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 SK-INFLUX®	Methylparaben, Propylparaben
Preservatives SK-INFLUX® V MB	Phenoxyethanol, 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.

Efficacy studies

Ex vivo incorporation 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 corneum* were removed by successive stripping with tape. Radioactivity in each strip was determined by liquid scintillation counting. The residual *Stratum corneum* was 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).

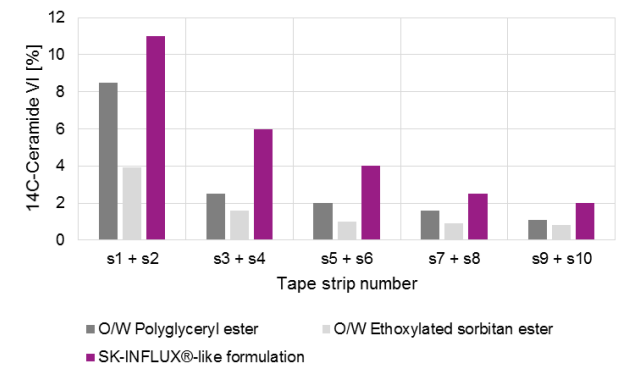

Fig. 1: *Ex vivo* incorporation study with ^{14}C-radio-labeled Ceramide VI

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)

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.

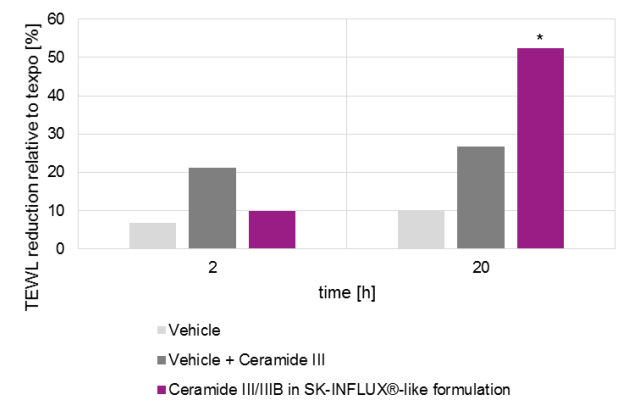

Fig. 2: Effect of a SK-INFLUX®-like formulation on barrier repair: reduction of the transepidermal water loss after acetone exposure

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.

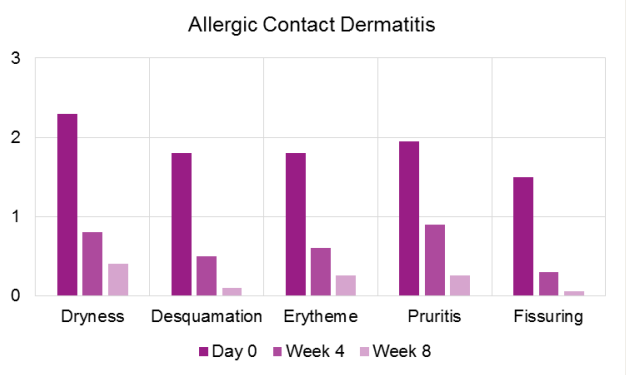

Fig. 3: Effect of the test formulation on the symptoms of patients suffering from Allergic Contact Dermatitis

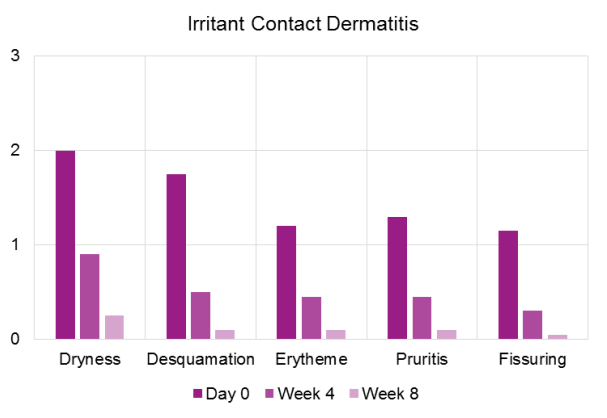

Fig. 4: Effect of the test formulation on the symptoms of patients suffering from Irritant Contact Dermatitis

