Technical Information

SK-INFLUX®

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
- Enhances skin moisturization
- Ideal for aging skin, dry skin and sensitive skin
- Enhanced delivery and exchange of skin lipids

INCI (PCPC name)

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

For Chinese CFDA 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	about 2.5%

Properties

- SK-INFLUX® is a skin-identical lipid concentrate, which restores the protective barrier function of the skin.
- SK-INFLUX® 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 acids and phytosphingosine makes it an ideal ingredient for personal care products with unique restoring capabilities.
- Application of SK-INFLUX® will result in enhanced moisturization and protection, ultimately leading to a less sensitive and less dry skin.
- Depending on the type of skin and desired effect, SK-INFLUX® is used with concentrations varying from 1 – 15%.
  However, for typical applications such as ageing and dry skin a dosage level of 3 – 5% is recommended.

Efficacy studies

Uptake of Ceramide into Stratum Corneum
(Ex vivo incorporation study)

Introduction: 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.

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

Methods: ^{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 was 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).

Results: 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).

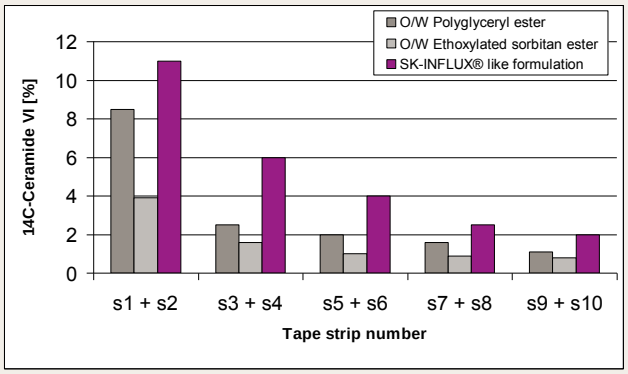

Fig. 1: Ex-vivo incorporation study with ^{14}C-radio-labeled Ceramide VI

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.

Other efficacy studies are available on request.

Preparation of emulsions

SK-INFLUX® should be added to the water phase before the homogenisation step.

Adding SK-INFLUX® 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).

When using SK-INFLUX® in **W/O emulsions** it has to be checked whether its addition to an existing W/O formula leads to phase inversion. A phase inversion can normally be prevented by using a sufficient amount of suitable W/O emulsifiers like ABIL® EM 90 (Cetyl PEG/PPG-10/1 Dimethicone), ISOLAN® GPS (Polyglyceryl-4 Diisostearate/Polyhydroxy-stearate/Sebacate) or ISOLAN® PDI (Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate). For W/O emulsions the maximal usage concentration of SK-INFLUX® should not exceed 3%.

Application

Consequently SK-INFLUX® has a wide range of applications, such as creams and lotions of the segments:

- Moisturizing products
- Ageing and anti-wrinkle products
- Skin repair
- Skin protection

Recommended usage concentration

Normal skin:	1.5 - 5% SK-INFLUX®
Dry skin:	3 - 5% SK-INFLUX®
Ageing skin:	3 - 5% SK-INFLUX®

Skin repair:	3 – 15% SK-INLUFX®
Protection:	3 – 15% SK-INLUFX®
W/O Emulsions	1.5 – 3% SK-INLUFX®

Packaging

25 kg package

Storage

- The product is stable for 2 years when stored at 10 – 15°C.
- Kept at room temperature the product is stable for half a year.
- The product should not be stored at temperatures lower than 10°C.

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.

Guideline formulations

O/W Anti-Ageing Cream with SK-INFLUX® WR 2/00-4	
Phase A	
TEGIN® 4100 Pellets (Glyceryl Stearate)	1.00%
TEGO® Alkanol 1618 (Cetearyl Alcohol)	3.00%
Stearic Acid	1.00%
TEGOSOFT® liquid (Cetearyl Ethylhexanoate)	5.00%
TEGOSOFT® CI (Cetearyl Isononanoate)	5.00%
TEGOSOFT® DC (Decyl Cocoate)	4.00%
Tocopheryl Acetate	2.00%
Phase B	
TEGO® Care CG 90(Cetearyl Glucoside)	1.00%
Glycerin	3.00%
Allantoin	0.10%
SK-INFLUX®	5.00%
Water	69.4%
Phase C	
TEGO® Carbomer 134 (Carbomer)	0.10%
Mineral Oil	0.40%
Phase D	
Sodium Hydroxide (10% in water)	q.s.
Preservative, Perfume	q.s.

Preparation:

1. Heat phase A and B separately to approx. 80°C.
2. Add phase A to phase B with stirring.[1)]
3. Homogenize.
4. Cool with gentle stirring to approx. 60°C and add phase C.
5. Homogenize for a short time.
6. Cool with gentle stirring and add phase D below 40°C.

