

dermosoft® decalact deo MB

Product Data Record (PDR)

1. General Information

1.1 Supplier

Evonik Nutrition & Care GmbH
 Business Line Care Solutions
 Goldschmidtstrasse 100
 D-45127 Essen / Germany
personal-care@evonik.com
<http://www.evonik.com/personal-care>

1.2 Product Description

Dermosoft® decalact deo MB is in fully compliance with current cosmetic regulation (EC) No. 1223/2009.

1.2.1 Raw Material Category/Function Multifunctionals

1.2.2 INCI Declaration

Sodium Caproyl/Lauroyl Lactylate, Triethyl Citrate, Salvia Officinalis (Sage) Oil

1.2.3 Composition

Components (INCI)	Source	Percentage %
Sodium Caproyl/Lauroyl Lactylate	Vegetable/ Microbial	68-72%
Triethyl Citrate	Vegetable/Microbial	27.5-30.5%
Salvia Officinalis (Sage) Oil	Vegetable	0.5 - 1.5%

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 Additives

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 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

Dermosoft® decalact deo MB is obtained by mixing of the components: the single ingredients are obtained by several manufacturing steps (saponification, fermentation & esterification) followed by purification.

Irridation: Dermosoft® decalact deo MB is not irradiated with Y-rays.

Dermosoft® decalact deo 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.

Origin of plant based materials (dominant origin of constituents): Palm (*Elaeis guineensis*), coconut (*Cocos nucifera*), sugarcane (*Saccharum*), sugar beet (*Beta vulgaris*), cassava (*Manihot esculenta*), corn (*Zea mays*) & salvia (*Salvia Officinalis*).

CITES: Dermosoft® decalact deo MB is not based on raw materials from species listed in CITES appendices.

GMO-Status:

The item contains moieties from 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.

2.2 By-Product/Impurities

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

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
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

2.3 CMR Substances

According to Cosmetic Regulation 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 Regulation (EC) No 1272/2008 in cosmetic products shall be prohibited.

Some of the CMR substances mentioned below and listed in Annex VI to Regulation

(EC) 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 Nr.	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. 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, shall be indicated in the list of ingredients in addition to the terms perfume or aroma.

Some of the substances listed in Annex III of EC 1223/2009 might be introduced to the blend as a by-product from *Salvia Officinalis* (Sage) Oil.

Following the requirements of EC Regulation 1223/ 2009 § 19 (1; g) these substances do not have to be included in the INCI list if our product dermosoft® decalact deo is employed, according to our recommendation, in a concentration from 0.3 – 1.0 %.

An analytical proof for the absence of traces of those substances is not performed in our cosmetic blend.

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 Cosmetics 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

dermosoft® decalact deo MB is manufactured in: Germany

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

1080 days after production (unopened original packaging)

5. Regulatory Status

5.1 HS-Code:	382499
EU-CN-Code	38249992

5.2 Regulatory Status (Chemical Regulations)

Europe

Components	REACH status	CAS No.	EINECS / EC No.
Fatty acids, C10-12, esters with polylactic acid, sodium salts / Sodium Caproyl/Lauroyl Lactylate	Reg. No. 01-2119957863-23	1312021-45-6	Not applicable: New substance ECHA Inventory list no. 700-937-1
Triethyl Citrate	Reg. No. 01-2119955435-32	77-93-0	201-070-7
Sage, Salvia officinalis, ext. / Salvia Officinalis (Sage) Oil	Reg. No. 01-2120769905-38	84082-79-1	282-025-9

Other countries

Country		yes / no	Remark
Sodium Caproyl/Lauroyl Lactylate			
Australia	AICS:	no	
China	IECSC:	no	
Canada	DSL: NDSL:	no no	
Taiwan	TCSI:	no	
Triethyl Citrate			
Australia	AICS:	yes	
China	IECSC:	yes	
Canada	DSL: NDSL:	Yes n.a.	
Taiwan	TCSI:	yes	
Salvia Officinalis (Sage) Oil			
Australia	AICS:	yes	
China	IECSC:	yes	
Canada	DSL: NDSL:	yes n.a.	
Taiwan	TCSI:	yes	

5.2.1 Regulatory Status (Cosmetic Regulations)

Country		yes / no	Remark
Sodium Caproyl/Lauroyl Lactylate			
China	CFDA:	no	
Japan	JSQI: JCIA:	no yes	JCIA No. 564158
Triethyl Citrate			
China	CFDA:	yes	IECIC No.04859
Japan	JSQI: JCIA:	no yes	JSQI (51) Standard "108905" exists, but compliance is not controlled JCIA No. 551073
Salvia Officinalis (Sage) Oil			
China	CFDA:	yes	IECIC No.07492
Japan	JSQI: JCIA:	no yes	JSQI (51) Standard "523140" (Sage Oil) exists, but compliance is not controlled JCIA No. 556142

6. Toxicology and Ecotoxicology

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

7. Packaging

10 kg can

25 kg can

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