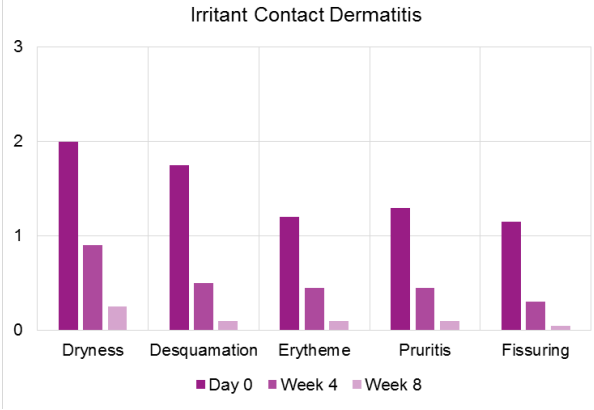


Fig. 4: Effect of the test formulation on the symptoms of patients suffering from Irritant Contact Dermatitis

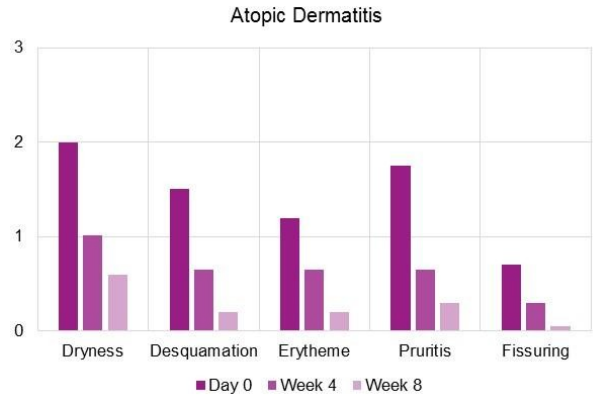


Fig. 5: Effect of the test formulation on the symptoms of patients suffering from Atopic Dermatitis

The data show that SK-INFLUX®/SK-INFLUX® V MB may improve the barrier properties and the clinical condition of skin suffering from contact dermatitis.

Dermolife di Margonari Maria Franca
Via Don Emilio Perugini 14 - 38121 Vigo Meano TRENTO (IT)
Tel : +39 340 585 1384
Mail : info@dermolife.it
Web : www.dermolife.it
P.I. 02202500225
C.F. MRGMFR66A69L378D

Formulation hints

In emulsions SK-INFLUX®/SK-INFLUX® V MB should be added to the water phase before the homogenization step.
Adding SK-INFLUX®/SK-INFLUX® V MB to an existing recipe of an O/W emulsion drops the viscosity significantly. The reason for this is a rearrangement of the liquid crystalline structures. But the emulsion is not necessarily less stable in spite of the lower viscosity. To increase the viscosity it is suggested to increase the amount of consistency enhancer, e.g. the amount of TEGO® Alkanol 18 (Stearyl Alcohol).

Since SK-INFLUX®/SK-INFLUX® V MB contains an anionic emulsifier cationic emulsifier systems should be avoided due to possible interactions.

Preparation of O/W emulsions: SK-INFLUX®/SK-INFLUX® V MB must be added to the water phase before the homogenization step.

Preparation of W/O emulsions: SK-INFLUX®/SK-INFLUX® V MB must be added to the water phase before the homogenization step. Due to the anionic emulsifier in the SK-INFLUX®/SK-INFLUX® V MB phase inversion can occur. It can be prevented by using a sufficient amount of suitable W/O emulsiers like ABIL® EM 90, ISOLAN® GPS or ISOLAN® PDI. For W/O emulsion we recommend to use max. 2% SK-INFLUX®/SK-INFLUX® V MB.

Recommended usage concentration of SK-INFLUX®/SK-INFLUX® V MB

Normal skin:	1.5 – 5%
Dry skin:	3 – 5%
Aging skin:	3 – 5%
Skin repair/Protection:	3 – 15%

Guideline Formulations

If you are interested in guideline formulations please visit our homepage https://personal-care.evonik.com.

Hazardous goods classification

Information concerning

- classification and labelling according to regulations for transport and for dangerous substances
- protective measures for storage and handling
- measures in case of accidents and fires
- toxicity and ecological effects

is given in our material safety data sheets.

