

SAFETY DATA SHEET

Dextran Powder

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name

Dextran Powder

▼ Other means of identification

EC No.: 232-677-5

CAS No.: 9004-54-0

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

Relevant identified uses of the substance or mixture

Active pharmaceutical ingredient for pharmaceutical preparations and other industrial uses.

▼ Uses advised against

No special

1.3. Details of the supplier of the safety data sheet

Company and address

Pharmacosmos A/S

Roervangsvej 30

4300 Holbaek

Denmark

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Contact person

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E-mail

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Revision

04-02-2022

SDS Version

3.0

Date of previous version

2019-05-31 (2.0)

1.4. Emergency telephone number

Contact The National Poisons Information Service (dial 111, 24 h service).

See section 4 "First aid measures".

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Not classified according to Regulation (EC) No. 1272/2008 (CLP)

2.2. Label elements

Hazard pictogram(s)

Not applicable

Signal word

Not applicable

Hazard statement(s)

Not applicable

Safety statement(s)

General

-

Prevention

-
Response

-
Storage

-
Disposal

▼ Hazardous substances

No special

2.3. Other hazards

Additional labelling

Not applicable

▼ Additional warnings

This mixture/product does not contain any substances considered to meet the criteria classifying them as PBT and/or vPvB.

SECTION 3: Composition/information on ingredients

▼ 3.1. Substances

Product/substance	Identifiers	% w/w	Classification	Note
Dextran	CAS No.: 9004-54-0 EC No.: 232-677-5 REACH: Index No.:	95-100%		

See full text of H-phrases in section 16. Occupational exposure limits are listed in section 8, if these are available.

Other information

No special

SECTION 4: First aid measures

4.1. Description of first aid measures

▼ General information

In the case of accident: Contact a doctor or casualty department – take the label or this safety data sheet. Contact a doctor if in doubt about the injured person's condition or if the symptoms persist. Never give an unconscious person water or other drink.

▼ Inhalation

Upon breathing difficulties or irritation of the respiratory tract: Bring the person into fresh air and stay with him/her.

▼ Skin contact

Upon irritation: rinse with water. In the event of continued irritation, seek medical assistance.

▼ Eye contact

Upon irritation of the eye: Remove contact lenses. Flush eyes with plenty of water or salt water (20-30°C) and continue until irritation stops.

Ingestion

Provide plenty of water for the person to drink and stay with him/her. In case of malaise, seek medical advice immediately and bring the safety data sheet or label from the product. Do not induce vomiting, unless recommended by the doctor. Have the victim lean forward with head down to avoid inhalation of- or choking on vomited material.

Burns

Not applicable

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

No special

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

No special

Information to medics

Bring this safety data sheet or the label from this product.

SECTION 5: Firefighting measures

▼ 5.1. Extinguishing media

No special

▼ 5.2. Special hazards arising from the substance or mixture

Fire will result in dense smoke. Exposure to combustion products may harm your health. Closed containers, which are exposed to fire, should be cooled with water. Do not allow fire-extinguishing water to enter the sewage system and nearby surface waters.

▼ 5.3. Advice for firefighters

Fire fighters should wear appropriate personal protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

No specific requirements

▼ 6.2. Environmental precautions

Avoid discharge to lakes, streams, sewers, etc.

6.3. Methods and material for containment and cleaning up

Collect spills carefully. Moist the material with water in order to prevent the formation and propagation of dust. To the extent possible cleaning is performed with normal cleaning agents. Avoid use of solvents.

▼ 6.4. Reference to other sections

See section 13 on "Disposal considerations" in regard of handling of waste.

See section 8 "Exposure controls/personal protection" for protective measures.

SECTION 7: Handling and storage

▼ 7.1. Precautions for safe handling

Smoking, drinking and consumption of food is not allowed in the work area.

See section 8 "Exposure controls/personal protection" for information on personal protection.