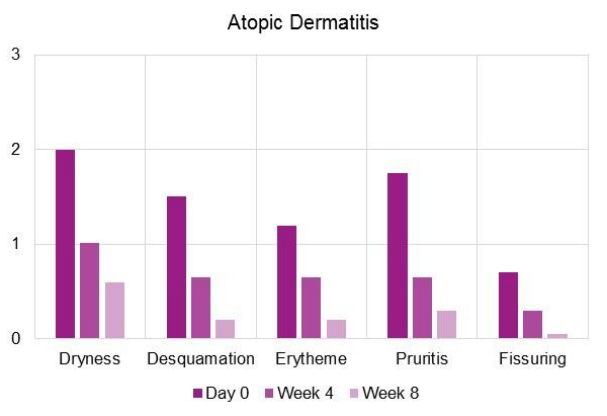

Fig. 5: Effect of the test formulation on the symptoms of patients suffering from Atopic Dermatitis

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.
Source: E. Berardesca et al., Contact Dermatitis, 2001, 45, 280-285. Evaluation of efficacy of a skin lipid mixture in patients with irritant contact dermatitis, allergic contact dermatitis or atopic dermatitis: a multicenter study

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.

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

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.

E 06/20

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EVONIK
POWER TO CREATE

Product specification

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

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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.

The Standard Test Methods can be obtained from specialized publishers. Evonik's test methods are available on request.

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15 September 2020

SK-INFLUX®

Product Data Record (PDR)

1. General Information

1.1 Supplier

Evonik Operations GmbH
Division Nutrition & Care
Business Line Care Solutions
Rellinghauser Straße 1-11
45128 Essen | Germany
personal-care@evonik.com
https://www.evonik.com/personal-care

1.2 Product Description

SK-INFLUX® is in full compliance with current Cosmetic Regulation (EC) No 1223/2009.

1.2.1 Raw Material Category/Function

Cosmetic Active Ingredient Blend based on Sphingolipids

1.2.2 INCI Declaration

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

1.2.3 Composition

Components (INCI EU/US)	Source	Percentage [%]
Ceramide NP	Vegetable/microbial	1.0
Ceramide AP	Vegetable/synthetic/microbial	0.5 - 0.6
Ceramide EOP	Vegetable/synthetic/microbial	0.001
Phytosphingosine	Vegetable/microbial	0.5 - 0.6
Cholesterol	Animal	0.5
Sodium Lauroyl Lactylate	Vegetable/microbial	9 - 11
Carbomer	Synthetic	0.2 - 0.4
Xanthan Gum	Vegetable/microbial	0.2 - 0.5
Aqua/Water		add 100

This composition information serves for information of our customers only. It is neither relevant for the composition listing according to Cosmetic 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.

1.2.4 Additives (Antioxidants, Preservatives)

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

Known restrictions: please refer to 6.2.1

Unless mentioned in our PDR under section 2.2 (By-Products) or 2.3 (CMR), no components which are listed in Annex II of the Cosmetic 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. Production Process

2.1 General Information on the Production Process

SK-INFLUX® is obtained by mixing of components.

Description and Origin of plant based materials:
Palm (Elaeis guineensis), corn (Zea mays), rape/canola (Brassica), sunflower (Helianthus anuus), soy (Glycine max)

Irradiation: SK-INFLUX® was not irradiated with γ-rays.

Except for INCI Cholesterol (based on Lanolin), SK-INFLUX® is produced in the absence of any animal derived material of any type. Based on the information on the
manufacturing process and production site no contamination with BSE/ TSE risk materials is to be expected.

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

GMO Status:
The item contains moieties from corn, soy and rape (including oils and other refined ingredients). During the production no GMOs and derivatives from GMOs are used. All reasonable measures have been taken to avoid cross-contamination with GMOs or derivatives from GMOs.

