Edition 5
06 December 2021

dermosoft® Pentiol eco

Product Data Record (PDR)

1. General Information

1.1 Supplier

Evonik Operations GmbH
Division Nutrition & Care
Business Line Care Solutions
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https://www.evonik.com/personal-care

1.2 Product Description

dermosoft® Pentiol eco is in full compliance with current Cosmetic Regulation (EC) No 1223/2009.

1.2.1 Raw Material Category/Function

Multifunctionals

1.2.2 INCI Declaration

Pentylene Glycol

1.2.3 Composition

Components (INCI EU/US)	Source	Percentage [%]
Pentylene Glycol	Vegetable	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 (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

Dermosoft® Pentiol eco is obtained by dehydration of pentoses and subsequent hydrogenation of the resulting intermediate.

Description and Origin of plant based materials:
Sugar cane (Saccharum)

Irradiation: dermosoft® Pentiol eco was not irradiated with γ-rays.

dermosoft® Pentiol eco 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: dermosoft® Pentiol eco is not based on raw materials from species listed in CITES appendices.

GMO Status:
The item does not contain moieties from GMO risk crops (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	
Furfural	98-01-1	no	NMT 10 ppm
Furfuryl alcohol (FA)	98-00-0	no	NMT 10 ppm
Tetrahydrofurfuryl alcohol (THFA)	97-99-4	no	NMT 10 ppm
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

dermosoft® Pentiol eco is manufactured in: USA

3. Animal Testing

We hereby confirm that we have never conducted any animal tests with our product dermosoft® Pentiol eco 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 dermosoft® Pentiol eco 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: 290539

EU-CN-Code: 29053995

6.2 Regulatory Status (Chemical Regulations)

Europe

Components Chemical Name/INCI	REACH Status*	CAS No.	EINECS / EC No.
Pentane-1,2-diol/Pentylene Glycol	Reg. No. 01-2119491291-39	5343-92-0	226-285-3

*) 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
Pentylene Glycol	Australia	AIIC	yes	
	China	IECSC	yes	
	Canada	DSL	no	but listed on Revised In Commerce List (R-ICL) by CAS No. 5343-92-0
	Canada	NDSL	yes	
	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
Pentylene Glycol	China	CFDA	yes	IECIC No. 00005
	Japan	JSQI	no	JSQI specification exists (JSQI No. 532168), but compliance is not controlled
	Japan	JCIA	yes	JCIA No. 552223

7. Toxicology and Ecotoxicology

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

8. Packaging

5 kg can
800 kg (32 x 25 kg can)