

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

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## DEXPANTHENOLUM

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

#### 1.1 Product identifier

Product name: Dexpanthenol  
Dexpanthenolum  
Dexpanthenol  
Dexpanthénol  
Dexpanthenol

N° CAS: 81-13-0

N° EC: 201-327-3

#### 1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

#### 1.3 Details of the supplier of the safety data sheet

Company: FAC SECUNDUM ARTEM NV  
Oostmalsebaan 1c (unit 5)  
2960 Sint-Lenaarts  
Belgium

Telephone: (+32) (0)3 457 11 76

Email: info@magis-pharma.be

Web page: www.magis-pharma.be

#### 1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

##### Classification according to (EC) n° 1272/2008

The substance is not classified according to Regulation (EC) 1272/2008 (CLP).

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s): Not applicable.

Signal word(s): Not applicable.

Hazard statements: Not applicable.

Precautionary statements: Not applicable.

Additional applicable label elements: Not applicable.

#### 2.3 Other hazards

None.

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### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

Product name:	Dexpanthenol
IUPAC name:	(2R)-2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethylbutanamide
Synonyms:	D-panthenol Pantothenol D-Pantothenyl alcohol Provitamin B5
N° CAS:	81-13-0
N° EC:	201-327-3
Molecular Formula:	C <sub>9</sub> H <sub>19</sub> NO <sub>4</sub>
Content:	Dexpanthenol contains not less than 98.0 per cent and not more than the equivalent of 101.0 per cent of (2R)-2,4- dihydroxy-N-(3-hydroxypropyl)-3,3-dimethylbutanamide, calculated with reference to the anhydrous substance.

#### 3.2 Mixtures

Not applicable.

### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures

General notes:	Consult a doctor. Show the safety data sheet to the doctor on duty.
After inhalation:	Take to fresh air. If breathing is irregular, call a doctor immediately. Only give artificial respiration if breathing stops or under medical supervision.
After skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Remove all contaminated clothing immediately. Get medical attention if irritation develops and persists.
After eye contact:	Remove contact lenses and rinse immediately with plenty of water, including under the eyelids, for at least 15 minutes. Get medical attention.
After ingestion:	If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

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

No specific symptoms are known.

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

Treat symptomatically.

### SECTION 5: FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

Suitable extinguishing media:	Foam, dry powder, carbon dioxide, sand, water mist. Neighbouring fires (containers exposed to fire): Water spray or fog.
Unsuitable extinguishing media:	Direct water jet.

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### 5.2 Special hazards arising from the substance/mixture

Heating or fire may give off toxic fumes.

### 5.3 Advice for firefighters

Surrounding fires:

Cool containers with water to prevent decomposition of product and development of potential health hazards. Always use full fire protection. Collect water from which must not enter sewage system. Dispose of contaminated water used for extinguishing and residues in accordance with current regulations.

Protection against fire:

Helmet with visor, flame retardant clothing (jacket and trousers with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a face mask with full face shield covering the operator or the car (self protective) in case of large amounts of smoke, a self-contained breathing apparatus (EN 137).

Hazardous combustion products:

Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

**For non-emergency personnel**

Wear personal protective equipment.

**For emergency responders**

Wear personal protective equipment.

### 6.2 Environmental precautions

Avoid penetration of products into sewers, surface water, ground water.

### 6.3 Methods and material for containment and cleaning up

Clean up with absorbent material (e.g. cloth, fleece).

Store in suitable, closed containers for disposal.

### 6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:

Not available.

Personal protection:

Personal protective equipment, see section 8.

Technical protective measures:

Not available.

Handling:

Not available.

### 7.2 Conditions for safe storage, including any incompatibilities

Storage:

In an airtight container.

Conditions for safe storage, including any incompatibilities:

The product does not require special storage measures. Store containers in a cool, dry place. Storage in upright position.

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Storage – away from:

Not available.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Contains no substances with occupational exposure limit values.

### 8.2 Exposure controls

#### Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a viscoelastic tray.

Hygiene measures: Handle with proper industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

#### Individual protection measures

Eye/face protection: Protective face shields and safety goggles according to EN166.