2.2 By-Product/Impurities

Potentially occurring by – products are not added intentionally. Impurities e.g. residual solvents are technically unavoidable.

Description	Expected Values
Residual organic solvents	not applicable
Free amines	not applicable
Nitrosamines	not applicable
Monochloroacetic Acid	not applicable
Dichloroacetic acid	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
VOC	< 3 % according to SR (Swiss Right) 814.018
DEG	not applicable

2.3 CMR Substances

According to Cosmetic Regulation (EC) No 1223/2009 the use of substances classified as CMR (**C**arcinogenic, **M**utagenic or **R**eprotoxic) substances of category 1A or 1B or 2, under Part 3 of Annex VI to CLP Regulation (EC) No 1272/2008 in cosmetic products shall be prohibited.

Some of the CMR substances mentioned below and listed in Annex VI to CLP 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 California Safe Cosmetics Act, SB 484.

The presence of these substances has to be seen as non-intended and it is technically unavoidable in good manufacturing practice. Traces of CMR substances can derive from impurities of the starting materials or the manufacturing process.

CMR Substance	CAS No.	Starting material	Max. concentration/ Remark
Ethylene Oxide	75-21-8	no	
Propylene Oxide	75-56-9	no	
Octamethylcyclotetrasiloxane (D4)	556-67-2	no	
2-Ethylhexanoic Acid	149-57-5	no	
n-Hexane	110-54-3	no	
Methyl Chloride	74-87-3	no	
Dimethyl Sulphate	77-78-1	no	
1,4-Dioxane	123-91-1	no	
Formaldehyde	50-00-0	no	For more information on formaldehyde please refer to our factsheet available via our intoBeauty website. https://intobeauty.evonik.com/

2.4 "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 of Cosmetic Regulation (EC) No 1223/2009, shall be indicated in the list of ingredients in addition to the terms "Perfume" or "Aroma".
None of those substances have been intentionally added to our cosmetic ingredients or are formed during the manufacturing process according to our knowledge of the chemistry. An analytical proof for the absence of traces of those substances is not performed in our cosmetic ingredients.

2.5 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.

2.6 Nanomaterial

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

2.7 Substances of Very High Concern (SVHC)

The candidate list of substances of very high concern is regularly updated and published by ECHA. If applicable, the information on the substance/s from the candidate list, contained in our product in reportable amounts, is included in section 3 of the product related Safety Data Sheet (SDS).

2.8 Country of Origin

SK-INFLUX® is manufactured in: the Netherlands

3. Animal Testing

We hereby confirm that we have never conducted any animal tests with our product SK-INFLUX® nor that we have ordered such tests at third parties or third parties have conducted such tests with our knowledge and acceptance to fulfil the requirements of Cosmetic Regulation (EC) No 1223/2009.

Therefore SK-INFLUX® is in full compliance with Cosmetic Regulation (EC) No 1223/2009.

4. Microbiological Status

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

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

5. Shelf Life / Storage Conditions

720 days after production (unopened original packaging)
at 8 - 15 °C. Avoid temperatures below 6°C. At room temperature (22 +/-2 °C) 180 days after production (unopened original packaging)

