

SAFETY DATA SHEET

Dexafer-200 (Iron dextran solution for injection)

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

1.1. Product identifier

Trade name

Dexafer-200 (Iron dextran solution for injection)

Product no.

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

Relevant identified uses of the substance or mixture

Medicinal product for veterinary use.

Relevant identified uses of the substance or mixture (REACH)

Not applicable

Uses advised against

Not for human use.

1.3. Details of the supplier of the safety data sheet

Company and address

Pharmacosmos A/S

Roervangsvej 30

4300 Holbaek

Denmark

T: +45 5948 5959

F: +45 5948 5960

Contact person

Lise Larsen

E-mail

info@pharmacosmos.com

SDS date

2019-06-03

SDS Version

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

Skin Sens. 1; H317, May cause an allergic skin reaction.

2.2. Label elements

Hazard pictogram(s)



Signal word

Warning

Hazard statement(s)

May cause an allergic skin reaction.

Safety statement(s)

General

Prevention

P280, Wear protective gloves/protective clothing/eye protection/face protection.

According to EC-Regulation 2015/830

P261, Avoid breathing mist/vapour.

Response

P333+P313, If skin irritation or rash occurs: Get medical advice/attention.

P362+P364, Take off contaminated clothing and wash it before reuse.

Storage

Disposal

P501, Dispose of contents/container to an approved waste disposal plant.

Hazardous substances

Iron Dextran

2.3. Other hazards

Animal studies (rodents) indicate that repeated intramuscular or subcutaneous injections can produce sarcomas at the site of injection

SECTION 3: Composition/information on ingredients

3.1 Substances

3.2 Mixtures

Product/Ingredient name	Identifier number	% w/w	CLP	Note
Iron Dextran	CAS No.: 9004-66-4 EC No.: REACH No.: Index No.:	40-60%	Skin Sens. 1, H317	
Phenol	CAS No.: 108-95-2 EC No.: 203-632-7 REACH No.: Index No.: 604-001-00-2	<1%	Acute Tox. 3, H301 Acute Tox. 3, H311 Skin Corr. 1B, H314 Acute Tox. 3, H331 Muta. 2, H341 STOT RE 2, H373 Aquatic Chronic 2, H411	EU

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

Other information

Phenol has a specific concentration limit (SCL).

EU: European occupational exposure limit

The classification of Iron Dextran is based on internal test data.

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. The doctor can contact the National Poisons Information Service: Dial 0344 892 0111 (24 h service).

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

Bring the person into fresh air and stay with him/her.

Skin contact

Remove contaminated clothing and shoes immediately. Ensure to wash exposed skin thoroughly with water and soap. Skin cleanser can be used. DO NOT use solvents or thinners.

Eye contact

Remove contact lenses and open eyes widely. Flush eyes with water or saline water(20-30°C) for at least 15 minutes. Seek medical assistance and continue flushing during transport.

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

According to EC-Regulation 2015/830

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

Sensitisation: This product contains substances, which may trigger allergic reaction upon dermal contact. Manifestation of allergic reactions typically takes place within 12-72 hours after exposure.

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

If skin irritation or rash occurs: Get medical advice/attention.

Information to medics

Bring this safety data sheet.

SECTION 5: Firefighting measures**5.1. Extinguishing media**

Recommended: alcohol-resistant foam, carbonic acid, powder, water mist. Waterjets should not be used, since they can spread the fire.

5.2. Special hazards arising from the substance or mixture

No special

5.3. Advice for firefighters

Wear self-contained breathing apparatus and protective clothing to prevent contact. Upon direct exposure contact The National Poisons Information Service (dial 111, 24 h service) in order to obtain further advice.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

No specific requirements

6.2. Environmental precautions

No specific requirements

6.3. Methods and material for containment and cleaning up

Use sand, sawdust, earth, vermiculite, diatomaceous earth to contain and collect non-combustible absorbent materials and place in container for disposal, according to local regulations.

To the extent possible cleaning is performed with normal cleaning agents. Avoid use of solvents.

6.4. Reference to other sections

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

See section on 'Exposure controls/personal protection' for protective measures.

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Smoking, storage of tobacco, consumption and storage of food or liquids are not allowed in the workrooms.

See section on 'Exposure controls/personal protection' for information on personal protection.

7.2. Conditions for safe storage, including any incompatibilities

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

Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

Storage temperature

Should be stored according to conditions described on the label.

