Technical Information

Ceramide III / Ceramide IIIB

Reinforcing the skins natural protective lipid barrier

Intended use

Actives for skin care

Benefits at a glance

- Reinforces the natural lipid barrier of dry and ageing skin
- Improves long term moisturization and protects the skin from external influences
- Repairs and protects damaged hair (mechanical properties, liveliness, combability, shine)
- Human-skin identical molecule
- Natural product with high purity
- Active at low concentrations

INCI (PCPC name)

Ceramide III Ceramide NP

Ceramide IIIB Ceramide NP

For Chinese SFDA listed as:

Ceramide 3

Chemical and physical properties (not part of specifications)

Form	powder
Active matter	approx. 95%

Properties

- Ceramide III and Ceramide IIIB support the renewal of the skin's natural protective layer and form an effective barrier against moisture loss. These human-skin-identical molecules are therefore particularly suitable for long term protection and repair of sensitive and dry skin

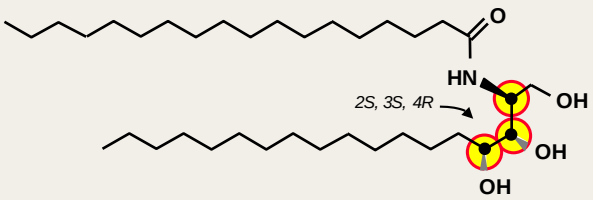

Fig.1 : Structural formula of Ceramide III.

Ceramide III consists of a Phytosphingosine backbone acylated with a saturated fatty acid (stearic acid). All Ceramides based on the Phytosphingosine backbone have three stereo-active groups. Of the 8 possible configurations, only the 2S,3S,4R configuration is naturally found in the human skin (Fig.1).

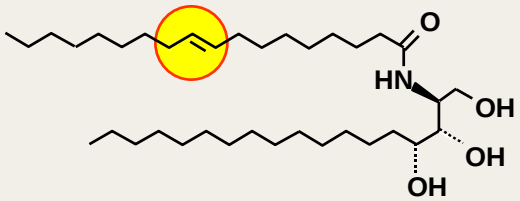

Fig. 2: Structural formula of Ceramide III B.

Ceramide IIIB consists of a Phytosphingosine backbone acylated with oleic acid. Ceramide IIIB differs from Ceramide III in that it has one unsaturated bond in its fatty acid chain (Fig.2).

- Our efficacy studies have shown that Ceramide III is effective starting from 0.05% concentrations. Depending on the type of skin and desired effect, the advised concentration varies between 0.05% - 0.5% or even up-to 1%.

- In hair care formulations Ceramide III and Ceramide IIIB are able to restore damaged hair and to protect hair against chemical and UV damage.
- Ceramides are produced using patented biofermentation processes. In contrast to various pseudo ceramides that are on the market, the ceramides produced according to this process have the same stereo-chemical configuration as the ceramides present in the human skin. This unique configuration is regarded to be crucial for optimal performance.
- The production conditions are strictly standardised and carried out under GMP conditions. Its high purity and constant quality are prerequisites for an optimal safety and efficacy of the end product.

Efficacy studies

- Two Ceramide III formulations (0.05% and 0.5%), and a control product were applied on the forearms of volunteers twice/day for 7 consecutive days. One area remained untreated. The measurements were performed before application, and during the application period at 1, 3 and 7 days. After the application was ceased (day 7), the measurements were continued on day 8, 10 and 13. The water retention capacity of the skin was determined by measuring skin hydration using a corneometer.

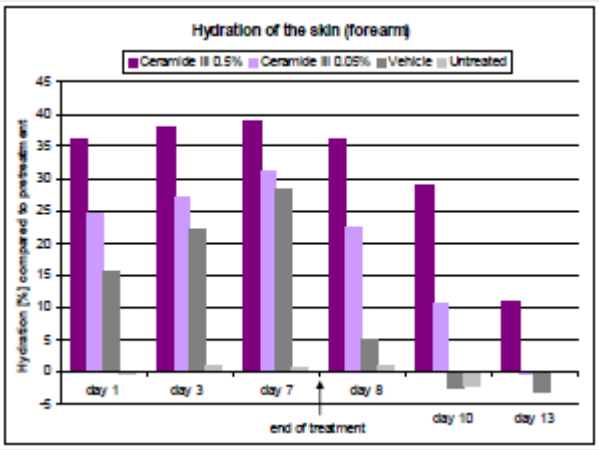

Fig. 3:
During the application week Ceramide III resulted in a statistically significant increase in water retention capacity of the skin compared to the Control. A dose-response effect with 0.05% and 0.5% Ceramide III was seen.