Skin protection: Choose body protection according to the quantity and concentration of the hazardous substance in the workplace.

Hand protection: Handle with gloves. The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the resulting EN 374 standard.

Respiratory protection: It does not normally require the use of respiratory personal protective equipment.

Thermal hazards: Not determined.

#### Environmental exposure control

Not available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance: A colourless or slightly yellowish, viscous hygroscopic liquid, or a white or almost white, crystalline powder.

Odour: Odourless.

Odour threshold: Not available.

pH: (5%): 9.0 - 10.5

Melting/freezing point: -25.0 °C

Initial boiling point: 235.6 °C

Boiling range: Not available.

Flash point: 150.5 °C

Evaporation rate: Not available.

Flammability (solid/gas): Not available.

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Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Freely soluble in ethanol (96 per cent).
Solubility in water:	Very soluble in water. > 509 g/l (20 °C)
Partition coefficient (n-octanol/water):	LogPow -1.06 (20 °C)
Auto-ignition temperature:	Ignition point: > 400 °C
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

### 9.2 Other information

Molecular weight: 205.25 g/mol  
Density (20 °C): 1.2 g/ml  
Refraction index: 1.497 - 1.501

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

No special hazards to be mentioned.

### 10.2 Chemical stability

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

### 10.3 Possibility of hazardous reactions

Possible incompatibility with the materials listed under 10.5.

### 10.4 Conditions to avoid

High temperatures.

### 10.5 Incompatible materials

Strong acids and bases. Strong oxidising agents.

### 10.6 Hazardous decomposition products

No decomposition if used according to instructions.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity: Acute oral toxicity (LD<sub>50</sub>, mouse): 15000 mg/kg  
Acute oral toxicity (LD<sub>50</sub>, rat): 21000 mg/kg  
Acute dermal toxicity (LD<sub>50</sub>, rat): > 3500 mg/kg

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Skin corrosion/irritation:	Not irritating.
Serious eye damage/irritation:	Not irritating.
Respiratory/skin sensitisation:	Not sensitising.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	The IARC working group evaluated the biological effects of talc and concluded, due to in vivo and in vitro studies, that there is insufficient evidence of carcinogenicity or genetic toxicity in both animal and human experiments.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not classified.
STOT-repeated exposure:	Not classified.
Aspiration Hazard:	Not available.
Other:	There are no known health related events due to exposure to the product. In any case, it is recommended to comply with the rules of good industrial hygiene.

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

LC <sub>50</sub> (fish):	> 1000 mg/L/96 hours ( <i>Pimephales promelas</i> )
EC <sub>50</sub> (crustaceans):	> 100 mg/L/48 hours ( <i>Daphnia magna</i> )
EC <sub>50</sub> (algae/aquatic plants):	> 100 mg/L/72 hours ( <i>Desmodesmus subspicatus</i> )

### 12.2 Persistence and degradability

Readily biodegradable.

### 12.3 Bioaccumulative potential

Not available.

### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

According to available data, the product does not contain PBT or vPvB substances in concentrations higher than 0.10 %.

### 12.6 Other adverse effects

Not available.

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### SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated container: Dispose of as unused product.

### SECTION 14: TRANSPORT INFORMATION

#### Transport information according to ADR/RID/IMDG/ICAO/IATA

##### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : It is not dangerous in transport.

##### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : It is not dangerous in transport.

##### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : It is not dangerous in transport.

##### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : It is not dangerous in transport.

##### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : It is not dangerous in transport.

##### 14.6 Special precautions for user

It is not dangerous in transport.

##### 14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

##### 14.8 Additional transport information

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

### SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not applicable.

Risk phrases: Not applicable.

Safety phrases: Not applicable.

#### 15.2 Chemical safety assessment

A chemical safety assessment of the product has not been carried out.

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### SECTION 16: OTHER INFORMATION

#### 16.1 Changes since the previous version

Not applicable.

#### 16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

#### 16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

#### 16.4 Method of classification in case of mixture

Not applicable.

#### 16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

#### 16.6 Training advisement

Not available.

#### 16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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## 16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

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