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Technical Information

TEGO® Natural Betaine

The immediate Hydro-Regulator

Intended use

Active for skin care

Benefits at a glance

- TEGO® Natural Betaine is a natural amino acid derivative from sugar beet
- Shows strong water binding capacity
- Retains skin moisture

INCI (PCPC name)

Betaine

Chemical and physical properties (not part of specifications)

Appearance (20 °C)	white crystals
Active content (Betaine Monohydrat)	>= 99%
Solubility in water	160 g/ 100 g
Solubility in ethanol	8.7 g/ 100 g

Properties

TEGO® Natural Betaine is a naturally occurring substance. It can be found in various species, like plants, animals as well as in the human organism. It functions as an osmo-protectant as its amphoteric structure counteracts against osmotic pressure. In this way especially halophile organisms living in high salinity environment protected themselves from osmotic stress.

TEGO® Natural Betaine is a natural amino acid derivative (trimethylglycin). Due to its structure it is hygroscopic and has moisturizing properties. Its strong water binding capacity ensures a retention of skin moisture.

TEGO® Natural Betaine is obtained from sugar beet molasses by an extraction process.

Efficacy studies

- Water binding capacity

In a comparative in vitro trial the water binding capacity of TEGO® Natural Betaine and Glycerin were tested. First both products were dried in a desiccator and the weight was determined. The relative humidity was then stepwise increased in 10% intervals from 20% up to 80%. At every humidity step the substances were equilibrated for 24 h and the weight was determined. Afterwards the relative humidity was decreased back from 80% to 20% and the weight was again determined stepwise.

Result: TEGO® Natural Betaine shows a higher water binding capacity compared to Glycerin and it supports a high water retention (Fig.: 1).

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

Le informazioni sopra riportate non Vi sollevano dall'obbligo di identificare il prodotto prima dell'impiego. DERMOLIFE non si assume alcuna responsabilità per danni a persone o cose derivanti dall'impiego dei prodotti da noi commercializzati

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

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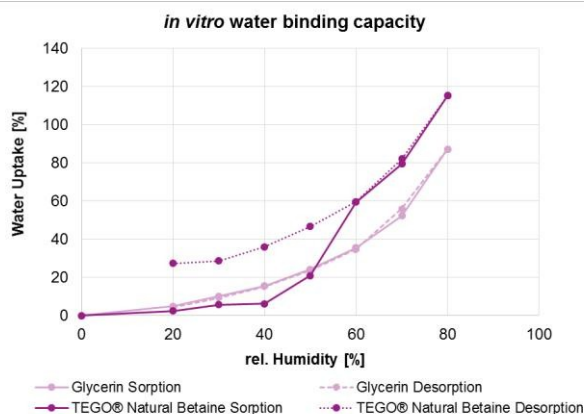


Fig.1: Water binding capacity with sorption and desorption graphs

- Immediate skin moisturization

To evaluate the skin moisturization benefits of TEGO® Natural Betaine, in vivo studies were performed with 16 volunteers. The moisturization was determined using a Corneometer CM 825 (Courage & Khazaka, Cologne, D). Measurements were carried out under standardized conditions in a climatic room at ambient temperature and 55% relative humidity. The panellists were acclimatized for 15 minutes before each measurement.

At the beginning of each test the baseline water content ($t=0$) was determined for every test area. Further measurements followed after application of the test formulations at different time points. The differences between the initial baseline corneometer units (CU) and the CU after application were calculated for each panellists and presented as Δ CU (delta CU) for every test product.

The test products were randomized over both inner forearms of the volunteers with 4 test fields per arm. The studies included always a control and a vehicle test field.

A standard O/W test emulsion was prepared and 0 % (vehicle), 1%, 2.5%, and 5% of TEGO® Natural Betaine were incorporated. Subsequently, 4 $\mu\text{g}/\text{cm}^2$ of each O/W emulsion were applied to the marked, randomized 5 cm^2 test fields of the forearms. Two hours and six hours later, the skin moisture was measured again.

Result: TEGO® Natural Betaine shows a significant improvement of skin moisturization (Fig.: 2).

