

**93219-DEXPANTHENOL****1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.****1.1 Identification of the substance or preparation.**

Name: Dexpanthenol

Bulk code: 93219

Internal code: 405159

**1.2 Synonyms.**

(R) -panthenol ; D- panthenol ; D- pantothenyl alcohol; dexpanthenol ; pantothenoyl ; provitamin B<sub>5</sub>

**2. DESCRIPTION**

Appearance: clear viscous liquid

Color: colorless to light yellow

Odor: practically odorless

Origin: synthetic, petroleum derived

Geographical origin: Switzerland

**3. COMPOSITION/INFORMATION OF THE COMPONENTS.**

Ingredients: Dexpanthenol 100%

Formula: C<sub>9</sub>H<sub>19</sub>NO<sub>4</sub>

CAS: 81-13-0

EINECS: 201-327-3

Molecular weight: 205.25 g/mol

INCI: Panthenol

**Method of production:** Dexpanthenol is produced synthetically by condensation of d - pantolactone with aminopropanol .

**4. PHYSICAL-CHEMICAL DATA.**

For more detailed information, please refer to the analysis bulletin.

**Solubility:** It is very soluble in water, alcohol, methanol and propylene glycol , slightly soluble in glycerol and practically insoluble in fats and oils.

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### 5. PROPERTIES/USES.

Excipient for pharmaceutical use.

Cosmetic use.

Food use.

It is an agent whose functions are as a skin and hair conditioner and as a humectant.

### 6. DOSAGE.

Cosmetic use:

- In rinse-off products (except those intended for feminine intimate hygiene): 5%
- In products that do not require rinsing (body lotion, face cream, hand cream, liquid foundation, eye shadow, mascara and deodorants): 5%
- In products that do not require rinsing ( eyeliner ): 1%
- Sun care products: 5%
- Lip care products (lipstick): 5%
- Toothpaste and mouthwashes: 4%
- Children's cosmetics: 5%

These recommendations are based on conservative safety assessments. These recommendations do not take into consideration any potential incompatibility of ingredients with the final cosmetic or other exposure scenarios. These aspects should be reviewed at formulation levels by those responsible for the final cosmetic product.

Excipient pharmaceutical use:

- No data available.

Food use:

- No data available.

### 7. OBSERVATIONS.

The product has been handled in a NON-sterile room, so the product is NOT STERILE.

The documentation corresponding to the regulatory part of the product that is available for it is the one we reflect below.

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### NUTRITIONAL INFORMATION:

The product must be labelled in accordance with Annex I of Regulation 1169/2011.

Trans fats (another naturally occurring trans fat in those of animal origin) are less than 2g per 100g of fat (Regulation (EC) 1925/2006).

The following table contains the nutritional values of the product in accordance with Regulation (EU) 1169/2011 of 25 October 2011 on the provision of food information to consumers:

Energy content total	kJ/100g	0
Energy content total	kcal/100g	0
<b>Content in:</b>		
Fat	g/100g	0
➤ thereof saturated fatty acids	g	0
➤ thereof mono-unsaturated fatty acids	g	0
➤ thereof poly-unsaturated fatty acids	g	0
Carbohydrates	g/100g	0
➤ thereof sugars	g	0
➤ thereof polyols	g	0
➤ thereof starch	g	0
Fibre	g/100g	0
Protein	g/100g	0
Salt (Sodium content x 2.5)	g/100g	0