After the application was ceased, areas treated with the Control showed a rapid decrease in hydration. On the contrary, Ceramide III showed a significant longer lasting hydration, up to 6 days after the last application (day 13) using 0.5% Ceramide III (Fig. 3).

- In a second study two Ceramide III formulations (0.2% and 0.5%) and a control product were applied on the forearms of volunteers twice/day for 7 consecutive days. One area remained untreated. Measurements were evaluated before application (baseline) and two hours after the last application (day 7). The test areas were then exposed to a 5% aqueous solution of Sodium Dodecyl Sulphate (SDS) for 2 hours to induce skin irritation.

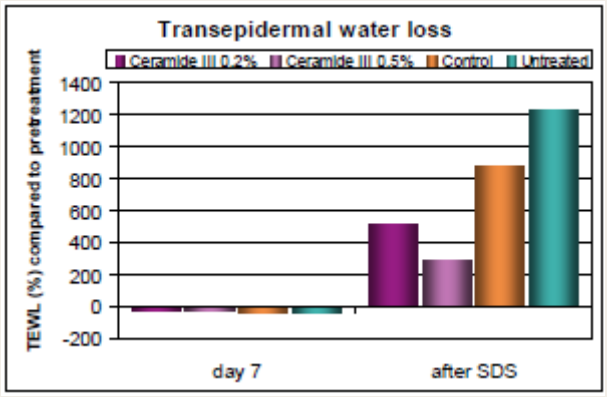

Fig. 4:
The graph shows the TEWL (%) compared to pretreatment. After 7 days of application on healthy skin, no disturbance of the normal skin physiology was seen. Application of Ceramide III does not occlude the skin.
After irritation with SDS, untreated skin and areas treated with the Control showed a large increase in TEWL. The areas treated with Ceramide III showed a lower increase in TEWL after SDS, demonstrating the protective effect of Ceramide III on the skin.

Other efficacy studies are available on request.

Preparation

Emulsions

Ceramides are amphiphilic molecules and can be incorporated into the lamellar liquid crystalline structures built up by emulsifier and consistency agents in the external water phase of cosmetic O/W emulsions.
In general, ceramides are nearly insoluble in common cosmetic oils at room temperature. They can be clearly solved in most cosmetic oils by heating up to 90°C. The oils differ in the temperature at which the mixture becomes turbid again while cooling. The

solubility in the oil phase seems not to be crucial for the stability of the formulation with respect to recrystallisation of ceramide. **It is very important, however, that the ceramide is clearly and completely solved in the oil phase at the beginning of and during the homogenization step.** Towards this end both the water phase and the oil phase should have a temperature of at least 90°C. Oils with a good solvency for ceramides should be chosen, e. g. TEGOSOFT® APM (PPG-3 Myristyl Ether), TEGOSOFT® TN (C12-15 Alkyl Benzoate) and TEGOSOFT® CT (Caprylic/Capric Triglyceride).
To obtain a pleasant skin feel it is suggested to combine those oils with low viscosity oils such as TEGOSOFT® OP (Ethylhexyl Palmitate), TEGOSOFT® DC (Decyl Cocoate) and TEGOSOFT® P (Isopropyl Palmitate).

Ceramide III, especially at higher concentrations (0.5% and higher), has a strong negative influence on the freeze stability of an O/W emulsion. By choosing polar oils, adding Carbomer and/or increasing the oil phase up to 25% the freeze stability can be optimized.
Ceramide IIIB has a significantly better solubility in cosmetic oils and a much lower tendency to recrystallise.
By following the above mentioned guidelines formulations will have a long-term stability against recrystallisation of ceramide.

Clear aqueous formulations

Ceramide III and Ceramide IIIB show a very low solubility in water and besides Ceramide III has a very high melting point. Nevertheless it is possible to develop clear aqueous formulations with Ceramide III and Ceramide IIIB (for example shampoos, clear Leave in Conditioners).
For the solubilization of the ceramides it is necessary to find a suitable solubilizer which can be heated up to a temperature of about 90°C or even higher to ensure that the ceramides are melted completly.
During the addition of the other ingredients of the formulation (surfactants, water, conditioners, thickeners and so on) the temperature must be kept at 80 - 85°C.
Suitable solubilizers for the ceramides are TAGAT® CH 40 (PEG-40 Hydrogenated Castor Oil), TEGOSOFT® PC 31 (Polyglyceryl-3 Caprate), TEGOSOFT® PC 41 (Polyglyceryl-4 Caprate) or Sodium Lauroyl Lactylate.
For a clear Leave in Conditioner TAGAT® CH 40 (PEG-40 Hydrogenated Castor Oil) is especially suitable, for a shampoo formulation TEGOSOFT® PC 31 (Poly- glyceryl-3 Caprate) or TEGOSOFT® PC 41 (Polyglyceryl-4 Caprate) also can be used.
Another problem of shampoo formulations is the tendency of Ceramide III to crystallise after 1 - 3 months.
This crystallisation can be avoided if a combination of two or more different ceramides (Ceramide III, IIIB, VI) are used.

