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.

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).

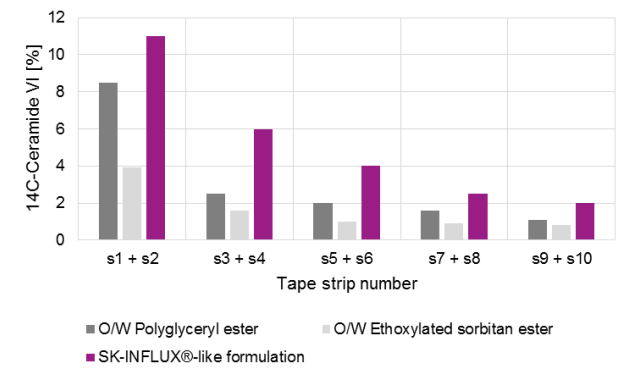

Fig. 1: *Ex vivo* incorporation study with ^{14}C-radio-labeled Ceramide VI

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.

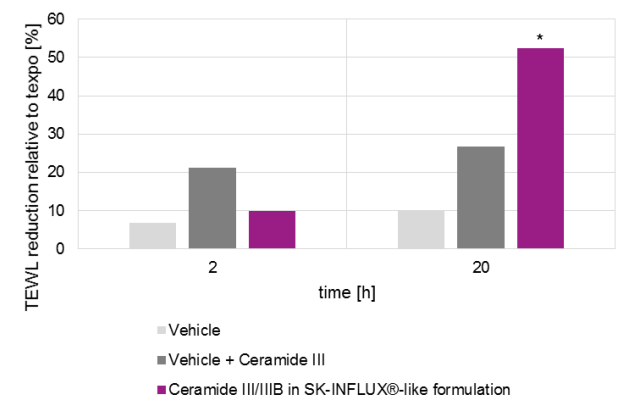

Fig. 2: Effect of a SK-INFLUX®-like formulation on barrier repair: reduction of the transepidermal water loss after acetone exposure

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.

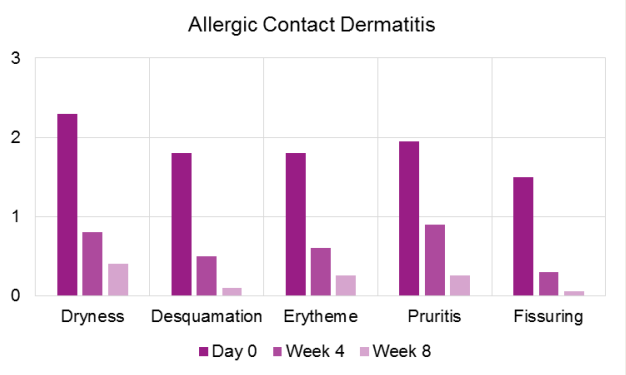

Fig. 3: Effect of the test formulation on the symptoms of patients suffering from Allergic Contact Dermatitis

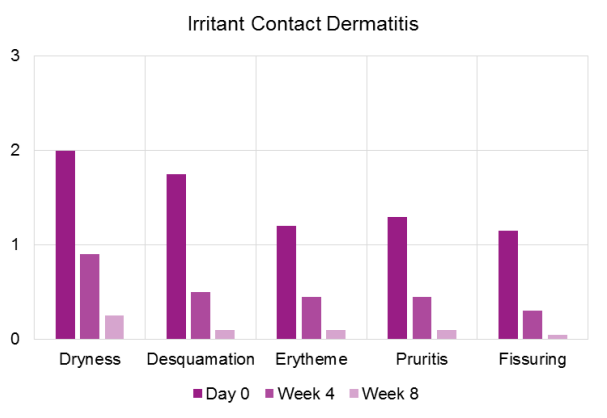

Fig. 4: Effect of the test formulation on the symptoms of patients suffering from Irritant Contact Dermatitis