6. Regulatory Status

6.1 **HS-Code:** 382499

EU-CN-Code: 38249992

6.2 Regulatory Status (Chemical Regulations)

Europe

Components Chemical Name/INCI	REACH Status*	CAS No.	EINECS / EC No.
Octadecanamide, N-[(1S,2S,3R)-2,3-dihydroxy-1-(hydroxymethyl) heptadecyl]/Ceramide NP	Reg. No. 01-2120766288-41	34354-88-6	812-962-6
9-Octadecenamide, N-[(1S,2S,3R)-2,3-dihydroxy-1-(hydroxymethyl) heptadecyl]-, (9Z)-/Ceramide NP	Reg. No. 01-2120766289-39	178436-06-1	812-963-1
9-Octadecenamide, N-[(1S,2S,3R)-2,3dihydroxy-1-(hydroxymethyl)heptadecyl],-2-hydroxy-/Ceramide AP	Reg. No. 01-2120824464-56	212070-45-6	936-560-6
Ceramide EOP	Exempt; < 1t/Y	100403-19-8	309-560-3
(2S,3S,4R)-2-aminooctadecane-1,3,4-triol / 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 2-(1-carboxylatoethoxy)-1-methyl-2-oxoethyl laurate/Sodium Lauroyl Lactylate	Reg. No. 01-2120793005-56	13557-75-0	236-942-6
2-Propenoic acid, homopolymer/Carbomer	Exempt; polymer	9003-01-4	Polymer
Xanthan Gum	Exempt; natural polymer	11138-66-2	234-394-2
Methyl 4-hydroxybenzoate/Methylparaben	Reg. No. 01-2119463264-40	99-76-3	202-785-7
Propyl 4-hydroxybenzoate/Propylparaben	Reg. No. 01-2119969462-29	94-13-3	202-307-7

*) Any REACH registration no. referred to in this document covers the substance manufactured and/or imported into the European Community by Evonik Nutrition and Care GmbH (or by our affiliates or by our EU suppliers). In case that a customer purchases material produced outside the EU which was not imported into the EU before supply and subsequently imports that material into the EU, this is not covered by any of our existing REACH registrations.

Non EU - Countries/ Regions:

Component	Country	Inventory	yes / no	Remark
Ceramide NP	Australia	AIIC (former AICS)	no	but up to 100 kg/a in sum of CAS No. 100403-19-8
	China	IECSC	yes	

Component	Country	Inventory	yes / no	Remark
	Canada	DSL	no	CAS No. 100403-19-8 is on the revised in-commerce list
	Canada	NDSL	no	
	Taiwan	TCSI	yes	under CAS No. 100403-19-8
Ceramide AP	Australia	AIIC (former AICS)	no	
	China	IECSC	yes	
	Canada	DSL	no	CAS No. 100403-19-8 is on the revised in-commerce list
	Canada	NDSL	no	
	Taiwan	TCSI	yes	by CAS No. 100403-19-8 (CAS No. 212070-45-6 is not listed)
Ceramide EOP	Australia	AIIC (former AICS)	no	but up to 100 kg/a in sum of CAS No. 100403-19-8
	China	IECSC	yes	
	Canada	DSL	no	CAS No. 100403-19-8 is on the revised in-commerce list
	Canada	NDSL	no	
	Taiwan	TCSI	yes	
Phytosphingosine	Australia	AIIC (former AICS)	yes	This chemical has been assessed as a component of dermal cosmetic products at concentrations no more than 0.1%. This chemical is not to be used in topical products intended for the eye.
	China	IECSC	yes	under CAS No. 13552-11-9
	Canada	DSL	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
	Canada	NDSL	no	
	Taiwan	TCSI	yes	
Cholesterol	Australia	AIIC (former AICS)	yes	
	China	IECSC	yes	
	Canada	DSL	yes	
	Canada	NDSL	n.a.	
	Taiwan	TCSI	yes	
Sodium Lauroyl Lactylate	Australia	AIIC (former AICS)	yes	
	China	IECSC	yes	

Component	Country	Inventory	yes / no	Remark
	Canada	DSL	no	CAS No. 13557-75-0 is on the revised in-commerce list
	Canada	NDSL	no	
	Taiwan	TCSI	yes	
Carbomer	Australia	AIIC (former AICS)	yes	
	China	IECSC	yes	
	Canada	DSL	yes	
	Canada	NDSL	n.a.	
	Taiwan	TCSI	yes	
Xanthan Gum	Australia	AIIC (former AICS)	yes	
	China	IECSC	yes	
	Canada	DSL	yes	
	Canada	NDSL	n.a.	
	Taiwan	TCSI	yes	
Methylparaben	Australia	AIIC (former AICS)	yes	
	China	IECSC	yes	
	Canada	DSL	yes	
	Canada	NDSL	n.a.	
	Taiwan	TCSI	yes	
Propylparaben	Australia	AIIC (former AICS)	yes	
	China	IECSC	yes	
	Canada	DSL	yes	
	Canada	NDSL	n.a.	
	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

