

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

93219-DEXPANTHENOL

Version 1 Date of compilation: 26/10/2017

Version 5 (replaces version 4)

Revision date: 10/09/2023



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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING.

1.1 Product identifier.

Product Name: DEXPANTHENOL
Product Code: 93219
Chemical Name: dexpanthenol
CAS No: 81-13-0
EC No: 201-327-3

1.2 Relevant identified uses of the substance or mixture and uses advised against.

cosmetic use
Excipient pharmaceutical use

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **GUINAMA**
Address: C/ Oslo N°3
City: 46185 La Pobla de Vallbona
Province: Valencia
Telephone: +34961869090 / 902119816
Fax: +34961850352
E-mail: ventas@guinama.com
Web: www.guinama.com

1.4 Emergency telephone number: +34961869090 / 902119816 (Only available during office hours; Monday-Friday; 08:00-18:00)

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture.

The product is not classified as hazardous within the meaning of Regulation (EC) No 1272/2008.

2.2 Label elements.

Este producto no esta clasificado como peligroso según el Reglamento CE 1272/2008.

2.3 Other hazards.

The substance is not PBT
The substance is not vPvB
Substance does not have endocrine disrupting properties.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

3.1 Substances.

Identifiers	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008	
			Classification	Specifics concentration limits and Acute toxicity estimate
CAS No: 81-13-0 EC No: 201-327-3	dexpanthenol	0 - 2.5 %	-	-

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3.2 Mixtures.

Not applicable.

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.

Due to the composition and type of the substances present in the product, no particular warnings are necessary.

Inhalation.

If breathing stops, seek emergency medical attention. Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

Eye contact.

Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance.

Skin contact.

Remove contaminated clothing.

Ingestion.

Keep calm. NEVER induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed.

No known acute or delayed effects from exposure to the product.

4.3 Indication of any immediate medical attention and special treatment needed.

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

SECTION 5: FIREFIGHTING MEASURES.

5.1 Extinguishing media.

Suitable extinguishing media:

Extinguisher powder or CO₂. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable extinguishing media:

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the substance or mixture.

Special risks.

Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters.

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account.

Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.

For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions.

Product not classified as hazardous for the environment, avoid spillage as much as possible.

6.3 Methods and material for containment and cleaning up.

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Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.

Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations (see section 13).

6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

SECTION 7: HANDLING AND STORAGE.

7.1 Precautions for safe handling.

The product does not require special handling measures, the following general measures are recommended:

For personal protection, see section 8.

In the application area, smoking, eating, and drinking must be prohibited.

Follow legislation on occupational health and safety.

Never use pressure to empty the containers. They are not pressure-resistant containers. Keep the product in containers made of a material identical to the original.

7.2 Conditions for safe storage, including any incompatibilities.

The product does not require special storage measures. As general storage measures, sources of heat, radiation, electricity and contact with food should be avoided.

Keep away from oxidising agents and from highly acidic or alkaline materials.

Store the containers between 15 and 25 °C, in a dry and well-ventilated place.

Store according to local legislation. Observe indications on the label. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

The product is not affected by Directive 2012/18/EU (SEVESO III).

7.3 Specific end use(s).

Not available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

8.2 Exposure controls.

Measures of a technical nature:

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Physical state: Liquid

Colour: Colorless-pale yellow

Odour: Odorless

Odour threshold: Not applicable/Not available due to the nature/properties of the product

Melting point: Not applicable/Not available due to the nature/properties of the product

Freezing point: -25,0 °C

Boiling point or initial boiling point and boiling range: 235.6 °C

Flammability: Not applicable/Not available due to the nature/properties of the product

Lower explosion limit: Not applicable/Not available due to the nature/properties of the product

Upper explosion limit: Not applicable/Not available due to the nature/properties of the product

Flash point: 150.5 °C

Auto-ignition temperature: non-pyrophoric °C

Decomposition temperature: Not applicable/Not available due to the nature/properties of the product

pH: 9-10.5 (5%)