D 09/19

Application

SK-INFLUX®/SK-INFLUX® V MB has a wide range of applications, such as O/W creams and lotions of the segments:

- Moisturizing products
- Anti-aging and anti-wrinkle products
- Skin repair
- Skin protection

Dermolife di Margonari Maria Franca
Via Don Emilio Perugini 14 - 38121 Vigo Meano TRENTO (IT)
Tel : +39 340 585 1384
Mail : info@dermolife.it
Web : www.dermolife.it
P.I. 02202500225
C.F. MRGMFR66A69L378D

Product specification

Material **SK-INFLUX**
Spec.Code **K00 STANDARD**

Inspection Characteristics	Method	Limits	Units	Z
Ceramide VI	GM_1554_01	>=0.5	%	C
Identification	GM_1554_01	conform		C
Ceramide III+IIIB	GM_1554_01	>=1.0	%	C
Heavy Metals	GM_1551_03	<=20.0	ppm	C
Arsenic	GM_1551_03	<=2.0	ppm	C
Phytosphingosine	GM_1554_01	>=0.5	%	C
pH-Value	GM_1565_01	5.0-7.0		C
Total Plate Count	GM_3000_01	<=100	CFU/g	X
Density / 25°C	GM_0110_10		***	X

Identification	conform

Report on inspection certificate: X = specific/actual value, C = unspecific value/conformity, T = not reported

Appearance @ 25°C: off-white viscous liquid, with slight lactylated

smell

***: dimensionless parameter

This document is computer printed and therefore valid without signature.
All warranty claims in respect of the conformity of our product are subject to our General Terms and Conditions of Sale and Delivery. The data listed above reflects the criteria for our internal quality tests. We do not hereby make any express or implied warranty, whether for specific properties or for fitness for any particular application or purpose. All values are valid for the product when despatched from the works.

Dermolife di Margonari Maria Franca
Via Don Emilio Perugini 14 - 38121 Vigo Meano TRENTO (IT)
Tel : +39 340 585 1384
Mail : info@dermolife.it
Web : www.dermolife.it
P.I. 02202500225
C.F. MRGMFR66A69L378D

SK-INFLUX®

Product data record (PDR)

1. General information

1.1 Supplier

Evonik Nutrition & Care GmbH
Business Line Care Solutions
Goldschmidtstrasse 100
D-45127 Essen / Germany
personal-care@evonik.com
http://www.evonik.com/personal-care

1.2 Product Description

1.2.1 Raw material category /function

Cosmetic Active Ingredient blend based on Sphingolipids

1.2.2 Ingredients according to INCI

Ceramide NP; Ceramide AP; Ceramide EOP; Phytosphingosine; Cholesterol; Sodium Lauroyl Lactylate; Carbomer; Xanthan Gum

1.2.3 Composition (INCI)

Components	Source	Percentage
Ceramide NP	vegetable/ microbial	1 %
Ceramide AP	vegetable/ synthetic/ microbial	0.5 %
Ceramide EOP	vegetable/ synthetic/ microbial	0.001 %
Phytosphingosine	vegetable/ microbial	0.5 %
Cholesterol	animal	0.5 %
Sodium Lauroyl Lactylate	vegetable	10 %
Carbomer	synthetic	0.3 %
Xanthan Gum	vegetable/ microbial	0.3 %
Water		ad 100 %

This composition information serves for information of our customers only.
It is neither relevant for the composition listing according to Regulation (EC) No 1223/2009, nor does it reflect the chemical composition according to the different chemical regulations in the world which is disclosed in the table "information on ingredients/hazardous components" in the relevant parts of the respective (Material) Safety Data Sheets.

Dermolife di Margonari Maria Franca
Via Don Emilio Perugini 14 - 38121 Vigo Meano TRENTO (IT)
Tel : +39 340 585 1384
Mail : info@dermolife.it
Web : www.dermolife.it
P.I. 02202500225
C.F. MRGMFR66A69L378D

1.2.4 Solvents, preservatives and other additives

INCI	CAS No./ REACH Reg. No.	EINECS / EC No.	content	Function
Methylparaben	99-76-3 01-2119463264-40	202-785-7	0.3 %	preservative
Propylparaben	94-13-3 01-2119969462-29	202-307-7	0.2 %	preservative

Unless mentioned in our PDR under section 2.1 (By products) or 2.2 (CMR), no components which are listed in Annex II of the Regulation (EC) No 1223/2009 and its modifications and updates are added to and are not to be expected in the above mentioned product due to the raw materials used and the production process.

2. Information on production process

General description of production process:
Mixture

The product is not irradiated.

Except for the Cholesterol SK-INFLUX® is produced in the strictest absence of any animal derived material of any type.

Residual plant based source (dominant origin of main constituents): Palm oil/Palm kernel Oil, Sugar Beet, Corn, Rapeseed Oil, Sunflower Oil

CITES:
SK-INFLUX® is not based on raw materials from species listed in CITES appendices.

The production does not use micro-organism, which has been genetically modified, nor does it contain remains of micro-organism, which have been genetically modified.