### ALLERGENS:

#### - Food allergens:

Product allergen labelling (Reg (EU) 1169/2011* Annex II)	Yes	No	Comments
Cereals containing gluten (wheat, rye, barley, oats, spelt, kamut (khorasan) or their hybridised strains) and products thereof		X	
Crustaceans and products thereof		X	
Eggs and products thereof		X	
Fish and products thereof		X	
Peanuts and products thereof		X	
Soybeans and products thereof		X	
Milk and products thereof (incl. lactose)		X	
Nuts (almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia/Queensland nuts) and products thereof		X	
Celery and products thereof		X	
Mustard and products thereof		X	
Sesame seeds and products thereof		X	
Sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10mg/litre expressed as SO <sub>2</sub> in the product intended for the ultimate consumer		X	
Lupins and products thereof		X	
Molluscs (gastropods, bivalves, cephalopods) and products thereof		X	
Allergen labelling required		X	
Allergen declaration	X		
Allergen labelling/policy statement	X		
General policy on allergen cross contamination	X		
<b>Other sensitizers and constituents</b>	<b>Yes</b>	<b>No</b>	<b>Comments</b>
Maize and products thereof		X	
Sugar (sucrose)		X	
Benzoates		X	
BHA/BHT		X	
<b>Other sensitizers and constituents</b>	<b>Yes</b>	<b>No</b>	<b>Comments</b>
Cinnamon, cocoa, vanilla, chicken, yeast, legumes (other than peanut), pulses, coriander, umbelliferae, flavour (any artificial/natural), aspartame, carrot, buckwheat, glutamate (% if naturally occurring), chestnuts, pine nut, coconut <sup>3</sup>		X	

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### STORAGE:

Store at room temperature, in a cool, dry place, protected from light and with the container tightly closed, away from sources of heat and humidity.

It may crystallize with prolonged storage.

It is fairly stable to air and light. It is hygroscopic and heat sensitive; heating above 70 °C may cause racemization . However, it can be heated to 40 °C for short periods in order to improve fluidity.

### SHELF LIFE:

3 years. For more detailed information, please consult the analysis bulletin.

### LEGAL REQUIREMENTS:

The product complies with:

- Regulation (EC) 852/2004 and 853/2004 on food hygiene regulations.
- Regulation (EC) 178/2002 and 931/2011 on traceability of food ingredients.
- Regulation (EC) 1169/2011 on consumer information.

### BSE/TSE:

The product is not derived from animal or human products, and no animal or human products are used during its manufacture.

The product is outside the scope of Regulation (EC) No 999/2001.

### GMO:

Due to the manufacturing process, the product does not contain GMO-DNA.

The product does not fall within the scope of Regulation (EC) 1829/2003 or Regulation (EC) 1830/2003.

The product does not require GMO labeling as defined in the previous regulations.

### CMR:

This product does not contain intentionally added substances classified and listed as CMR in Annexes II to VI under Regulation (EC) 1223/2009 or in Annex VI under Regulation (EC) 1272/2008.

The product complies with Article 17 of Regulation (EC) No 1223/2009<sup>1</sup> on traces of prohibited substances which are technically unavoidable resulting from good manufacturing practices and do not cause harm to human health when the product is applied under normal or reasonably foreseeable conditions of use.

### SVHC:

Based on the composition of the product and the manufacturing process, the product does not contain any of the substances listed by ECHA in concentrations greater than 0.1%.

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### NANOMATERIALS:

The product does not contain nanomaterials as defined in Regulation (EC) 1223/2009, Article 2(k).

The product does not contain any engineered nanomaterials as defined in Article 2.1 (h) of Regulation 1169/2011.

### MICROPLASTICS:

According to Commission Regulation (EU) 2023/2055 of 25 September, the product is outside the scope of the Regulation since Dexpanthenol is not considered a polymer according to the regulations described.

### VOC:

The product does not contain VOC substances according to the List of the Swiss Regulation on the Regulation of VOC content.

### IRRADIATION:

The product has not been treated with irradiation or ionisation in accordance with Directives 1999/2/EC and 1999/3/EC.

### ETHYLENE OXIDE:

The manufacturer does not use ethylene oxide for sterilization or any other purpose in manufacturing facilities, in storage or in distribution centers. The product complies with Commission Regulation (EC) 396/2005 and (EU) 231/2012 and their amendments.

### PESTICIDES:

The product is not expected to contain pesticides as specified in the Pharmacopoeia and in (EC) No 396/2005. Furthermore, the product does not contain ingredients of plant origin.

