

# **Product specification**

MaterialDERMOFEEL PA-12Spec.CodeK00 STANDARD

Inspection Characteristics	Method	Limits	Units	Z
Appearance		OK		С
Loss on drying		15.00-36.00	%	X
pH-Value 1 %		9.0-12.0	pH-Value	Х
Chloride		< = 0.02	%	С
Sulphate		< = 0.02	%	С
Calcium content		< = 0.02	%	С
Arsenoxide As2O3		< = 0.0003	%	С
Heavy Metals		< = 0.003	%	С
Total Phosphorus content		13.80-25.00	%	Х
Inorganic Phosphorus		0.0000-0.0200	%	Χ
Appearance	white powder or crystals			

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

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.

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# dermofeel® PA-12

# **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

Dermofeel® PA-12 is in full compliance with the current Cosmetic Regulation (EC) No. 1223/2009.

## 1.2.1 Raw Material Category/Function Chelating Agent

#### 1.2.2 INCI Declaration

Sodium Phytate

#### 1.2.3 Composition

Components (INCI)	Source	Percentage
Sodium Phytate	Vegetable	64-85 %

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
Water	7732-18-5/	231-791-2	15-36%	Residual solvent
	exempt Annex			
	IV, 1907/2006			

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

dermofeel® PA-12 is obtained by extraction from corn with diluted mineral acid subsequently neutralized.

Irridation: dermofeel® PA-12 was not irradiated with y-rays.

dermofeel® PA-12 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.

Residual plant based source (dominant origin of main constituents): corn

CITES: dermofeel® PA-12 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

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. <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, 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 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

Dermofeel® PA-12 is manufactured in China.

# 3. Animal Testing

We hereby confirm that we have never conducted any animal tests with our product dermofeel® PA-12 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® PA-12 is in full compliance with Cosmetic Regulation (EC) No. 1223/2009.

# 4. Microbiological Status

Total Viable Count max. 100 cfu/g

Pathogens\* absent/g

# 5. Shelf Life / Storage Conditions

1080 days after production (unopened original packaging)

Please note:

The product is very hygroscopic. Keep it the container sealed and store it in a dry place.

# 6. Regulatory Status

**6.1 HS-Code**: 291990

**EU-CN-Code** 29199000

# 6.2 Regulatory Status (Chemical Regulations)

Europe

Components	REACH status	CAS No.	EINECS / EC No.
Esters of sodium hydrogen phosphate with myo- Inositol, plant-derived / Sodium Phytate	Reg. No. 01-2120795381-48	17211-15-3	241-253-9

<sup>\*</sup>Pathogens are: Enterobacteria, Pseudomonas, Enterococci, Candida albicans, Staphylococci



## Other Countries/Regions

Country		yes / no	Remark
Sodium Phy	/tate		
Australia	AICS:	no	But CAS 14306-25-3 (Myo-Inositol, hexakis(dihydrogen phosphate), sodium salt) is listed
China	IECSC:	no	But CAS 14306-25-3 (Myo-Inositol, hexakis(dihydrogen phosphate), sodium salt) is listed
Canada	DSL: NDSL:	no no	
Taiwan	TCSI:	no	But CAS 14306-25-3 (Myo-Inositol, 1,2,3,4,5,6-hexakis(dihydrogen phosphate), sodium salt) is listed

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 (Cosmetic Regulations)

Country		yes / no	Remark
Sodium Ph	nytate	l .	
China	CFDA:	yes	IECIC No.08594
Japan	JSQI: JCIA:	No yes	JCIA No. 559718

# 7. Toxicology and Ecotoxicology

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

# 8. Packaging

20 kg cardboard drum, wooden cover

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