

# dermofeel® SL MB

## Product Data Record (PDR)

### 1. General Information

#### 1.1 Supplier

Evonik Nutrition & Care GmbH  
Business Line Care Solutions  
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personal-care@evonik.com  
<https://www.evonik.com/personal-care>

#### 1.2 Product Description

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

##### 1.2.1 Raw Material Category/Function

Emulsifier

##### 1.2.2 INCI Declaration

Sodium Stearoyl Lactylate

##### 1.2.3 Composition

Components (INCI EU/US)	Source	Percentage [%]
Sodium Stearoyl Lactylate	Vegetable/microbial	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 (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) or 2.3 (CMR), no components which are listed in Annex II of the Cosmetic 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. Production Process

### 2.1 General Information on the Production Process

dermofeel® SL MB is obtained by esterification of vegetable stearic acid with lactic acid deriving from sugar by fermentation.

Irradiation: dermofeel® SL MB was not irradiated with  $\gamma$ -rays.

dermofeel® SL MB 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.

Description and Origin of plant based materials:

Palm (*Elaeis guineensis*), sugar cane (*Saccharum*), sugar beet (*Beta vulgaris*)

CITES: dermofeel® SL MB 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

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

Description	Expected Values
Residual organic solvents	not applicable
Free amines	not applicable
Nitrosamines	not applicable
Monochloroacetic Acid	not applicable
Dichloroacetic acid	not applicable
Pesticides	meets the valid regulatory requirements for limits on agricultural pesticides
Heavy metals (As, Cd, Hg, Pb, Ni, Cr, Sb, Co)	max. 20 ppm
As	max. 3 ppm
Pb	max. 2 ppm
Hg	max. 1 ppm
Cd	max. 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
DEG	not applicable

## 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	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	no	
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. <a href="https://intobeauty.evonik.com/">https://intobeauty.evonik.com/</a>

## 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

dermofeel® SL MB is manufactured in: Malaysia

## 3. Animal Testing

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

1080 days after production (unopened original packaging)

## 6. Regulatory Status

6.1 **HS-Code:** 291811

**EU-CN-Code:** 29181100

### 6.2 Regulatory Status (Chemical Regulations)

Europe

Components Chemical Name/INCI	REACH Status*	CAS No.	EINECS / EC No.
Esterification product of C16-C18 even numbered, saturated fatty acids and lactic acid, sodium salt/Sodium Stearoyl Lactylate	Reg. No. 01-2120779437-39	25383-99-7	246-929-7

\*) Any REACH registration no. referred to in this document covers the substance manufactured and/or imported into the European Community by Evonik Nutrition and Care 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 Stearoyl Lactylate	Australia	AICS	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, Philippines, USA

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

Other countries:

Component	Country	Inventory	yes / no	Remark
Sodium Stearoyl Lactylate	China	CFDA	yes	IECIC No. 08062
	Japan	JSQI	no	JSQI specification exists (JSQI No. 520619), but compliance is not controlled
	Japan	JCIA	yes	JCIA No. 559390

## 7. Toxicology and Ecotoxicology

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

## 8. Packaging

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.

## Product specification

**Material** DERMOFEEL SL MB  
**Spec.Code** K00 STANDARD

Inspection Characteristics	Method	Limits	Units	Z
Appearance	GM_0170_00			C
Saponification Value	GM_0030_01	190.0-230.0	mg KOH/g	X
Acid Value	GM_0010_01	75.0-95.0	mg KOH/g	X

Appearance beige powder

Report on inspection certificate: X = specific/actual value, C = unspecific value/conformity, T = not reported

This product contributes to the production of certified sustainable palm oil according to the rules set out by RSPO Supply Chain Mass Balance (MB).

RSPO Certification Number: RSPO-V-14-13553.

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.