[1)]Important: If phase A has to be charged into the vessel first, phase B must be added **without stirring.**

Skin Protection Cream with SK-INFLUX® WR 1/00-11	
Phase A	
TEGO® Alkanol S 2 (Steareth-2)	2.40%
TEGO® Alkanol S 20 P (Steareth-20)	0.60%
TEGO® Alkanol 1618 (Cetearyl Alcohol)	3.00%
Stearic Acid	1.00%
Isohexadecane	6.00%
TEGOSOFT® APS (PPG-11 Stearyl Ether)	3.00%
Cyclomethicone	1.00%
Phase B	
Glycerin	3.00%
SK-INFLUX®	5.00%
Water	74.0%
Phase C	
TEGO® Carbomer 134 (Carbomer)	0.20%
Mineral Oil	0.80%
Phase D	
Sodium Hydroxide (10% in water)	q.s.
Preservative, Perfume	q.s.

Preparation:

1. Heat phase A and B separately to approx. 80 °C.
2. Add phase A to phase B with stirring.[1)]
3. Homogenize.
4. Cool with gentle stirring to approx. 60 °C and add phase C.
5. Homogenize for a short time.
6. Cool with gentle stirring and add phase D below 40 °C.

[1)]Important: If phase A has to be charged into the vessel first, phase B must be added **without stirring.**

O/W Lotion with SK-INFLUX® SP 14/03-4	
Phase A	
TEGO® Care 450 (Polyglyceryl-3 Methylglucose Distearate)	2.00%
TEGOSOFT® CT (Caprylic/Capric Triglyceride)	5.00%
TEGOSOFT® DO (Decyl Oleate)	5.00%
TEGOSOFT® DC (Decyl Cocoate)	4.00%
TEGOSOFT® OS (Ethylhexyl Stearate)	4.00%
Tocopheryl Acetate	0.50%
Phase B	
Propylene Glycol	3.00%
Allantoin	0.10%
SK-INFLUX®	5.00%
Water	68.6%
Phase C	
TEGO® Carbomer 141 (Carbomer)	0.40%
TEGOSOFT® OS (Ethylhexyl Stearate)	1.60%
Phase D	
Sodium Hydroxide (10% in water)	0.80%
Preservative, Perfume	q.s.

Preparation:

1. Heat phase A and B separately to approx. 80°C.
2. Add phase A to phase B with stirring.[1)]
3. Homogenize.
4. Cool with gentle stirring to approx. 60°C and add phase C.
5. Homogenize for a short time.
6. Cool with gentle stirring and add phase D below 40°C.

[1)]Important: If phase A has to be charged into the vessel first, phase B must be added **without stirring.**

Low Viscous O/W Lotion with SK-INFLUX® WR 4/00-3	
Phase A	
TEGO® Care 215 (Ceteareth-15; Glyceryl Stearate)	2.50%
TEGO® Alkanol 18 (Stearyl Alcohol)	1.00%
TEGOSOFT® OS (Ethylhexyl Stearate)	5.20%
TEGOSOFT® CR (Cetyl Ricinoleate)	3.00%
TEGOSOFT® HP (Isocetyl Palmitate)	2.00%
ABIL® 350 (Dimethicone)	0.50%
Phase B	
Glycerin	3.00%
SK-INFLUX®	5.00%
Water	76.8%
Phase C	
TEGO® Carbomer 141 (Carbomer)	0.20%
TEGOSOFT® OS (Ethylhexyl Stearate)	0.80%
Phase D	
Sodium Hydroxide (10% in water)	q.s.
Preservative, Perfume	q.s.

Preparation:

1. Heat phase A and B separately to approx. 80°C.
2. Add phase A to phase B with stirring.[1)]
3. Homogenize.
4. Cool with gentle stirring to approx. 60°C and add phase C.
5. Homogenize for a short time.
6. Cool with gentle stirring and add phase D below 40°C.

[1)]Important: If phase A has to be charged into the vessel first, phase B must be added **without stirring**.

W/O Lotion with SK-influx WR 6/06-7	
Phase A	
ISOLAN® GPS (Polyglyceryl-4 Diisostearate/ Polyhydroxystearate/ Sebacate)	2.00%
Microcrystalline Wax (Paracera M; Paramelt B.V.)	0.10%
Hydrogenated Castor Oil	0.10%
TEGOSOFT® DEC (Diethylhexyl Carbonate)	6.80%
TEGOSOFT® TN (C12-15 Alkyl Benzoate)	6.00%
TEGOSOFT® CT (Caprylic/Capric Triglyceride)	6.00%
Phase B	
Glycerin	3.00%
Magnesium Sulfate Heptahydrate	1.50%
SK-INFLUX®	2.00%
Water	72.5%
Phase Z	
Preservative, Perfume	q.s.

