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TEGO® Betain F 50

Product data record (PDR)

1. General information

1.1 Supplier

Evonik Nutrition & Care GmbH
Personal Care Business Line
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1.2 Product Description

1.2.1 Raw material category/function Surfactant

1.2.2 Ingredients according to INCI

INCI	Source	Percentage
Cocamidopropyl Betaine	vegetable / synthetic	100 %

1.2.3 Solvents, preservatives and other additives

INCI	CAS No.	EINECS / EC No.	content	Function
Water	7732-18-5	231-791-2	approx. 53.5 %	Solvent

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:
Conversion of fats/fatty acids and diamine into amidoamine, followed by reaction with chloroacetic acid to produce betaine

The product is not irradiated.

TEGO® Betain F 50 is produced in the strictest absence of any animal derived material of any type.

Residual plant based source (dominant origin of main constituents): coconut oil

CITES:
TEGO® Betain F 50 is not based on raw materials from species listed in CITES appendices.

GMO-Status:
The item does not contain moieties from rape, soy, cotton, rice, sugar beet, corn (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.

2.1 By-products/Impurities

1,4-Dioxane	not applicable
Residual organic solvents	not applicable
Dichloroacetic acid	max. 10 ppm
Monochloroacetic acid	max. 5 ppm
Pesticides	meets the valid regulatory requirements for limits on agricultural pesticides
Nitrosamines (Volatile)	not detectable
Dimethylaminopropylamine	max. 10 ppm
Amidoamine/Amid Ammonium Salts	max. 0.3 %
Total heavy metals	max. 20 ppm
As, Cd, Co, Cr, Hg, Ni, Pb, Sb	Each < 1 ppm
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

Any by-products are not added intentionally during the process and are technically unavoidable.

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 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 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/Remark
Ethylene Oxide	no	
Propylene Oxide	no	
Octamethylcyclotetrasiloxane (D4)	no	
2-Ethylhexanoic Acid	no	
n-Hexane	no	
Methyl Chloride	no	
Dimethyl Sulphate	no	
Formaldehyde	no	Formaldehyde is a ubiquitous material and may be detected in small traces in almost all natural and synthetic products. For details, a separate statement is available on request.

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.

2.5 Nanomaterial

The product is not a nanomaterial according to the Cosmetics Regulation (EC) No 1223/2009, the Commission Recommendation on the definition of nanomaterial 2011/696/EU and the French Decree No. 2012-232. For details, a separate statement is available on request.

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 (unopened original packaging)

5. Regulatory Status

5.1 HS-Code 340219
EU-CN-Code 34021900

5.2 Regulatory status (chemical regulations)

Europe

Components	REACH status	CAS No.	EINECS / EC No.
Cocamidopropyl Betaine	Reg. No. 01-2119488533-30	not assigned	931-296-8

Other countries/regions

Country		yes / no	Remark
Australia	AICS:	yes	CAS No. 61789-40-0
China	IECSC:	yes	CAS No. 97862-59-4
Canada	rev. ICL: DSL: NDSL:	yes yes	CAS No. 97862-59-4 is on the revised in-commerce list (for import of the raw material to Canada) CAS No. 61789-40-0 is on the DSL (still possible for export of Cosmetic formulations to Canada)
Taiwan	TCSI:	yes	CAS No. 97862-59-4

In the following countries the relevant authorities currently do not request 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: JCIA:	yes yes	JSQI No. 522079, but specifications not controlled JCIA No. 551186

6. Toxicology and Ecotoxicology

Refer to summary of ecotoxicological and toxicological data

7. Packaging size

LATAM 880 kg (4 x 220 kg drum)
APAC, EMEA, LATAM, NAFTA 1000 kg IBC
NAFTA 800 kg (4 x 200 kg drum)

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