### RESIDUAL SOLVENTS:

Dexpanthenol complies with :

- ICH Guidelines for Residual Solvents Q3C (R8)
- Chemical Tests <467> USP/NF: Residual Solvent Limits
- General Chapter 5.4 <Residual Solvents> and Ph Limit Test 2.4.24. Eur  
:<Identification and control of residual solvents>

Only class 2 solvents such as Dichloromethane (max. 50 ppm) and Methanol (max. 200 ppm) are likely to be present, always below the limits set by the ICH.

### CONTAMINANTS/IMPURITIES:

Due to the manufacturing process and as a technically unavoidable substance derived from it, the product may contain aminopropanol and other amino compounds in quantities less than 0.5%.

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The following substances are not expected to be present: ethanol and denatured alcohol, formaldehyde and formaldehyde releasers, acetaldehyde, phthalates , glycol ethers, 1,4-Dioxane, free amines, nitrosamines , acrylamide, monomer residues, dioxins, PCBs and PAHs.

The product does not contain any added oils or fats, whole milk or dairy products including butterfats, eggs or derivatives, cocoa butter or derivatives, or coconut oil, therefore it does not fall within the scope of Commission Regulation (EU) 2023/915 on maximum levels for certain contaminants in foodstuffs. The manufacturer also has procedures in place to prevent and control potential contamination with dioxins, dioxin-like PCBs and non-dioxin-like PCBs, PAHs, mycotoxins , 3-MCDP/E and glycidyl esters .

The product complies with the relevant European legislation on pyrroizilidine alkaloids . Melamine is not intentionally added to the product, nor is melamine used during the manufacturing process or in the facility.

The product complies with Regulation (EU) 2017/2158 for the presence of acrylamide.

### HEAVY METALS:

There are appropriate procedures to prevent and control heavy metal contamination. Regulation (EU) 2023/915 repealing Regulation (EC) 1881/2006 sets maximum levels for certain contaminants in foods and food supplements, stipulating, among others, maximum levels for certain heavy metals.

The following specifications are met:

Heavy metals max 10ppm

Arsenium max 1.0ppm

Lead max 1.0ppm

Mercury max 0.1ppm

Cadmium max 0.5pp,

Nickel max 2.0ppm

Antimony max 2.0ppm

Procedures are based on relevant quality standards and/or good manufacturing practices (GMP), including hazard analysis and critical control points (HACCP).

### CALIFORNIA PROPOSITION 65:

Based on the manufacturing process, some trace amounts of impurities listed in California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986 and Proposition 65 List dated January 27, 2017) may be present in chemicals used in the manufacturing process. These will be below the maximum limits set out below:

Dichloromethane  $\leq$  50 ppm

Methanol  $\leq$  200 ppm

Cadmium  $\leq$  0.5 ppm

Lead  $\leq$  1.0 ppm

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Arsenic  $\leq 1.0$  ppm

Mercury  $\leq 0.1$  ppm

Nickel  $\leq 2.0$  ppm

Inclusion rates may vary in finished consumer products due to the impact of other ingredients in the final formulation. Consider the reference values above when calculating consumer exposure in the commercially available product.

### ALLERGENS:

- **Cosmetic allergens/prohibited substances:** The product does not contain fragrance allergens as defined in Regulation 1223/2009 and its amendments and these are not intentionally added during the manufacturing process and are therefore not expected to be present in the final product. Furthermore, none of the substances listed in Annexes II, III, IV, V, VI of the Cosmetics Regulation 1223/2009 (EC) are expected to be present.

### HALAL:

Halal certified .

### KOSHER:

Kosher certified .

### VEGAN/VEGETARIAN:

The manufacturer complies with applicable laws and regulations and avoids animal testing wherever possible. The manufacturer has been active for many years in reducing the use of animal testing, by using proven alternative testing methods where available and accepted and only uses animal testing if requested by government legal bodies to comply with legal obligations.

The manufacturer does not accept any responsibility for the product meeting the vegan requirements defined by different

NGO. The information relates to the production process, raw materials used in this process and the possible use of animals in toxicological tests.

