Edition 5
28 February 2022

# Verstatil® SL

# 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

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

#### 1.2.1 Raw Material Category/Function

Preservative

#### 1.2.2 INCI Declaration

Aqua; Sodium Levulinate; Potassium Sorbate

#### 1.2.3 Composition

| Components (INCI EU/US) | Source | Percentage [%] |
|---|---|---|
| Aqua/Water | | 63 – 69 |
| Sodium Levulinate | Vegetable | 22 – 26 |
| Potassium Sorbate | Synthetic | 9 – 11 |

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

Verstatil® SL is obtained by mixing of components and pH–adjustment.

Description and Origin of plant based materials:
Corn (Zea mays)

Irradiation: Verstatil® SL was not irradiated with γ-rays.

Verstatil® SL 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: Verstatil® SL is not based on raw materials from species listed in CITES appendices.

GMO Status:
The item contains moieties from 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.

### 2.2 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 occuring 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 |
|---|---|
| none | |

**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 (**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 (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

Verstatil® SL is manufactured in: Germany

## 3. Animal Testing

We hereby confirm that we have never conducted any animal tests with our product Verstatil® SL 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 Verstatil® SL 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: 380894

**EU-CN-Code:** 38089490

### 6.2 Regulatory Status (Chemical Regulations)

Europe

| Components Chemical Name/INCI | REACH Status* | CAS No. | EINECS / EC No. |
|---|---|---|---|
| 4-oxovaleric acid, sodium salt/ Sodium l evulinate | Reg No. 01-2120764150-64 | 19856-23-6 | 243-378-4 |
| Potassium Sorbate | Reg No. 01-2119950315-41 | 24634-61-5 | 246-376-1 |
| Water/Aqua | Exempt; Annex IV | 7732-18-5 | 231-791-2 |

*) 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 |
|---|---|---|---|---|
| Sodium Levulinate | Australia | AIIC | no | but authorized because sodium levulinate is introduced in a solution |
| | China | IECSC | yes | |
| | Canada | DSL | yes | |
| | Canada | NDSL | n.a. | |
| | Taiwan | TCSI | yes | |
| Potassium Sorbate | Australia | AIIC | yes | |
| | China | IECSC | yes | |
| | Canada | DSL | yes | |
| | 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 |
|---|---|---|---|---|
| Sodium Levulinate | China | CFDA | yes | IECIC No. 07759 |
| | Japan | JSQI | no | |
| | Japan | JCIA | yes | JCIA No. 557441 |
| Potassium Sorbate | China | CFDA | yes | IECIC No. 05911 |
| | Japan | JSQI | no | JSQI specification exists (JSQI No. 105522), but compliance is not controlled |
| | Japan | JCIA | yes | JCIA No. 551753 |

**Known restrictions:**
**Europe:**
**Potassium Sorbat**e is listed in Annex V (No.4) of the Cosmetic Regulation (EC) No 1223/2009: Max concentration in ready for use preparation: 0.6 % of the acid.
**Japan:**
**Sorbic acid and its salts** are restricted according to Annex III of the Japanese Standard for Cosmetics (2000/2001) in all kinds of cosmetic applications by max. 0.5 % (as total).

## 7. Toxicology and Ecotoxicology

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

## 8. Packaging

800 kg (32 x 25 kg can)
800 kg (4 x 200 kg drum)
1000 kg IBC

## 9. Other Information

China Raw Material Submission Code: 110853-01292-1836