▼ 7.2. Conditions for safe storage, including any incompatibilities

No special conditions required.

▼ Recommended storage material

Always store in containers of the same material as the original container.

▼ Storage temperature

Should be stored according to conditions described on the label.

▼ Incompatible materials

Strong acids, strong bases, strong oxidizing agents, and strong reducing agents.

7.3. Specific end use(s)

This product should only be used for applications quoted in section 1.2

SECTION 8: Exposure controls/personal protection

▼ 8.1. Control parameters

No substances are listed in the national list of substances with an occupational exposure limit.

▼ DNEL

No data available

▼ PNEC

No data available

▼ 8.2. Exposure controls

Control is unnecessary if the product is used as intended.

▼ **General recommendations**

Smoking, drinking and consumption of food is not allowed in the work area.

▼ **Exposure scenarios**

There are no exposure scenarios implemented for this product.

Exposure limits

Occupational exposure limits have not been defined for the substances in this product.

▼ **Appropriate technical measures**

Airborne gas and dust concentrations must be kept at a minimum. Provide efficient mechanical ventilation. If not possible use suitable respiratory equipment.

▼ **Hygiene measures**

Wash hands after use.

Measures to avoid environmental exposure


No specific requirements

Individual protection measures, such as personal protective equipment

Generally

Use only CE marked protective equipment.

▼ **Respiratory Equipment**

Work situation	Type	Class	Colour	Standards	
If ventilation at the work place is insufficient, use a half- or full mask with a appropriate particle filter.	S/SL	-	White	EN149	


Skin protection

No specific requirements

Hand protection

No specific requirements

▼ **Eye protection**

Type	Standards	
Wear face shield alternatively safety glasses with side shields.	EN166	

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

▼ **Physical state**

Powder

Colour

White

▼ **Odour / Odour threshold**

None

pH

5.5-7.0

▼ **pH in solution**

Density (g/cm³)

No data available

▼ **Relative density**

No data available

▼ **Kinematic viscosity**

No data available

▼ **Particle characteristics**

No data available

Phase changes

▼ **Melting point/Freezing point (°C)**

No data available

▼ Softening point/range (waxes and pastes) (°C)

Does not apply to solids.

Boiling point (°C)

No data available

Vapour pressure

No data available

▼ Relative vapour density

Does not apply to solids.

Decomposition temperature (°C)

No data available

Data on fire and explosion hazards

Flash point (°C)

No data available

Ignition (°C)

No data available

Auto flammability (°C)

No data available

▼ Lower and upper explosion limit (% v/v)

No data available

Solubility

Solubility in water

Soluble

n-octanol/water coefficient

No data available

▼ Solubility in fat (g/L)

No data available

9.2. Other information

▼ Evaporation rate (n-butylacetate = 100)

No data available

▼ Other physical and chemical parameters

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available

▼ 10.2. Chemical stability

The product is stable under the conditions, noted in section 7 "Handling and storage".

10.3. Possibility of hazardous reactions

No special

10.4. Conditions to avoid

No special

10.5. Incompatible materials

Strong acids, strong bases, strong oxidizing agents, and strong reducing agents.

10.6. Hazardous decomposition products

The product is not degraded when used as specified in section 1.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

▼ Acute toxicity

Based on available data, the classification criteria are not met.

▼ Skin corrosion/irritation

Based on available data, the classification criteria are not met.

▼ Serious eye damage/irritation

Based on available data, the classification criteria are not met.

▼ **Respiratory sensitisation**

Based on available data, the classification criteria are not met.

▼ **Skin sensitisation**

Based on available data, the classification criteria are not met.

▼ **Germ cell mutagenicity**

Based on available data, the classification criteria are not met.

▼ **Carcinogenicity**

Based on available data, the classification criteria are not met.

▼ **Reproductive toxicity**

Based on available data, the classification criteria are not met.

▼ **STOT-single exposure**

Based on available data, the classification criteria are not met.