2.1 By products/Impurities

Residual organic solvents	not applicable
Free amines	not applicable
Nitrosamines	not applicable
Monochloroacetic acid	not applicable
Dichloroacetic acid	not applicable
1,4-Dioxane	not applicable
Pesticides	meets the valid regulatory requirements for limits on agricultural pesticides
Heavy metals (Cu; Pb; Pt; Pd; Hg; As; Cd; Ni)	max. 20 ppm
As	max. 2 ppm
Latex	not to be expected in the product due to the raw materials used and the production process

Dermolife di Margonari Maria Franca
Via Don Emilio Perugini 14 - 38121 Vigo Meano TRENTO (IT)
Tel : +39 340 585 1384
Mail : info@dermolife.it
Web : www.dermolife.it
P.I. 02202500225
C.F. MRGMFR66A69L378D

VOC	< 3 % according to SR (Swiss Right) 814.018

Any by-products are not added intentionally during the process and are technically unavoidable.

2.2 CMR (Carcinogenic, Mutagenic or Reprotoxic)

The use in cosmetic products of substances classified as CMR substances, of category 1A or 1B or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited.

Further Information:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF

Some of the CMR substances mentioned below and listed in Annex VI to Regulation (EC) No 1272/2008 may be used as starting materials or solvents for the production of our cosmetic raw materials and may require reporting under California Proposition 65 or the Safe Cosmetics Act, SB 484.

The presence of these prohibited substances has to be seen as non-intended. It is stemming from impurities of the starting materials or the manufacturing process which is technically unavoidable in good manufacturing practice.

CMR substance	Starting material	max. concentration/Remark
Ethylene Oxide	no	
Propylene Oxide	no	
Octamethylcyclotetrasiloxane (D4)	no	
2-Ethylhexanoic Acid	no	
n-Hexane	no	
Methyl Chloride	no	
Dimethyl Sulphate	no	
Formaldehyde	no	Formaldehyde is a ubiquitous material and may be detected in small traces in almost all natural and synthetic products. For details, a separate statement is available on request.

2.3 "Allergens" according to the Regulation (EC) No 1223/2009

The presence of substances, the mentioning of which is required under the column 'Other' in Annex III, shall be indicated in the list of ingredients in addition to the terms perfume or aroma.

The cosmetic raw materials and the cosmetic actives supplied by Evonik Personal Care are manufactured without the use of perfumes and fragrances. An analytical proof for the absence in traces of the substances to be mentioned in addition to the terms perfume or aroma is not performed in cosmetic raw materials, which are chemically produced.

None of these substances have been intentionally added to our cosmetic raw materials or are formed during the manufacturing process according to our knowledge of the chemistry.

Dermolife di Margonari Maria Franca
Via Don Emilio Perugini 14 - 38121 Vigo Meano TRENTO (IT)
Tel : +39 340 585 1384
Mail : info@dermolife.it
Web : www.dermolife.it
P.I. 02202500225
C.F. MRGMFR66A69L378D

2.4 Food Ingredients listed in Annex II of Regulation (EU) No 1169/2011

None of these substances have been intentionally added to our cosmetic raw materials or are formed during the manufacturing process according to our knowledge of the chemistry.

2.5 Nanomaterial

The product is not a nanomaterial according to the Cosmetics Regulation (EC) No 1223/2009, the Commission Recommendation on the definition of nanomaterial 2011/696/EU and the French Decree No. 2012-232. For details, a separate statement is available on request.

3. Microbiological status

Total Viable Count	max. 100 cfu/g
Pathogens*	absent/g

*Pathogens are: Enterobacteria, Pseudomonas, Enterococci, Candida albicans, Staphylococci

4. Shelf life / storage conditions

720 days after production at 8 - 15 °C, 6 months at room temperature (22 +/-2 °C) (in unopened original packaging under clean and dry conditions). Avoid temperatures below 6°C.

5. Regulatory Status

5.1	HS-Code	382499
	EU-CN-Code	38249992

5.2 Regulatory status (chemical regulations)

Europe

Components	REACH status	CAS No.	EINECS / EC No.
Ceramide NP	Reg. Nos. 01-2120766288-41 01-2120766289-39	 34354-88-6 178436-06-1	 812-962-6 812-963-1
Ceramide AP	exempted (< 1t/a)	100403-19-8	309-560-3
Ceramide EOP	exempted (< 1t/a)	100403-19-8	309-560-3
Phytosphingosine	Reg. No. 01-0000018379-59	554-62-1	439-210-6
Cholesterol	Reg. No. 01-2119976283-30	57-88-5	200-353-2
Sodium Lauroyl Lactylate	Reg. No. 01-2120793005-56	13557-75-0	236-942-6
Carbomer	Polymer	9003-01-4	Polymer
Xanthan Gum	exempted (natural polymer)	11138-66-2	234-394-2

I metodi di analisi non indicati sono metodi interni del produttore ottenibili su specifica richiesta