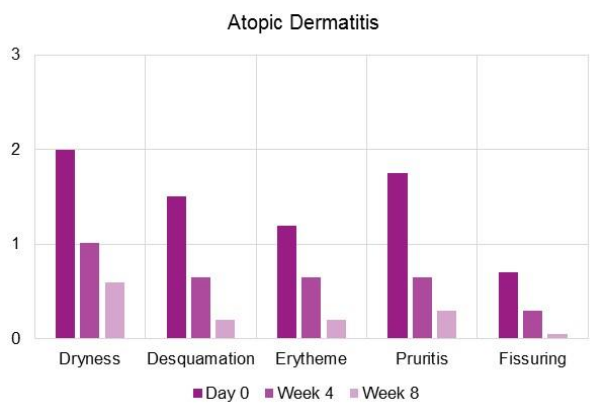

Fig. 5: Effect of the test formulation on the symptoms of patients suffering from Atopic Dermatitis

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%

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

Mask in Lotion
CHN BR 043-20

Phase A	
TEGO® Care CG 90 (Cetearyl Glucoside)	1.00%
TEGOSOFT® PC 31 (Polyglyceryl-3 Caprate)	0.50%
TEGO® Alkanol 16 (Cetyl Alcohol)	0.80%
Phytosphingosine SLC (Salicyloyl Phytosphingosine)	0.10%
TEGOSOFT® DC MB (Decyl Cocoate)	5.00%
TEGOSOFT® CT (Caprylic/Capric Triglyceride)	5.00%
Triisostearin	2.00%
ABIL® 350 (Dimethicone)	1.00%
Tocopheryl Acetate	0.50%
Phase B	
Water	78.11%
Glycerin	3.00%
KELCOGEL CG-HA (Gellan Gum)	0.03%
Keltrol CG-SFT (Xanthan Gum)	0.20
HyaCare® (Sodium Hyaluronate)	0.03
HyaCare® 50 (Hydrolyzed Hyaluronic Acid)	0.03
Phase C	
SK-INFLUX® V MB	2.00
Phase D	
Euxyl PE 9010 (Phenoxyethanol, Ethylhexylglycerin)	0.70

Preparation:

1. Heat phase A to approx. 85 °C.
2. Disperse gums in water and heat to approx. 85 °C. Then add other ingredients of phase B.
3. Add phase A to phase B with stirring. [1)]
4. Homogenize.
5. Cool with gentle stirring and add phase C and D at approx. 40 °C.
6. Cool down with stirring

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

Body Lotion for improved Barrier Function
MAC 851/7

Phase A	
TEGO® Care LTP (Sorbitan Laurate; Polyglyceryl-4 Laurate; Dilauryl Citrate)	1.50%
TEGOSOFT® OP (Ethylhexyl Palmitate)	8.10%
TEGOSOFT® DC MB (Decyl Cocoate)	3.50%
TEGOSOFT® CI (Cetearyl Isononanoate)	3.00%
TEGO® Carbomer 140 (Carbomer)	0.15%
TEGO® Carbomer 141 (Carbomer)	0.15%
Xanthan Gum	0.10%
Phase B	
SK-INFLUX® V MB	5.00%
Glycerin	3.00%
Water	75.5%
Phase C	
Sodium Hydroxide (10% in water)	q.s.
Phase Z	
Preservative, Perfume	q.s.

Preparation:

1. Add phase A to phase B with stirring.[1)]
2. Homogenize.
3. Add phase C and stir well.

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

Silky Body Lotion
JS 8/16-4

Phase A	
TEGOSOFT® OS (Ethylhexyl Stearate)	5.00%
ABIL® EM 90 (Cetyl PEG/PPG-10/1 Dimethicone)	2.50%
Hydrogenated Castor Oil	0.50%
Paraffin (and) Microcrystalline Wax (Microcrystalline Wax)	0.50%
TEGOSOFT® CT (Caprylic/Capric Triglyceride)	10.0%
TEGOSOFT® DEC (Diethylhexyl Carbonate)	5.00%
TEGOSOFT® TN (C12-15 Alkyl Benzoate)	5.00%
Phase B	
Water	63.3%
Glycerin	3.00%
LACTIL® (Sodium Lactate; Sodium PCA; Glycine; Fructose; Urea; Niacinamide; Inositol; Sodium Benzoate;Lactic Acid)	2.00%
SK-INFLUX® V MB	2.00%
Sodium Chloride	0.50%
Phase C	
Euxyl K 900 (Benzyl Alcohol, Ethylhexylglycerin, Tocopherol)	0.70%
Phase Z	
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, add phase C and homogenize again.

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