

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 ampho-teric 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 step-wise.

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

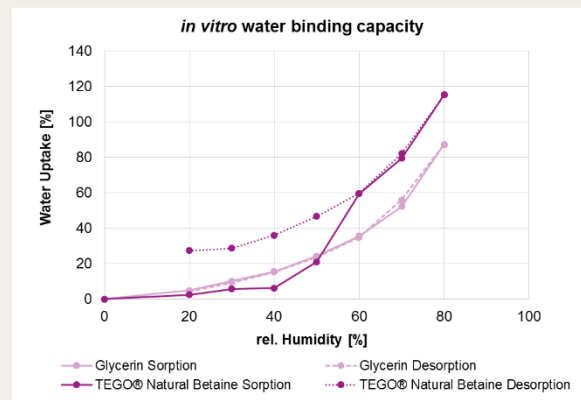


Fig.1: Water binding capacity with sorption and desorption graphs.

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).

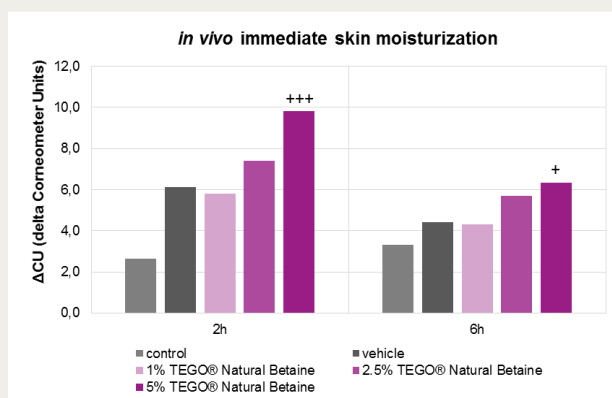


Fig.2: Immediate moisturization at 2 and 6 hours
(+p < 0.05, +++p < 0.001).

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

2.5–5.0% TEGO® Natural Betaine

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 of chemicals
- protective measures for storage and handling
- measures in case of accidents and fire
- toxicological and ecotoxicological effects

is given in our safety data sheets.

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This information and all further technical advice are based on our present knowledge and experience. However, it implies no liability or other legal responsibility on our part, including with regard to existing third party intellectual property rights, especially patent rights. In particular, no warranty, whether express or implied, or guarantee of product properties in the legal sense is intended or implied. We reserve the right to make any changes according to technological progress or further developments. The customer is not released from the obligation to conduct careful inspection and testing of incoming goods. Performance of the product described herein should be verified by testing, which should be carried out only by qualified experts in the sole responsibility of a customer. Reference to trade names used by other companies is neither a recommendation, nor does it imply that similar products could not be used.

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Product Specification

Material TEGO NATURAL BETAINE
Spec.Code K00 STANDARD

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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			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.

TEGO® Natural Betaine

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

TEGO® Natural Betaine is in full compliance with current Cosmetic Regulation (EC) No 1223/2009.

1.2.1 Raw Material Category/Function

Cosmetic Active Ingredient based on Amino Acid Derivatives

1.2.2 INCI Declaration

Betaine

1.2.3 Composition

Components (INCI EU/US)	Source	Percentage [%]
Betaine	Vegetable	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 (e.g. Antioxidants, Preservatives)

INCI	CAS No. / REACH Reg. No.	EINECS / EC No.	Content	Function
no additives				

Unless mentioned in our PDR under section 2.2 (By-Products/ Impurities) or 2.3 (CMR Substances), no components which are listed in Annex II of the current Cosmetic Regulation (EC) No 1223/2009 are added to and are not to be expected in the above mentioned product, due to the raw materials and the production process.

2. Production Process

2.1 General Information on the Production Process

The product is obtained by extraction from sugar beet molasses.

Description and Origin of plant based materials:
 Sugar beet (*Beta vulgaris*)

Irradiation: TEGO® Natural Betaine was not irradiated with γ -rays.

TEGO® Natural Betaine 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: TEGO® Natural Betaine is not based on raw materials from species listed in CITES appendices.

GMO Status:

The item contains moieties from sugar beet (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

Below listed compound are technically unavoidable by-products or traces of unremovable impurities (e.g. residual solvents). They are not added intentionally.

Information on potentially occurring by - products, impurities and selected substances of general interest known to be CMR are summarized in section "2.3 CMR Substances".

Known by-products and product specific impurities*

Description	Expected values
Residual water content	NMT 15 %

Additional standard parameters**

Description	Expected values
Sum of heavy metals (as Pb)	NMT 20 ppm
As, Cd, Co, Cr, Cu, Hg, Ni, Pb, Sb	each NMT 1 ppm
Residual organic solvents	not applicable
VOC	NMT 3 % according to SR (Swiss Right) 814.018
Pesticides	meets the valid regulatory requirements for limits on agricultural pesticides
Latex	not to be expected in the product due to the raw materials used and the production process

* monitored by dedicated product analysis or statistical testing

** monitored by statistical testing and/or spot checks

2.3 CMR Substances

According to Cosmetic Regulation (EC) No 1223/2009 the use of substances classified as CMR (Carcinogenic, Mutagenic or Reprotoxic) 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 (EO)	75-21-8	no	
Propylene oxide (PO)	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 sulfate	77-78-1	no	
Dioxane (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 Allergens listed on Annex II of Regulation (EU) No 1169/2011

None of these substances have been intentionally added to our cosmetic raw materials.

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

TEGO® Natural Betaine is manufactured in: Finland

3. Animal Testing

We hereby confirm that we have never conducted any animal tests with our product TEGO® Natural Betaine 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 TEGO® Natural Betaine 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

1080 days after production (unopened original packaging)

Store < 24 °C. Product is hygroscopic

6. Regulatory Status

6.1 HS-Code: 292390

EU-CN-Code: 29239000

6.2 Regulatory Status (Chemical Regulations)

Europe

Components Chemical Name/INCI	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

*) Any REACH registration no. referred to in this document covers the substance manufactured and/or imported into the European Community by Evonik Operations 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
Betaine	Australia	AIIC	yes	CAS No. 107-43-7
	China	IECSC	yes	CAS No. 107-43-7
	Canada	DSL	yes	CAS No. 107-43-7
	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, USA

6.2.1 Regulatory Status (Non EU - Cosmetic Regulations)

Other countries:

Component	Country	Inventory	yes / no	Remark
Betaine	China	CFDA	yes	IECIC No. 06665
	Japan	JSQI	no	JSQI specification exists (JSQI No. 523156), but compliance is not controlled
	Japan	JCIA	yes	JCIA No. 552183

7. Toxicology and Ecotoxicology

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

8. Packaging

480 kg (24 x 20 kg)

This information and all further technical advice are based on our present knowledge and experience. However, it implies no liability or other legal responsibility on our part, including with regard to existing third party intellectual property rights, especially patent rights. In particular, no warranty, whether express or implied, or guarantee of product properties in the legal sense is intended or implied. We reserve the right to make any changes according to technological progress or further developments. The customer is not released from the obligation to conduct careful inspection and testing of incoming goods. Performance of the product described herein should be verified by testing, which should be carried out only by qualified experts in the sole responsibility of a customer. Reference to trade names used by other companies is neither a recommendation, nor does it imply that similar products could not be used.