Emulsion based Hair care formulation

The production of an emulsion based hair care formulation (for example hair rinses or cream conditioners) is comparable to that described before for an O/W-Emulsion. The water phase and the oil phase (emulsifier, consistency enhancer, ceramides and possible small amouts of emollients) must be heated up to 90°C to ensure that the ceramides are clearly solubilized.
Monomeric Quats, for example VARISOFT®-Types, or Sodium Lauroyl Lactylate are especially suitable to improve the stability of hair rinses with ceramides.

Recommended usage concentration

0.05 - 1.0% Ceramide III or Ceramide IIIB

Application

Consequently Ceramide III and Ceramide IIIB have a wide range of applications, such as

- O/W creams and lotions of the segments:
  - Moisturizing
  - Skin repair
  - Baby care
  - Facial Care
  - Sun care

- Hair Care preparations
  - Hair Rinses
  - Leave-in Conditioners
  - Conditioning Shampoos

Packaging

Ceramide III:
0.20 kg package
2.50 kg bag

Ceramide IIIB:
0.25 kg package
2.50 kg bag

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 accidents and fires
- toxicity and ecological effects

is given in our material safety data sheets.

Guideline formulations

O/W Cream with Ceramide III WR 1/01-32	
Phase A	
ABIL® Care 85 (Bis-PEG/PPG-16/16 PEG/PPG-16/16 Dimethicone; Caprylic/Capric Triglyceride)	1.00%
TEGINACID® C (Ceteareth-25)	1.00%
TEGIN® M Pellets (Glyceryl Stearate)	4.00%
TEGO® Alkanol 1618 (Cetearyl Alcohol)	1.50%
Stearic Acid	0.50%
Ceramide III	0.50%
TEGOSOFT® DC (Decyl Cocoate)	5.00%
TEGOSOFT® OP (Ethylhexyl Palmitate)	5.00%
TEGOSOFT® CT (Caprylic/Capric Triglyceride)	6.50%
Phase B	
Water	71.25%
Glycerin	3.00%
Phase C	
Sodium Hydroxide (10% in water)	q.s.
Phase D	
TEGO® Carbomer 134 (Carbomer)	0.15%
TEGOSOFT® OP (Ethylhexyl Palmitate)	0.60%
Phase E	
Preservative, Perfume	q.s.

Preparation:

1. Heat phase A and B separately to 90°C.
2. Add phase A to B with stirring.[1)]
3. Homogenize.
4. Cool with gentle stirring to approx. 70°C and add phase C with gentle stirring.
5. Add phase D at approx. 60°C and homogenize for a short time.
6. Cool with gentle stirring below 30°C.

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

O/W Skin Repair Cream F 38/00-2	
Phase A	
TEGIN® 4100 Pellets (Glyceryl Stearate)	2.50%
TEGO® Alkanol 18 (Stearyl Alcohol)	1.50%
Stearic Acid	1.00%
Ceramide III	0.20%
TEGOSOFT® liquid (Cetearyl Ethylhexanoate)	9.80%
TEGOSOFT® OP (Ethylhexyl Palmitate)	5.00%
TEGOSOFT® CT (Caprylic/Capric Triglyceride)	3.00%
TEGOSOFT® DC (Decyl Cocoate)	2.00%
Phase B	
TEGO® Care CG 90 (Cetearyl Glucoside)	1.00%
Glycerin	3.00%
Water	70.50%
Phase C	
TEGO® Carbomer 134 (Carbomer)	0.10%
TEGOSOFT® liquid (Cetearyl Ethylhexanoate)	0.40%
Phase D	
Sodium Hydroxide (10% in water)	q.s.
Preservative, Parfum	q.s.

Preparation:

1. Heat phase A and B separately to 90°C.
2. Add phase A to B with stirring.[1)]
3. Homogenize.
4. Add phase C at approx. 60°C and homogenize for a short time.
5. 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 Repair Cream with 0.2% Ceramide III WR 2/00-26	
Phase A	
TEGO® Care 450 (Polyglyceryl-3 Methylglucose Distearate)	3.00%
TEGO® Alkanol 1618 (Cetearyl Alcohol)	2.10%
TEGIN® M Pellets (Glyceryl Stearate)	0.90%
TEGOSOFT® HP (Isocetyl Palmitate)	5.00%
TEGOSOFT® OS (Ethylhexyl Stearate)	8.80%
Avocado (Persea Gratissima) Oil	3.00%
Tocopheryl Acetate	1.00%
Ceramide III	0.20%
Phase B	
Propylene Glycol	3.00%
Allantoin	0.10%
Water	72.90%
Preservative, Parfum	q.s.

