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HyaCare® 50

Product data record (PDR)

1. General information

1.1 Supplier

Evonik Nutrition & Care GmbH
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1.2 Product Description

1.2.1 Raw material category: Cosmetic Active Ingredient based on Hyaluronic Acid

1.2.2 Ingredients according to INCI

Hydrolyzed Hyaluronic acid

1.2.3 Composition

Components	Source	Ratio
Hydrolyzed Hyaluronic acid	vegetable / microbial	100 %

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 Solvents, preservatives and other additives

	CAS No.	EINECS / EC No.	content	Function
no additives				

Unless mentioned in our PDR under section 2.1 (By products) or 2.2 (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. Information on production process

General description of production process:
HyaCare® 50 is produced using Biotechnology (microbial synthesis, water based recovery process, concentration, purification, controlled hydrolysis to a MW range of 20 – 70 kDa, spray drying to a fine powder).

Hyaluronic acid (HA) is produced by fermentation. The production host is a well known strain of Bacillus subtilis with a long history of safe use in industry. The production strain was constructed by insertion of the HA synthetic genes from a strain of Streptococcus equisimilis. The production organism is genetically modified. Fermentation and recovery, including the use of the production strain, takes place under the EU directive for contained use.

HyaCare® 50 is produced in the strictest absence of any animal derived material of any type.

HyaCare® 50 final product is free of genetically modified organism (GMO).

2.1 By products

		method
Residual solvents	not applicable	
Free amines	not applicable	Chromatography
Nitrosamines	not applicable	
Monochloroacetic acid	not applicable	Chromatography
Dichloroacetic acid	not applicable	Chromatography
1,4-Dioxane	not applicable	
Pesticides	meets the valid regulatory requirements for limits on agricultural pesticides	
Heavy metals (Cu; Pb; Pt; Pd; Hg; As; Cd; Ni)	max. 20 ppm	AAS-ICP
As	max. 2 ppm	AAS-ICP
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	

2.2 CMR (Carcinogenic, Mutagenic or Reprotoxic)

The use in cosmetic products of substances classified as CMR substances, of category 1A or 1B or 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited.

Further Information:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF

Some of the CMR substances mentioned below and listed in Annex VI to Regulation (EC) No 1272/2008 are used as starting materials or solvents for the production of our cosmetic raw materials and may require reporting under California Proposition 65 or the Safe Cosmetics Act, SB 484.

The presence of these prohibited substances has to be seen as non-intended. It is stemming from impurities of the starting materials or the manufacturing process which is technically unavoidable in good manufacturing practice.

CMR substance	Starting material	max. concentration	method
Ethylene Oxide	no		
Propylene Oxide	no		
Octamethylcyclotetrasiloxane (D4)	no		
2-Ethylhexanoic Acid	no		
n-Hexane	no		
Methyl Chloride	no		
Dimethyl Sulphate	no		

2.3 "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.

The cosmetic raw materials and the cosmetic actives supplied by Evonik Personal Care are manufactured without the use of perfumes and fragrances. An analytical proof for the absence in traces of the substances to be mentioned in addition to the terms perfume or aroma is not performed in cosmetic raw materials, which are chemically produced.

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.

2.4 Food Ingredients listed in Annex IIIa of Commission Directive 2007/68/EC.

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.

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 at 4 – 10 °C (in unopened original packaging under clean and dry conditions). Product is hydroscopic. Transport and short-term storage (up to 1 week) at RT (22 +/-2 °C) possible.

5. Regulatory Status

5.1 HS-Code 391390
EU-CN-Code 39139000

5.2 Regulatory status (chemical regulations)

Europe

Components	REACH status	CAS No.	EINECS / EC No.
Hydrolyzed Hyaluronic acid	Polymer	9004-61-9	232-678-0

Other countries

Country		yes / no	Remark
Australia	AICS:	yes	
China	IECSC:	yes	
Canada	DSL: NDSL:	yes	
Taiwan	TCSI:	yes	

In the following countries the relevant authorities currently do not require pre-market approval for cosmetic raw materials:

Brazil, Japan, South Korea, Philippines, USA

5.2.1 Regulatory status (cosmetic regulation)

Country		yes / no	Remark
China	CFDA:	yes	
Japan	JSQI:	no	

6. Toxicology and Ecotoxicology

Refer to summary of ecotoxicological and toxicological data

7. Packaging

0.5 kg