Kinematic viscosity: Not applicable/Not available due to the nature/properties of the product

Solubility: Easily soluble in Methanol. Slightly soluble in diethyl ether and ethanol

Hydrosolubility: >509 g/l

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Liposolubility: insoluble in oils and fat
Partition coefficient n-octanol/water (log value): -1.06
Vapour pressure: <0,0001
Absolute density: Not applicable/Not available due to the nature/properties of the product
Relative density: 1.2
Relative vapour density: Not applicable/Not available due to the nature/properties of the product
Particle characteristics: Not applicable/Not available due to the nature/properties of the product

9.2 Other information

Not applicable/Not available due to the nature/properties of the product

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.

The product does not present hazards by their reactivity.

10.2 Chemical stability.

Stable under the recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions.

The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid.

Avoid any improper handling.

10.5 Incompatible materials.

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

10.6 Hazardous decomposition products.

No decomposition if used for the intended uses.

SECTION 11: TOXICOLOGICAL INFORMATION.

11.1 Information on hazard classes as defined in Regulation (EC) N° 1272/2008.

Toxicological information.

Name	Acute toxicity			
	Type	Test	Kind	Value
dexpanthenol	Oral	LD50	Rat	>10000 mg/kg (-)
		LD50	mouse	15000 mg/kg (-)
	Dermal	LD50	Rat	3500 mg/kg
CAS No: 81-13-0 EC No: 201-327-3	Inhalation			

Acute oral toxicity : LD50 (Rat): > 10,000 mg/kg; LD50 (Mouse): 15,000 mg/kg

Acute inhalation toxicity: No data available

Acute dermal toxicity : LD50 (Rat): > 3,500 mg/kg

Skin irritation : No skin irritation (Rabbit, OECD Test Guideline 404): No phototoxic skin reaction (Guinea pig, CTFA Test Guideline)

Eye irritation : No eye irritation (Rabbit, OECD Test Guideline 405)

Sensitization : Does not cause sensitization. (Guinea pig): No photoallergenic skin reaction (Guinea pig, CTFA Testing Guideline)

Genotoxicity in vitro : not mutagenic (In vitro Mammalian Cell Gene Mutation Study, OECD Test Guideline 476): not genotoxic (In vitro Chromosomal Aberration Test, OECD Test Guideline 473)

Carcinogenicity : No indication of carcinogenic effects.

Reproductive toxicity: This information is not available.

Teratogenicity : There is no information available regarding the human species.

Specific target organ toxicity (STOT) - single exposure (Penetrating exposure): The substance or mixture is not classified as specific target organ toxicant, single exposure.

Specific target organ toxicity : NOAEL (Oral, Rat) : 200 mg/kg bw/repeated exposure (STOT) - repeated exposure

Subchronic toxicity study (90 days)

Aspiration toxicity : No aspiration toxicity classification

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11.2 Information on other hazards.

Endocrine disrupting properties

This product does not contain components with endocrine-disrupting properties with effects on human health.

Other information

Product:

: No known hypervitaminosis of provitamin B5 and vitamin B5.

Skin contact : Allergic contact dermatitis

Observations: (Isolated cases have been recorded)

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

Name	Ecotoxicity			
	Type	Test	Kind	Value
dexpanthenol CAS No: 81-13-0 EC No: 201-327-3	Fish	LC50	Oncorhynchus mykiss	>1000 mg/l (96 h) [1]
		[1] Directrices de ensayo 203 del OECD		
	Aquatic invertebrates	EC50	Daphnia magna	>100 mg/l (48 h) [1]
			[1] Directrices de ensayo 202 del OECD	
Aquatic plants	EC50b	Desmodesmus subspicatus	>100 mg/l (72 h) [1]	
			[1] Directrices de ensayo 201 del OECD	

Toxicity to bacteria : activated sludge

NOEC 569 mg/l

No inhibition was observed under the assay conditions of biodegradation.