6.2.1 Regulatory Status (Non EU - Cosmetic Regulations)

Other countries:

Component	Country	Inventory	yes / no	Remark
Ceramide NP	China	CFDA	yes	if INCI name Ceramide 3 (IECIC No.: 06016) is used
	Japan	JSQI	yes	JSQI specification is available on request (JSQI No. 532203)
	Japan	JCIA	yes	JCIA No. 561186
Ceramide AP	China	CFDA	yes	if INCI name Ceramide 6 II (IECIC No.: 06018) is used
	Japan	JSQI	yes	JSQI specification is available on request (Besshi)
	Japan	JCIA	yes	JCIA No. 561245
Ceramide EOP	China	CFDA	yes	if INCI name Ceramide 1 (IECIC No.: 06013) is used
	Japan	JSQI	yes	JSQI specification is available on request (Besshi)
	Japan	JCIA	yes	JCIA No. 561185
Phytosphingosine	China	CFDA	yes	IECIC No. 08597
	Japan	JSQI	yes	JSQI specification is available on request (Besshi)
	Japan	JCIA	yes	JCIA No. 555092
Cholesterol	China	CFDA	yes	IECIC No. 01819
	Japan	JSQI	no	JSQI specification exists (JSQI No. 001255), but compliance is not controlled
	Japan	JCIA	yes	JCIA No. 551269
Sodium Lauroyl Lactylate	China	CFDA	yes	IECIC No. 08427
	Japan	JSQI	no	JSQI specification exists (JSQI No. 532318), but compliance is not controlled
	Japan	JCIA	yes	JCIA No. 552646; 558931
Carbomer	China	CFDA	yes	IECIC No. 04079
	Japan	JSQI	no	JSQI specification exists (JSQI No. 101243), but compliance is not controlled
	Japan	JCIA	yes	JCIA No. 551011
Xanthan Gum	China	CFDA	yes	IECIC No. 03086
	Japan	JSQI	no	JSQI specification exists (JSQI No. 109058), but compliance is not controlled
	Japan	JCIA	yes	JCIA No. 551027
Methylparaben	China	CFDA	yes	IECIC No. 05214
	Japan	JSQI	no	JSQI specification exists (JSQI No. 522119), but compliance is not controlled

Component	Country	Inventory	yes / no	Remark
	Japan	JCIA	yes	JCIA No. 552434
Propylparaben	China	CFDA	yes	IECIC No. 05205
	Japan	JSQI	no	JSQI specification exists (JSQI No. 522119), but compliance is not controlled
	Japan	JCIA	yes	JCIA No. 552171

Known restrictions:
Methylparaben
Europe:
Methylparaben is listed in Annex V (No. 12) of the Cosmetic Regulation (EC) No 1223/2009.
Maximum concentration in ready for use preparation 0.4 % (as acid) for single esters, 0.8 % (as acid) for mixtures of esters.
Japan:
Parahydroxybenzoate esters and its sodium salt are restricted according to Annex III of the Japanese Standard for Cosmetics (2000/2001) in its concentration for all kind of cosmetics up to max. 1.0 % (as total).

Propylparaben
Europe:
Propylparaben is listed in Annex V (No. 12a) of the Cosmetic Regulation (EC) No 1223/2009.
Max concentration in ready for use preparation depending on application from 0.14 % (as acid) up to 0.8 % (as acid) for mixture of substances listed in Annex V (Nos: 12 & 12a).
Not to be used in leave-on products designed for application on the nappy area of children under three years of age.
Japan:
Parahydroxybenzoate esters and its sodium salt are restricted according to Annex III of the Japanese Standard for Cosmetics (2000/2001) in its concentration for all kind of cosmetics up to max. 1.0 % (as total).

7. Toxicology and Ecotoxicology

Refer to our document: "Summary of Toxicological and Ecotoxicological Data"

8. Packaging

5.0 kg
25.0 kg