Preparation:

1. Heat phase A and B separately to approx. 90°C.
2. Add phase A to phase B with stirring.[1)]
3. Homogenize.
4. Cool with gentle stirring.

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

Clear Conditioning Shampoo with Ceramide UR 354/3/20	
Ceramide IIIB	0.05%
Sodium Laureth Sulfate (Texapon NSO 28%)	30.00%
Parfum	0.50%
ABIL® Quat 3272 (Quaternium-80)	0.50%
Water	56.95%
TEGO® Betain F 50 (Cocamidopropyl Betaine)	10.00%
ANTIL® 171 (PEG-18 Glyceryl Oleate/Cocoate)	2.00%
Sodium Chloride	q.s.
Preservative	q.s.

Preparation:

1. Heat Ceramide IIIB and Texapon NSO to 85°C. The Ceramide must be melted.
2. Add the other ingredients slowly step by step in the given order and keep the temperature at
3. 80 - 85°C.
4. Once the formulation is homogeneous and clear, cool down to 30°C.

Anti-Aging Cream with Ceramide IIIB and Ubichinon F 52/00-10	
Phase A	
TEGO® Care 450 (Polyglyceryl-3 Methylglucose Distearate)	3.00%
TEGO® Alkanol 18 (Stearyl Alcohol)	1.00%
TEGIN® M (Glyceryl Stearate)	2.00%
TEGOSOFT® CT (Caprylic/Capric Triglyceride)	11.90%
TEGOSOFT® DC (Decyl Cocoate)	5.00%
Ceramide IIIB	0.10%
Ethylhexyl Methoxycinnamate	2.00%
Phase B	
Glycerin	3.00%
Water	69.00%
Phase C	
Aqua; Alcohol; Lecithin; Ubichinon (Rovisome Q 10)	3.00%
Preservative, Parfum	q.s.

Preparation:

1. Heat phase A and B separately to approx. 90°C.
2. Add phase A to phase B with stirring.[1)]
3. Homogenize.
4. Cool with gentle stirring.
5. Add phase C at 30°C.

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

After Sun Lotion with Ceramide III Ma 24/00-3	
Phase A	
TEGOSOFT® DC (Decyl Cocoate)	4.00%
TEGOSOFT® CR (Cetyl Ricinoleate)	2.00%
TEGOSOFT® HP (Isocetyl Palmitate)	3.00%
Isohexadecane	6.00%
Macadamia (Ternifolia Nut) Oil	2.00%
Tocopheryl Acetate	0.40%
Tocopherol	0.10%
Ceramide III	0.10%
Stearic Acid	1.00%
TEGIN® 4100 Pellets (Glyceryl Stearate)	0.30%
Phase B	
TEGO® Care CG 90 (Cetearyl Glucoside)	1.00%
Glycerin	2.00%
Panthenol	1.00%
Bisabolol	0.80%
Allantoin	0.10%
GluCare® S (Sodium Carboxymethyl Betaglucan)	0.10%
Water	74.70%
Phase C	
TEGO® Carbomer 141 (Carbomer)	0.20%
TEGOSOFT® HP (Isocetyl Palmitate)	0.80%
Phase D	
Sodium Hydroxide (10% in water)	0.40%
Preservative, Parfum	q.s.

Preparation:

1. Heat phase A and B separately to approx. 90°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**.

Leave-in Conditioner with Ceramides UR 354/1/30	
TAGAT® CH 40 (PEG-40 Hydrogenated Castor Oil)	2.00%
Ceramide III	0.05%
Perfume	0.20%
Water	90.00%
ABIL® Quat 3272 (Quaternium-80)	0.50%
ABIL® B 88183 (PEG/PPG-20/6 Dimethicone)	1.50%
LACTIL® (Sodium Lactate; Sodium PCA; Glycine; Fructose; Urea; Niacenamide; Inositol; Sodium Benzoate; Lactic Acid)	2.00%
TEGO® Betain F 50 (Cocamidopropyl Betaine)	1.00%
Citric Acid (30% in water)	2.80%
Preservative	q.s.

Preparation:

1. Heat TAGAT® CH 40 and the Ceramide III to 85°C. The Ceramide must be melted.
2. Add the other ingredients slowly step by step in the given order and keep the temperature at 80 - 85°C.
3. Cool down below 40°C and add the LACTIL®.
4. Once the formulation is homogeneous and clear, cool down to 30°C.

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