(OECD Test Guideline 302B): Pseudomonas putida

EC50 (17 h) > 10,000 mg/l

(nominal concentration)

(DIN 38412)

12.2 Persistence and degradability.

Easily biodegradable. 97% (21 d)

(OECD Test Guideline 301 A)

No information is available on the degradability

No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.

Information about the bioaccumulation.

Name	Bioaccumulation			
	Log Pow	BCF	NOECs	Level
dexpanthenol CAS No: 81-13-0 EC No: 201-327-3	-1.06	-	-	Very low

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12.4 Mobility in soil.

No information is available about the mobility in soil.
The product must not be allowed to go into sewers or waterways.
Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.

This substance/mixture contains no components considered to be persistently bioaccumulative and toxic (PBT) or very bioaccumulative and very persistent (vPvB) at levels of the 0.1% or higher.

12.6 Endocrine disrupting properties.

This product doesn't contain components with environmental endocrine disrupting properties.

12.7 Other adverse effects.

The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.
No information is available about other adverse effects for the environment.

SECTION 13: DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.
Follow the provisions of Directive 2008/98/EC regarding waste management.

SECTION 14: TRANSPORT INFORMATION.

Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6.

14.1 UN number or ID number.

Transportation is not dangerous.

14.2 UN proper shipping name.

Description:
ADR/RID: Not classified as hazardous for transport.
IMDG: Not classified as hazardous for transport.
ICAO/IATA: Not classified as hazardous for transport.

14.3 Transport hazard class(es).

Transportation is not dangerous.

14.4 Packing group.

Transportation is not dangerous.

14.5 Environmental hazards.

Transportation is not dangerous.
Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): Not applicable.

14.6 Special precautions for user.

Transportation is not dangerous.

14.7 Maritime transport in bulk according to IMO instruments.

Not classified as hazardous for transport.

SECTION 15: REGULATORY INFORMATION.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.

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The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: OTHER INFORMATION.

Changes regarding to the previous version:

- Changes in the information of the supplier (SECTION 1.3).
- Changes in the composition of the product (SECTION 3.2).
- Modifications in the first aid measures (SECTION 4.1).
- Modification of the information of the stability and reactivity conditions (SECTION 10.2).
- Modification of the information of the stability and reactivity conditions (SECTION 10.3).
- Modification of the information of the stability and reactivity conditions (SECTION 10.4).
- Modification of the information of the stability and reactivity conditions (SECTION 10.5).
- Modification of the information of the stability and reactivity conditions (SECTION 10.6).

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

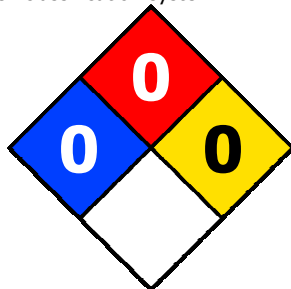
Physical hazards	On basis of test data
Health hazards	Calculation method
Environmental hazards	Calculation method

It is recommended that the product only be employed for the purposes advised.

Information on the TSCA Inventory (Toxic Substances Control Act) USA:

CAS No	Name	State
81-13-0	dexpanthenol	Registered

Risk classification system NFPA 704:



Health hazard: 0 (Normal Material)

Flammability: 0 (Will not burn)

Reactivity: 0 (Stable)

Abbreviations and acronyms used:

BCF: Bioconcentration factor.
EC50: Half maximal effective concentration.
LC50: Lethal concentration, 50%.
LD50: Lethal dose, 50%.
NOEC: No observed effect concentration.

Key literature references and sources for data:

<http://eur-lex.europa.eu/homepage.html>
<http://echa.europa.eu/>

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Regulation (EU) 2020/878.
Regulation (EC) No 1907/2006.
Regulation (EC) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemical substances and mixtures (REACH).

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.