

# VARISOFT BTMS

## REGISTRO DE DATOS DEL PRODUCTO

### 1. General Information

#### 1.1 Supplier

Gran Velada.S.L  
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#### 1.2 Product Description

VARISOFT is in full compliance with current Cosmetic Regulation (EC) No 1223/2009.

##### 1.2.1 Raw Material Category/Function

Cationic Surfactant with Conditioning Properties

##### 1.2.2 INCI Declaration

Distearoylethyl Dimonium Chloride; Cetearyl Alcohol

##### 1.2.3 Composition

| Components (INCI EU/US)           | Source              | Percentage [%] |
|-----------------------------------|---------------------|----------------|
| Distearoylethyl Dimonium Chloride | Vegetable/synthetic | approx. 65     |
| Cetearyl Alcohol                  | Vegetable           | approx. 35     |

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 mixing the compounds.

Description and Origin of plant based materials:

Palm (*Elaeis guineensis*), rape/canola (*Brassica*)

Irradiation: VARISOFT was not irradiated with  $\gamma$ -rays.

VARISOFT 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: VARISOFT is not based on raw materials from species listed in CITES appendices.

GMO Status:

The item contains moieties from rape seed (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.

Potentially occurring by – products are not added intentionally. Impurities e.g. residual solvents are technically unavoidable.

### 2.2 By-Product/Impurities

| Description                    | Expected Values   |
|--------------------------------|---|
| Residual organic solvents      | <del>not applicable</del>   |
| Free amines                    | 1.2 % (average)   |
| Nitrosamines                   | <del>not determined</del>   |
| Monochloroacetic Acid          | <del>not applicable</del>   |
| Dichloroacetic acid            | not applicable  |
| Pesticides                     | meets the valid regulatory requirements for limits on agricultural pesticides                         |
| Total heavy metals             | <del>max. 20 ppm</del>  |
| 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 <del>the production process</del> |
| VOC                            | < 3 % according to SR (Swiss Right) 814.018   |

## 2.3 CMR Substances

According to Cosmetic Regulation (EC) No 1223/2009 the use of substances classified as CMR (**C**arcinogenic, **M**utagenic or **R**eprotoxic) 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                    | 75-21-8  | no                |  |
| Propylene Oxide                   | 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  | yes               | < 50 ppm   |
| Dimethyl Sulphate                 | 77-78-1  | no                |  |
| 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. |

## 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 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.

## 2.6 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

VARISOFT is manufactured in: Germany

### 3. Animal Testing

We hereby confirm that we have never conducted any animal tests with our product VARISOFT® EQ 65 MB 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 VARISOFT® EQ 65 MB 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

720 days after production (unopened original packaging)

### 6. Regulatory Status

6.1 **HS-Code:** 382499

**EU-CN-Code:** 38249993

#### 6.2 Regulatory Status (Chemical Regulations)

Europe

| Components Chemical Name/INCI  | REACH Status*                               | CAS No.              | EINECS / EC No.      |
|--|---|----------------------|----------------------|
| Reaction mass of Ethanaminium, 2-hydroxy-N,N-dimethyl-N-[2-[(1-oxooctadecyl)oxy]ethyl]-, chloride and Ethanaminium, N,N-dimethyl-2-[(1-oxohexadecyl)oxy]-N-[2-[(1-oxooctadecyl)oxy]ethyl]-, chloride/Distearoylethyl Dimonium Chloride | Reg No. 01-2120857134-56                    | not assigned         | 951-974-7            |
| Hexadecan-1-ol, Octadecan-1-ol/Cetearyl Alcohol  | Reg. No. 01-2119485905-24; 01-2119485907-20 | 36653-82-4; 112-92-5 | 253-149-0; 204-017-6 |

\*) Any REACH registration no. referred to in this document covers the substance manufactured and/or imported into the European Community by GRAN VELADA. 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  |
|-----------------------------------|-----------|--------------------|----------|---|
| Distearoylethyl Dimonium Chloride | Australia | AIIC (former AICS) | no       | Self assessment: Low Risk (based on NICNAS Public Report File No: LTD/1912) |
|                                   | China     | IECSC              | yes      |   |
|                                   | Canada    | DSL                | no       |   |
|                                   | Canada    | NDSL               | yes      |   |
|                                   | Taiwan    | TCSI               | yes      |   |
| Cetearyl Alcohol                  | Australia | AIIC (former AICS) | yes      |   |
|                                   | China     | IECSC              | yes      |   |
|                                   | Canada    | DSL                | yes      |   |
|                                   | Canada    | NDSL               | n.a.     |   |
|                                   | Taiwan    | TCSI               | yes      |   |

Distearoylethyl Dimonium Chloride was assessed based on available data for this substance and interpretation was done according the assessment criteria as published in AICIS' Industrial Chemicals (General) Rules, 2019. We emphasize that our self-assessment does not relieve the importer from any requirements (e.g. reporting obligations) stipulated by AICIS. In case that the Australian authority requests full tox reports, we can share them under CDA in case GRAN VELADA has ownership rights.

In the following countries the relevant authorities currently do not request pre-market approval for cosmetic raw materials:

Brazil, Japan, South Korea, Philippines, USA

### 6.2.1 Regulatory Status (Non EU - Cosmetic Regulations)

Other countries:

| Component                         | Country | Inventory | yes / no | Remark  |
|-----------------------------------|---------|-----------|----------|---|
| Distearoylethyl Dimonium Chloride | China   | CFDA      | yes      | IECIC No. 02245   |
|                                   | Japan   | JSQI      | no       |   |
|                                   | Japan   | JCIA      | yes      | JCIA No. 557950   |
| Cetearyl Alcohol                  | China   | CFDA      | yes      | IECIC No. 03580   |
|                                   | Japan   | JSQI      | no       | JSQI No. 101316 exists, but specifications not controlled |
|                                   | Japan   | JCIA      | yes      | JCIA No. 551660   |

## 7. Toxicology and Ecotoxicology

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