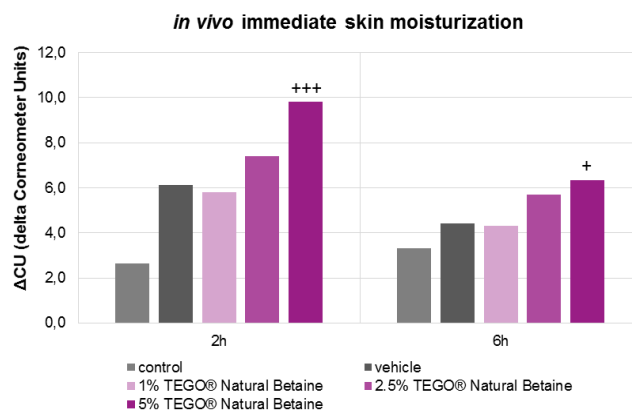


Fig.2: Immediate moisturization at 2 and 6 hours ($+p<0.05$, $+++p<0.001$)

Application

TEGO® Natural Betaine is recommended for use in Skin Care products:

- All kinds of moisturizing body and face care products
- Suitable for mass market formulations

Formulation hints

TEGO® Natural Betaine has excellent water solubility and is also soluble in ethanol, 1,2-propylene glycol and Glycerin between 20–30 °C while stirring.

In O/W emulsions, it is recommended to add TEGO® Natural Betaine as aqueous solution after the cooling process at temperatures below 40 °C.

In W/O emulsions TEGO® Natural Betaine is added to the water phase of the emulsion and the emulsion is prepared as usual.

Recommended usage concentration

2.5–5% TEGO® Natural Betaine

Packaging

6 x 50 kg drums / pallet

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Storage and processing recommendation

Store in a cool place in closed packaging. Due to the product's hygroscopic nature it must be kept dry during storage.

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

Body Lotion for Men (MAC 804/2/5)	
Phase A	
AXOL® C 62 Pellets (Glyceryl Stearate Citrate)	2.0%
TEGO® Alkanol 1618 (Cetearyl Alcohol)	1.0%
TEGOSOFT® MM (Myristyl Myristate)	3.0%
TEGOSOFT® CT (Caprylic/Capric Triglyceride)	5.0%
Octyldodecanol	2.0%
ABIL® 350 (Dimethicone)	3.0%
CERAMIDE IIIB (Ceramide NP)	0.1%
Tocopheryl Acetate	0.5%
Phase B	
Glycerin	5.0%
Water	66.4%
Phase C	
TEGO® Carbomer 141 (Carbomer)	0.2%
TEGOSOFT® CT (Caprylic/Capric Triglyceride)	0.8%
Phase D	
Ethanol	5.0%
Phase E	
TEGO® Natural Betaine (Betaine)	3.0%
Water	3.0%
Phase F	
Sodium Hydroxide (10%)	q.s.
Phase Z	
Preservative, Perfume	q.s.
Preparation:	
1. Heat phase A and B separately to 80 °C. Adjust the pH value of this solution to appr. 5 for a better solubility.	
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, E, F and Z below 40 °C.	
¹⁾ Important: If phase A has to be charged into the vessel first, phase B must be added without stirring.	

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Skin Vitalizing Moisturizer (MAC 829/2)	
Phase A	
AXOL® C 62 Pellets (Glyceryl Stearate Citrate)	1.5%
TEGO® Alkanol 1618 (Cetearyl Alcohol)	1.0%
TEGOSOFT® OS (Ethylhexyl Stearate)	6.5%
TEGOSOFT® CT (Caprylic/Capric Triglyceride)	5.0%
Butyrospermum parkii (Shea) Butter	1.0%
Phase B	
TEGO® Cosmo C100 (Creatine)	1.0%
Glycerin	3.0%
Water	70.0%
Phase C	
TEGO® Carbomer 141 (Carbomer)	0.2%
TEGOSOFT® OS (Ethylhexyl Stearate)	0.8%
Phase D	
TEGO® Natural Betaine (Betaine)	5.0%
Water	5.0%
Phase E	
Sodium Hydroxide (10% in water)	q.s.
Phase Z	
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 and E below 40 °C. 1) Important: If phase A has to be charged into the vessel first, phase B must be added without stirring.	

Age Correcting Hydro Lotion (MAC 831/9)	
Phase A	
ABIL® Care XL 80 (Bis-PEG/PPG-20/5 Dimethicone; Methoxy PEG/PPG-25/4 Dimethicone; Caprylic/Capric Triglyceride)	2.0%
TEGOSOFT® CI (Cetearyl Isononanoate)	8.0%
TEGOSOFT® DEC (Diethylhexyl Carbonate)	5.5%
Persea Gratissima (Avocado) Oil	2.0%
TEGO® Carbomer 341 ER (Acrylates/C10-30 Alkyl Acrylate Crosspolymer)	0.45%
Phase B	
TEGO® Natural Betaine (Betaine)	5.0%
TEGO® Stemlastin (Cyanidium Caldarium Extract)	2.5%
TEGO® SMO 80V (Polysorbate 80)	1.0%
Glycerin	3.0%
Water	70.55%
Phase C	
Sodium Hydroxide (10% in water)	q.s.
Phase Z	
Preservative, Perfume	q.s.
Preparation:	
1. Prepare phase A and B separately at room temperature. 2. Combine phases A and B without stirring. 3. Homogenize. 4. Add phase C and stir well.	

