

SAFETY DATA SHEET

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

1.1. Product identifier

Trade name

Uniferon[®] (Iron dextran solution for injection)

Product no.

-

REACH registration number

Not applicable

Other means of identification

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

Uses advised against

Not for human use.

The full text of any mentioned and identified use categories are given in section 16

1.3. Details of the supplier of the safety data sheet

Company and address

Pharmacosmos A/S
Roervangsvej 30
DK-4300 Holbaek
Denmark
T: +45 5948 5959
F: +45 5948 5960

Contact person

Lise Larsen

E-mail

info@pharmacosmos.com

SDS date

10-03-2015

SDS Version

1.0

1.4. Emergency telephone number

+45 5948 5959

See section 4 "First aid measures"

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Skin Sens. 1 // H317

See full text of H/R-phrases in section 2.2.

DPD/DSD Classification

Toxic (T).

May cause sensitisation by skin contact (R43).

2.2. Label elements

Hazard pictogram(s)

-

Signal word

-

Hazard statement(s)

May cause an allergic skin reaction. (H317)

Safety statement(s)	General	-
	Prevention	Obtain special instructions before use. (P201) Use personal protective equipment as required. (P281)
	Response	IF ON SKIN: Wash with plenty of soap and water. (P302+P352) IF exposed or concerned: Get medical advice/attention. (P308+P313)
	Storage	Store locked up. (P405)
	Disposal	Dispose of contents/container to an approved waste disposal plant. (P501)

Identity of the substances primarily responsible for the major health hazards

Iron Dextran

2.3. Other hazards

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

Additional labelling

-

Additional warnings

-

VOC

-

SECTION 3: Composition/information on ingredients

3.1/3.2. Substances

NAME:	Iron Dextran
IDENTIFICATION NOS.:	CAS-no: 9004-66-4
CONTENT:	40-60%
DSD CLASSIFICATION:	R43
CLP CLASSIFICATION:	Skin Sens. 1 H317

NAME:	phenol
IDENTIFICATION NOS.:	CAS-no: 108-95-2 EC-no: 203-632-7 Index-no: 604-001-00-2
CONTENT:	<1%
DSD CLASSIFICATION:	R68 T; R23/24/25 Xn; R48/20/21/22 C; R34
CLP CLASSIFICATION:	Acute Tox. 3, STOT RE 2, Skin. Corr. 1B, , Aquatic Chronic 2 H301, H311, H314, H331, H341, H373, H411
NOTE:	S

(*) See full text of H/R-phrases in chapter 16. Occupational exposure limits are listed in section 8, if these are available.

S = Organic solvent

Other information

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 this safety data sheet. Contact a doctor, if in doubt about the injured person's condition or if the symptoms continue. Never give an unconscious person water or similar.

Inhalation

Get the person into fresh air and stay with them.

Skin contact

Remove contaminated clothing and shoes at once. Skin that has come in contact with the material must be washed thoroughly with water and soap. Skin cleanser can be used. DO NOT use solvents or thinners.

Eye contact

Remove contact lenses. Flush eyes immediately with plenty of water (20-30°C) for at least 15 minutes and continue until irritation stops. Make sure you flush under the upper and lower eyelids. If irritation continues, contact a doctor.

Ingestion

In the case of ingestion, contact a doctor immediately and take this safety data sheet from the material with you. If the person is conscious, give them water. DO NOT try to induce vomiting, unless this is recommended by a doctor. Hold head facing down so that no vomit runs back into the mouth and throat. Prevent shock by keeping the injured person warm and calm. Give mouth-to-mouth resuscitation if breathing stops. If unconscious, roll the injured person onto side with the top leg bent at both knee and hip. Call an ambulance.

Treatment with deferoxamin as antidote

Burns

Rinse with water until the pain stops and continue for 30 minutes.

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

Neurotoxic effect: This product contains organic solvents, which can have an effect on the nervous system. Symptoms of neurotoxicity can be: loss of appetite, headache, dizziness, whistling in the ears, tingling sensations in the skin, sensitivity to the cold, cramps, difficulty in concentrating, tiredness, etc. Repeated exposure to solvents can result in the breaking down of the skin's natural fat layer. The skin will then be more prone to absorb dangerous substances, e.g. allergens.