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**

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Phenol

Long term exposure limit (8 hours): 2 ppm

Long term exposure limit (8 hours): 7,8 mg/m³

Short term exposure limit (15 minutes): 4 ppm

According to EC-Regulation 2015/830

Short term exposure limit (15 minutes): 16 mg/m³

Annotations:

Sk: Can be absorbed through the skin and lead to systemic toxicity.

The Control of Substances Hazardous to Health Regulations 2002. SI 2002/2677 The Stationery Office 2002.

DNEL / PNEC

8.2. Exposure controls

Compliance with the given occupational exposure limits values should be controlled on a regular basis.

General recommendations

Smoking, eating and drinking are not allowed in the work premises

Exposure scenarios

In the event exposure scenarios are appended to the safety data sheet, the operational conditions and risk management measures in these shall be complied with.

Exposure limits

Professional users are subjected to the legally set maximum concentrations for occupational exposure. See occupational hygiene limit values above.

Appropriate technical measures

Airborne gas and dust concentrations must be kept at a minimum and below current limit values (see above). Installation of an exhaust system if normal air flow in the work room is not sufficient is recommended. Ensure emergency eyewash and -showers are clearly marked.

Hygiene measures

In between use of the product and at the end of the working day all exposed areas of the body must be washed thoroughly. Always wash hands, forearms and face.

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	Recommended Filter type	Class	Colour	Standards
-	No specific requirements	-	-	-

Skin protection

Recommended	Standards	Type/Category
Dedicated work clothing should be worn.	-	-



Hand protection

Material	Glove thickness (mm)	Breakthrough time (min.)	Standards
Nitrile	-	-	EN374-2



Eye protection

Recommended	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

Form

Liquid

Colour

Brown

Odour

Characteristic

Odour threshold (ppm)

No data available

pH

5.2-6.5

Density (g/cm³)

1.1-1.8

Viscosity (40°C)

No data available

Phase changes

Melting point (°C)

No data available

Boiling point (°C)

No data available

Vapour pressure

No data available

Vapour density

No data available

Decomposition temperature (°C)

No data available

Evaporation rate (n-butylacetate = 100)

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

Explosion limits (% v/v)

No data available

Explosive properties

No data available

Oxidizing properties

No data available

Solubility

Solubility in water

Soluble

n-octanol/water coefficient

No data available

9.2. Other information

Solubility in fat (g/L)

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 the section "Handling and storage".

According to EC-Regulation 2015/830

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 toxicological effects

Acute toxicity

Product/Ingredient name	Species	Test	Route of exposure	Result
Iron Dextran	Rat	LOEC	Oral	60.00 mg/kg

Skin corrosion/irritation

No data available

Serious eye damage/irritation

No data available

Respiratory or skin sensitisation

May cause an allergic skin reaction.

Germ cell mutagenicity

No data available

Carcinogenicity

Data on: product

Result: Animal studies (rodents) indicate that repeated intramuscular or subcutaneous injections can produce sarcomas at the site of injection.

Reproductive toxicity

No data available

STOT-single exposure

No data available

STOT-repeated exposure

No data available

Aspiration hazard

No data available

Long term effects

Animal studies (rodents) indicate that repeated intramuscular or subcutaneous injections can produce sarcomas at the site of injection

SECTION 12: Ecological information

12.1. Toxicity

12.2. Persistence and degradability

12.3. Bioaccumulative potential

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. Other adverse effects

This product contains substances, which may cause adverse long-term effects to the aquatic environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

According to EC-Regulation 2015/830

Product is covered by the regulations on hazardous 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

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

Restrictions for application

People under the age of 18 shall not be exposed to this product cf. Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work.

Demands for specific education

No special

SEVESO**CATEGORIES**

Not applicable

NAMED DANGEROUS SUBSTANCES

Not applicable

Additional information

Not applicable

Sources

Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (CLP).

Regulation (EC) 1907/2006 (REACH).

15.2. Chemical safety assessment

No

SECTION 16: Other information

Full text of H-phrases as mentioned in section 3

H301, Toxic if swallowed.

H311, Toxic in contact with skin.

H314, Causes severe skin burns and eye damage.

H317, May cause an allergic skin reaction.

H331, Toxic if inhaled.

H341, Suspected of causing genetic defects.

According to EC-Regulation 2015/830

H373, May cause damage to organs through prolonged or repeated exposure α .

H411, Toxic to aquatic life with long lasting effects.

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

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

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

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 Regulation (EC) No. 1272/2008 (CLP) the evaluation of the classification of the mixture is based on:

The classification of the mixture in regard of health hazards are in accordance with the calculation methods given by

Regulation (EC) No. 1272/2008 (CLP)

The safety data sheet is validated by

SHCW/CHYMEIA

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.