Preparation:

1. Heat phase A to approx. 80°C.
2. Add phase B (80°C or room temperature) slowly while stirring.
3. Homogenize for a short time.
4. Cool with gentle stirring below 30°C and homogenize again.

W/O Cream with SK-influx WR 6/06-11	
Phase A	
ABIL® EM 90 (Cetyl PEG/PPG-10/1 Dimethicone)	2.00%
Hydrogenated Castor Oil	0.80%
Microcrystalline Wax (Paracera M; Paramelt B.V.)	1.20%
TEGOSOFT® DEC (Diethylhexyl Carbonate)	10.00%
Cyclomethicone	10.00%
Phase B	
Glycerin	3.00%
NaCl	0.50%
SK-INFLUX®	2.00%
Water	70.5%
Phase Z	
Preservative, Perfume	q.s.

Preparation:

1. Heat phase A to approx. 80°C.
2. Add phase B (80°C or room temperature) slowly while stirring.
3. Homogenize for a short time.
4. Cool with gentle stirring below 30°C and homogenize again.

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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_01	<=20.0	ppm	C
Arsenic	GM_1551_02	<=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_1553_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

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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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SK-INFLUX®

Product data record

1. General information

1.1 Manufacturer/Supplier

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1.2 Product Description

1.2.1 Raw material category

Skin Repair Active

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

Components	Source	Ratio
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.

1.2.4 Solvents, preservatives and other additives

	CAS No.	EINECS / EC No.	content	Function
Methylparaben	99-76-3	202-785-7	0.3 %	preservative
Propylparaben	94-13-3	202-307-7	0.2 %	preservative

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.

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

		method
Residual solvents	not applicable	
Free amines	not applicable	Chromatography
Nitrosamines	not applicable	
Monochloroacetic acid	not applicable	Chromatography
Dichloroacetic acid	not applicable	Chromatography
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	AAS-ICP
As	max. 2 ppm	AAS-ICP
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	

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 are 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	method
Ethylene Oxide	no		
Propylene Oxide	no		
Octamethylcyclotetrasiloxane (D4)	no		
2-Ethylhexanoic Acid	no		
n-Hexane	no		
Methyl Chloride	no		
Dimethyl Sulphate	no		

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 parfum 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 parfum 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.

2.4 Food Ingredients listed in Annex IIIa of Commission Directive 2007/68/EC.

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.

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

24 months after product release 10 – 15 °C, 6 months after product release at room temperature (unopened original packaging)

5. Regulatory Status

5.1 Customs tariff number 38249092

5.2 Regulatory status (chemical regulations)

Europe

Components	REACH status	CAS No.	EINECS / EC No.
Ceramide NP	pre-registered	100403-19-8	309-560-3
Ceramide AP	pre-registered	100403-19-8	309-560-3
Ceramide EOP	pre-registered	100403-19-8	309-560-3
Phytosphingosine	Reg. No. 01-0000018379-59	554-62-1	439-210-6
Cholesterol	pre-registered	57-88-5	200-353-2
Sodium Lauroyl Lactylate	pre-registered	13557-75-0	236-942-6
Carbomer	Polymer	9003-01-4	Polymer
Xanthan Gum	pre-registered	11138-66-2	234-394-2

Other countries

Country		yes / no	Remark
Ceramide NP			
Australia	AICS:	yes	for cosmetic use only under CAS No. 34354-88-6
China	IECSC:	yes	
Canada	DSL: NDSL:	no	CAS No. 100403-19-8 is on the revised in-commerce list
Taiwan	TCSI:	yes	

Country		yes / no	Remark
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:	no	
China	IECSC:	yes	CAS No. 13552-11-9
Canada	DSL: NDSL:	yes no	up to 100 kg/a but notified by Evonik Goldschmidt Canada for up to 1,000 kg/a
Taiwan	TCSI:	yes	
Cholesterol			
Australia	AICS:	yes	
China	IECSC:	yes	
Canada	DSL: NDSL:	yes	
Taiwan	TCSI:	yes	
Sodium Lauroyl Lactylate			
Australia	AICS:	no	
China	IECSC:	yes	
Canada	DSL: NDSL:	no	CAS No. 13557-75-0 is on the revised in-commerce list
Taiwan	TCSI:	yes	

Country		yes / no	Remark
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 require 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
Japan	JSQI:	yes	
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	

Country		yes / no	Remark
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