The analytical methods not listed are internal methods of the manufacturer obtainable upon specific request

Dermolife di Margonari Maria Franca
Via Don Emilio Perugini 14 - 38121 Vigo Meano TRENTO (IT)
Tel : +39 340 585 1384
Mail : info@dermolife.it
Web : www.dermolife.it
P.I. 02202500225
C.F. MRGMFR66A69L378D

Other countries/regions

Country		yes / no	Remark
Ceramide NP			
Australia	AICS:	no	but up to 100 kg/a in sum of CAS No. 100403-19-8
China	IECSC:	yes	under CAS No. 100403-19-8
Canada	DSL: NDSL:	no	CAS No. 100403-19-8 is on the revised in-commerce list
Taiwan	TCSI:	yes	under CAS No. 100403-19-8
Ceramide AP			
Australia	AICS:	no	but up to 100 kg/a in sum of CAS No. 100403-19-8
China	IECSC:	yes	
Canada	DSL: NDSL:	no	CAS No. 100403-19-8 is on the revised in-commerce list
Taiwan	TCSI:	yes	
Ceramide EOP			
Australia	AICS:	no	but up to 100 kg/a in sum of CAS No. 100403-19-8
China	IECSC:	yes	
Canada	DSL: NDSL:	no	CAS No. 100403-19-8 is on the revised in-commerce list
Taiwan	TCSI:	yes	
Phytosphingosine			
Australia	AICS:	yes	
China	IECSC:	yes	CAS No. 13552-11-9
Canada	DSL: NDSL:	no no	NSN 4 filed by Evonik Canada, Inc. for import up to 1000 kg/a; in addition, customers might import up to 100 kg/a
Taiwan	TCSI:	yes	
Cholesterol			
Australia	AICS:	yes	
China	IECSC:	yes	
Canada	DSL: NDSL:	yes	
Taiwan	TCSI:	yes	

I metodi di analisi non indicati sono metodi interni del produttore ottenibili su specifica richiesta

The analytical methods not listed are internal methods of the manufacturer obtainable upon specific request

Dermolife di Margonari Maria Franca
Via Don Emilio Perugini 14 - 38121 Vigo Meano TRENTO (IT)
Tel : +39 340 585 1384
Mail : info@dermolife.it
Web : www.dermolife.it
P.I. 02202500225
C.F. MRGMFR66A69L378D

Country		yes / no	Remark
Sodium Lauroyl Lactylate			
Australia	AICS:	yes	
China	IECSC:	yes	
Canada	DSL: NDSL:	no	CAS No. 13557-75-0 is on the revised in-commerce list
Taiwan	TCSI:	yes	
Carbomer			
Australia	AICS:	yes	
China	IECSC:	yes	
Canada	DSL: NDSL:	yes	
Taiwan	TCSI:	yes	
Xanthan Gum			
Australia	AICS:	yes	
China	IECSC:	yes	
Canada	DSL: NDSL:	yes	
Taiwan	TCSI:	yes	

In the following countries the relevant authorities currently do not request pre-market approval for cosmetic raw materials:

Brazil, Japan, South Korea, Philippines, USA

5.2.1 Regulatory status (cosmetic regulation)

Country		yes / no	Remark
Ceramide NP			
China	CFDA:	yes	if INCI name Ceramide 3 is used
Japan	JSQI:	yes	
Ceramide AP			
China	CFDA:	yes	if INCI name Ceramide 6 II is used

Dermolife di Margonari Maria Franca
Via Don Emilio Perugini 14 - 38121 Vigo Meano TRENTO (IT)
Tel : +39 340 585 1384
Mail : info@dermolife.it
Web : www.dermolife.it
P.I. 02202500225
C.F. MRGMFR66A69L378D

Japan	JSQI:	yes	

Country		yes / no	Remark
Ceramide EOP			
China	CFDA:	yes	if INCI name Ceramide 1 is used
Japan	JSQI:	yes	but specifications not controlled
Phytosphingosine			
China	CFDA:	yes	
Japan	JSQI:	yes	
Cholesterol			
China	CFDA:	yes	
Japan	JSQI:	yes	JSQI No. 001255, but specifications not controlled
Sodium Lauroyl Lactylate			
China	CFDA:	yes	
Japan	JSQI:	yes	JSQI No. 532318, but specifications not controlled
Carbomer			
China	CFDA:	yes	
Japan	JSQI:	yes	JSQI No. 101243, but specifications not controlled
Xanthan Gum			
China	CFDA:	yes	
Japan	JSQI:	yes	JSQI No. 109058, but specifications not controlled

6. Toxicology and Ecotoxicology

Refer to summary of ecotoxicological and toxicological data

7. Packaging size

5.0 kg
25.0 kg