

**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; pantothenoil; provitamin B<sub>5</sub>**2. DESCRIPTION**

Appearance: Clear, viscous liquid.

Colour: Colourless to light yellow.

Odour: Practically odourless.

Origin: Synthetic, derived from petroleum.

**3. COMPOSITION/INFORMATION ON COMPONENTS.**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 made synthetically by condensing d-pantolactone with aminopropanol.**4. PHYSICO-CHEMICAL DATA.**

For more information, see the analysis report.

**Solubility:** It is highly soluble in water, alcohol, methanol and propylene glycol, slightly soluble in glycerol and practically insoluble in fat and oil.**5. PROPERTIES/USES.**

Excipient for pharmaceutical use.

Cosmetic use.

## 93219-DEXPANTHENOL

In an agent that acts as a skin or hair conditioner or a moisturiser.

### 6. DOSAGE.

- In rinsing products (except those designed for intimate female hygiene): 5%
- In products that do not require rinsing (body lotion, face cream, hand cream, liquid base, eye shadow, mask and deodorants): 5%
- In products that do not require rinsing (eyeliner): 1%
- Suncare products: 5%
- Lip care products (lipstick): 5%
- Children's cosmetics: 5%

### 7. REMARKS.

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

### **STORAGE:**

Store at room temperature in a cool, dry place in a tightly closed container away from sunlight, heat sources and moisture.

It may crystallise during prolonged periods of storage.

It is relatively stable in air and light. It is hygroscopic and heat-sensitive; racemisation may occur if it is heated at more than 70°C. However, it may be heated at 40°C for short periods of time in order to improve its fluidity.

**The documentation available related to the product's regulatory compliance is included below.**

### **BSE/TSE:**

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

### **GMOs:**

Given its manufacturing process, the product does not contain GMO-DNA.

### **CMR:**

This product does not contain intentionally added substances classified and catalogued as CMR in Appendices II to VI of Regulation (EC) 1223/2009 or in Appendix VI of Regulation (EC) 1272/2008.

The product complies with article 17 of Regulation (EC) No. 1223/2009<sup>1</sup> on traces of prohibited substances that are technically inevitable as a result of good manufacturing practices and that do not harm human health when the product is applied in normal or reasonably anticipated conditions of use.

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**SVHC:**

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

**NANOMATERIALS:**

The product does not contain nanomaterials according to the definition given in Regulation (EC) 1223/2009, Article 2(k).

**VOCs:**

The product does not contain VOCs in accordance with the List of the Swiss Regulation on VOCs Content.

**IRRADIATION:**

The product has not undergone irradiation or ionisation.

**PESTICIDES:**

The product is not expected to contain pesticides in accordance with the provisions set out in the Pharmacopoeia and in Regulation (EC) No. 396/2005.

**RESIDUAL SOLVENTS:**

Dexpanthenol is compliant with:

- ICH guides for residual solvents Q3C (R8)
- Chemical test <467> USP/NF: Residual Solvent Limits
- General chapter 5.4 <Residual Solvents> and Limit Test 2.4.24 of Ph. 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 beneath the limits set by the ICH.

**IMPURITIES:**

Given the manufacturing process and as a technically inevitable substance arising from the same, the product may contain aminopropanol and other amino compounds in quantities less than 0.5%.

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 HAPs.

**HEAVY METALS:**

There are appropriate procedures in place to prevent and control contamination by heavy metals.

The following specifications are observed:

Heavy metals - max. 10 ppm

Arsenic - max. 1.0 ppm

Lead - max. 1.0 ppm

Mercury - max. 0.1 ppm

Cadmium - max. 0.5 ppm

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Nickel - max. 2.0 ppm

Antimony - max. 2.0 ppm

Procedures are based on the relevant quality and/or good manufacturing practice (GMP) standards, including the hazard analysis and critical control point (HACCP) standard.

### CALIFORNIA PROPOSITION 65:

Based on the manufacturing process, some traces of impurities listed in California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986 and Proposition 65's List dated 27 January 2017), which are present in the chemical products used in the manufacturing process, may be found in the product. These will be below the maximum limits set out next:

Dichloromethane  $\leq$  50 ppm

Methanol  $\leq$  200 ppm

Cadmium  $\leq$  0.5 ppm

Lead  $\leq$  1.0 ppm

Arsenic  $\leq$  1.0 ppm

Mercury  $\leq$  0.1 ppm

Nickel  $\leq$  2.0 ppm

Inclusion rates may vary in finished consumer products owing to the impact of other ingredients in the final formula. Bear in mind the aforementioned reference values when calculating consumer exposure in the commercially available product.

### ALLERGENS:

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

### HALAL:

The product is Halal certified.

### KOSHER:

The product is Kosher certified.

### TESTED ON ANIMALS:

The product has not been tested on animals for cosmetic purposes.

### RSPO:

The product does not contain palm oil or derivatives.

### REACH:

01-2119953737-24-0000

### REGULATORY STATUS:

## 93219-DEXPANTHENOL

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) <i>Note: Claims on finished cosmetic products must comply with national cosmetic legislation</i>
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

### Key:

#### Chemical Legislation

**Yes (Y):** The product contains only substances which are either listed in the respective chemical inventory, have been notified as new chemical substance by DSM or exempted from the chemical notification (e.g. natural)

**No (N):** The product contains at least a substance not listed or not notified or not exempted (not compliant with respective chemical inventory)

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

**Exempted (E):** under specific exemption applying to cosmetic ingredients (e.g. US, Japan)

#### Cosmetic Regulation

**Yes (Y):** product free for sales as cosmetic ingredient for the application and use level recommended. If any condition of use exists for the active substance, this must be mentioned

**No (N):** product not for sales in the respective country (contain at least a substance not allowed in cosmetic in the respective country)