▼ **STOT-repeated exposure**

Based on available data, the classification criteria are not met.

▼ **Aspiration hazard**

Based on available data, the classification criteria are not met.

11.2. Information on other hazards

▼ **Long term effects**

No special

▼ **Endocrine disrupting properties**

No special

▼ **Other information**

No special

SECTION 12: Ecological information

12.1. Toxicity

No data available

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

This mixture/product does not contain any substances considered to meet the criteria classifying them as PBT and/or vPvB.

▼ **12.6. Endocrine disrupting properties**

No special

▼ **12.7. Other adverse effects**

No special

SECTION 13: Disposal considerations

▼ **13.1. Waste treatment methods**

Product is not covered by regulations on dangerous waste.

Regulation (EU) No 1357/2014 of 18 December 2014 on waste.

EWC code

Not applicable

Specific labelling

Not applicable

Contaminated packing

Packaging containing residues of the product must be disposed of similarly to the product.

SECTION 14: Transport information

▼ 14.1. - 14.4.

Not dangerous goods according to ADR, IATA and IMDG.

ADR/RID

Not applicable

IMDG

Not applicable

MARINE POLLUTANT

No

▼ IATA

Not applicable

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Not applicable

▼ 14.7. Maritime transport in bulk according to IMO instruments

No data available

SECTION 15: Regulatory information

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

▼ Restrictions for application

Restricted to professional users.

▼ Demands for specific education

No specific requirements

▼ SEVESO - Categories / dangerous substances

Not applicable

Additional information

Not applicable

▼ Sources

Regulation (EU) No 1357/2014 of 18 December 2014 on waste.

CLP Regulation (EC) No 1272/2008, as retained and amended in UK law.

EC-Regulation 1907/2006 (REACH), as amended by UK REACH Regulations SI 2019/758

15.2. Chemical safety assessment

No

SECTION 16: Other information

▼ Abbreviations and acronyms

ADN = European Provisions concerning the International Carriage of Dangerous Goods by Inland Waterway

ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road

ATE = Acute Toxicity Estimate

BCF = Bioconcentration Factor

CAS = Chemical Abstracts Service

CE = Conformité Européenne

CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]

CSA = Chemical Safety Assessment

CSR = Chemical Safety Report

DMEL = Derived Minimal Effect Level

DNEL = Derived No Effect Level

EINECS = European Inventory of Existing Commercial chemical Substances

ES = Exposure Scenario

EUH statement = CLP-specific Hazard statement

EWC = European Waste Catalogue

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IARC = International Agency for Research on Cancer (IARC)

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)

OECD = Organisation for Economic Co-operation and Development

PBT = Persistent, Bioaccumulative and Toxic

PNEC = Predicted No Effect Concentration

RID = The Regulations concerning the International Carriage of Dangerous Goods by Rail

RRN = REACH Registration Number

SCL = A specific concentration limit.

SVHC = Substances of Very High Concern

STOT-RE = Specific Target Organ Toxicity - Repeated Exposure

STOT-SE = Specific Target Organ Toxicity - Single Exposure

TWA = Time weighted average

UN = United Nations

UVCB = Complex hydrocarbon substance

VOC = Volatile Organic Compound

vPvB = Very Persistent and Very Bioaccumulative

▼ Additional information

In accordance with Article 31 of REACH, a safety data sheet is not required for this product. This safety data sheet has been created on a voluntary basis to distribute relevant information as required under Article 32 of REACH.

▼ The safety data sheet is validated by

Morten Givard / Sikma Consult / www.sikma.dk

▼ Other

A change (in proportion to the last essential change (first cipher in SDS version, see section 1)) is marked with a blue triangle.

The information in this safety data sheet applies only to this specific product (mentioned in section 1) and is not necessarily correct for use with other chemicals/products.

It is recommended to hand over this safety data sheet to the actual user of the product. Information in this safety data sheet cannot be used as a product specification.



Country-language: GB-en