

TEGO® Natural Betaine

Product data record (PDR)

1. General information

1.1 Supplier

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1.2 Product Description

1.2.1 Raw material category Cosmetic Active Ingredient based on Amino Acid Derivatives

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				

Unless mentioned in our PDR under section 2.1 (By products) or 2.2 (CMR), 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:
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.

Residual plant based source (dominant origin of main constituents): 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 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 perfume 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 perfume 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 II of Regulation (EU) No 1169/2011

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

720 days after production 24 at room temperature (22 +/- 2 °C) or below (in unopened original packaging under clean and dry conditions). Product is hygroscopic.

5. Regulatory Status

5.1 HS-Code 292390
EU-CN-Code 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	209-684-7
		refers to the registered 107-43-7	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

7. Packaging

20 kg