Dexpantenol is manufactured using conventional processes and does not contain, to our knowledge, any intentionally added animal products, by-products or animal-derived materials .

The product is suitable for vegan, vegetarian use.

### PROHIBITED SUBSTANCES:

The manufacturer does not use substances that appear on the WADA prohibited substances list.

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### TESTED ON ANIMALS:

The product has not been tested on animals for cosmetic purposes by or on behalf of the manufacturer after September 2004, in accordance with the requirements of Regulation (EC) No 1223/2009 and therefore complies with Article 18.

### ISO 16128:

These results are in accordance with both the definitions and calculations of the ISO 16128 standard (with and without water):

Calculation with formulation water				Calculation without formulation water			
Natural origin index	Natural index	Organic origin index	Organic index	Natural origin index	Natural index	Organic origin index	Organic index
0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

\* ISO 16128-1:2016, ISO 16128-2:2017, and subsequent amendments.

The values for single molecules are determined by renewable carbon content method.

### RSPO:

The product does not contain palm oil or derivatives.

### REGULATORY STATUS:

Country/region <sup>1</sup>	Chemical Inventory	Chemical Registration status based on the listing of individual ingredients in inventory and volume exemption applying (Y/N/R/E)	Cosmetic <sup>1</sup> (Y/N) Note: Claims on finished cosmetic products must comply with national cosmetic legislation
Andean	No inventory	No inventory	Y
ASEAN	No inventory	No inventory	Y
Australia	AICS	Y	Y (see chemical)
Canada	DSL NDSL ICL	Y - -	Y (see chemical)
China	IECSC	Y	See separate statement
Europe	EINECS/ELINCS REACH	Y	Y
Japan	ENCS (CSCL)	E	Y D-Panthenol: • Leave-on products: max. 3.0% • Rinse-off products: no upper limit For products which can be applied on mucous membrane (leave-on and rinse-off): max. 0.30%
Korea	KECI (TCCA)	E	Y
Mercosur	No inventory	No inventory	Y
Mexico	INSQ	Inventory is not supported by legal framework	Y Panthenol: For all type of cosmetic products: max. 5.0%
New Zealand	NZIoC	Y	Y
Philippines	PICCS	E	Y
Switzerland	EINECS/ELINCS	Y	Y
Taiwan	NECI	Y	Y
USA	TSCA	E	Y Panthenol: CIR: safe as used, see CIR report

<sup>1</sup> above product can be freely imported and sold as cosmetic ingredient also into further countries as e.g. Algeria, Bahrain, Brunei Darussalam, Egypt, Morocco, the Russian Federation, Tunisia, Turkey, the United Arab Emirates, as long as the safe use is warranted and the products do comply with the legal requirements as laid down in the Regulation on Cosmetic Products (EC) No. 1223/2009



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### Legend:

#### Chemical legislation

Yes (Y): The product contains only substances that are included in the respective chemical inventory, that have been notified by the manufacturer as a new chemical substance or that are exempt from chemical notification (e.g. naturally occurring).

No (N): The product contains at least one substance that is not listed, not notified or not exempt (does not comply with the respective chemical inventory)

Restricted (R): The product contains at least one substance not listed, not notified or not exempted from the respective chemical notification, but can be imported into the respective country under volume exemption (e.g. Australia, Canada, Europe, Switzerland).

Exempt (E): under specific exemption that applies to cosmetic ingredients (e.g. US, Japan)

#### Cosmetic Regulations

Yes (Y): Product free of sale as a cosmetic ingredient for the recommended application and level of use. If there are any conditions of use for the active substance, these must be mentioned.

No (N): Product not suitable for sale in the respective country (contains at least one substance not permitted in cosmetics in the respective country).

### CSAR:

Submission code : 002292-00666-4838

### EUDR:

The product falls outside the scope of Regulation (EU) 2023/1115 (EUDR) on deforestation.

### REACH

01-2119953737-24-0000