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Moisturizing Foot Cream (MM 281/9)	
Phase A	
TEGO® Care 450 (Polyglyceryl-3 Methylglucose Distearate)	3.0%
TEGIN® M Pellets (Glyceryl Stearate)	2.0%
TEGO® Alkanol 18 (Stearyl Alcohol)	2.0%
TEGOSOFT® OER (Oleyl Erucate)	6.0%
TEGOSOFT® P (Isopropyl Palmitate)	5.0%
TEGOSOFT® APM (PPG-3 Myristyl Ether)	4.0%
Octyldodecanol	4.0%
CERAMIDE III (Ceramide NP)	0.1%
Phase B	
Glycerin	5.0%
Water	58.9%
Phase C	
TEGO® Natural Betaine (Betaine)	3.0%
Urea	3.0%
Water	5.0%
Phase Z	
Preservative, Perfume	q.s.
Preparation: 1. Heat phase A and B separately to 90 °C. 2. Add phase A to phase B with stirring ¹⁾ . 3. Homogenize. 4. Cool with gentle stirring and add phase C and Z below 40 °C. ¹⁾ Important: If phase A has to be charged into the vessel first, phase B must be added without stirring.	

Especially concerning Active Ingredients

This product information is not intended to provide legal or regulatory advice about product uses or claims in any jurisdiction and should not be relied upon for such guidance (especially in the United States, Canada, and Mexico). Since global regulatory requirements differ, parties accessing this information are solely responsible for determining whether the products and/or claims comply with applicable local laws and regulations, including but not limited to import and export regulations. Please contact your local Evonik representative for more product information. Evonik assumes no liability for any use of our products that is not in compliance with the requirements of the country of the user.

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Product specification

Material TEGO NATURAL BETAINE
Spec.Code K00 STANDARD

Inspection Characteristics	Method	Limits	Units	Z
Content	GM_1505_01	>=99.0	%	X
Water Content	GM_0080_01	<=15.00	%	X
Sulphate	GM_0916_05	<=0.010	%	X
pH-Value 5% solids	GM_0131_05	5.0-7.0	pH-Value	X
Appearance 20°C	GM_0170_00	OK		X

Appearance 20°C white powder

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

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.

Material: TEGO NATURAL BETAINE		Spec-Code: K00 STANDARD	Page 1 from 1
Print date: 06.07.2015	Valid from: 05.01.2010	Version: 3	

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TEGO® Natural Betaine

Product data record

1. General information

1.1 Manufacturer/Supplier
Evonik Nutrition & Care GmbH
Business Line Personal Care
Goldschmidtstrasse 100
D-45127 Essen / Germany
Phone: +49 (201) 173-2524
Fax: +49 (201) 173-1828
personal-care@evonik.com
<http://www.evonik.com/personal-care>

1.2 Product Description

1.2.1 Raw material category **Moisturizer**

1.2.2 Ingredients according to INCI

Betaine

1.2.3 Composition

Components	Source	Ratio
Betaine	vegetable	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
no additives				

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.

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2. Information on production process

General description of production process:
Extraction from sugar beet molasses

The product is not irradiated.

TEGO® Natural Betaine is produced in the strictest absence of any animal derived material of any type.

Origin of vegetable starting material: sugar beet

GMO-Status:

The item does not contain ingredients that might have been derived from GM sources. However max 0.9 % cross-contamination is possible. Any protein or DNA is not present. Consequently the product will be PCR negative when tested.

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
Pesticides	meets the valid regulatory requirements for limits on agricultural pesticides	
Total heavy metals	max. 20 ppm	AAS-ICP
As, Cd, Co, Cr, Hg, Ni, Pb, Sb	Each < 1 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

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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 production (unopened original packaging)

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5. Regulatory Status

5.1 Customs tariff number 29239000

5.2 Regulatory status (chemical regulations)

Europe

Components	REACH status	CAS No.	EINECS / EC No.
Betaine	exempt Reg. No. 01-2119520508-42	590-47-6 refers to the registered 107-43-7	209-684-7 203-490-6

Other countries

Country		yes / no	Remark
Australia	AICS:	yes	CAS No. 107-43-7
China	IECSC:	yes	CAS No. 107-43-7
Canada	DSL: NDSL:	yes	CAS No. 107-43-7
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
China	CFDA:	yes	
Japan	JSQI:	yes	JSQI No. 523156, but specifications not controlled

6. Toxicology and Ecotoxicology

Refer to summary of ecotoxicological and toxicological data

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