Sensitivity effects: This product contains substances which can give an allergic reaction on contact with skin. The allergic reaction will typically set in 12-72 hours after exposure as the substance penetrates the skin and reacts with proteins in the outer skin. The body's immune system sees the chemically changed protein as a foreign body and will try to destroy it.

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

IF exposed or concerned:
Get immediate 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. Water jets should not be used, since they can spread the fire.

5.2. Special hazards arising from the substance or mixture

If the product is exposed to high temperatures, as in the case of fire, dangerous catabolic substances are produced. These are: Carbon oxides. Some metal oxides. Fire will result in thick black smoke. Exposure to catabolic products can damage your health. Fire fighters should use proper protection gear. Closed containers, which are exposed to fire, should be cooled with water. Do not let fire-extinguishing water run into sewers and other water courses.

5.3. Advice for firefighters

Wear self-contained breathing apparatus and protective clothing to prevent contact.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid direct contact with spilled substances. Avoid inhalation of vapours from waste material.

6.2. Environmental precautions

Avoid discharge to lakes, streams, sewers, etc. In the event of a leakage to the surroundings, contact the local environmental authorities. Consider putting up waste collecting trays/basins to prevent leakage to the surroundings.

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. Cleaning should be done as far as possible using normal cleaning agents. Solvents should be avoided.

6.4. Reference to other sections

See section on "Disposal considerations" with regard to the 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, consumption of food or liquid, and storage of tobacco, food or liquids are not allowed in the workrooms. See section on 'Exposure controls/personal protection' for information on personal protection. Avoid direct contact with the product.

7.2. Conditions for safe storage, including any incompatibilities

Always store in containers of the same material as the original. Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

Storage temperature

Room temperature 5 to 30°C at a relative humidity of 20-80%

7.3. Specific end use(s)

This product should only be used for applications described in Section 1.2

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

OEL

Phenol (EH40/2005)
Long-term exposure limit (8-hour TWA reference period): 2 ppm | - mg/m³
Short-term exposure limit (15-minute reference period): - ppm | - mg/m³
Comments: Sk (Sk = Can be absorbed through skin)

DNEL / PNEC

No data available.

8.2. Exposure controls

Compliance with the stated exposure limits values should be checked on a regular basis.

General recommendations

Observe general occupational hygiene.

Exposure scenarios

If there is an appendix to this safety data sheet, the indicated exposure scenarios must be complied.

Exposure limits

Trade users are covered by the rules of the working environment legislation on maximum concentrations for exposure. See work hygiene threshold values below.

Appropriate technical measures

Airborne gas and dust concentrations must be kept as low as possible and below the current threshold values (see below). Use for example an exhaust system if the normal air flow in the work room is not sufficient. Make sure that eyewash and emergency showers are clearly marked.

Hygiene measures

Whenever you take a break in using this product and when you have finished using it, all exposed areas of the body must be washed. Always wash hands, forearms and face.

Measures to avoid environmental exposure

Keep damming materials near the workplace. If possible collect spillage during work.

Individual protection measures, such as personal protective equipment



Generally

Only CE-marked personal protection equipment should be used. Use only CE marked protective equipment.

Respiratory Equipment

No specific requirements.

Skin protection

Special work clothing should be used. When working with this product for a long period of time, use a protective suit.

Hand protection

Use protective gloves. The concrete work situation is not known. Contact the suppliers of the gloves for help on the glove type. Please note that elastic gloves stretch when used. The thickness of the gloves, and therefore their penetration time, will be reduced. Moreover, the temperature of the glove in use is about 35°C, while the standard test, EN 374-3, is done at 23°C. The penetration time is therefore reduced by a factor of 3.

Eye protection

Use face shield. Use safety glasses with a side shield as an alternative.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Form	Colour	Odour	pH	Viscosity	Density (g/cm ³)
Liquid	Brown	Characteristic	5.2-6.5	-	1.1-1.8

Phase changes

Melting point (°C)	Boiling point (°C)	Vapour pressure (mm Hg)
-	-	-

Data on fire and explosion hazards

Flashpoint (°C)	Ignition (°C)	Self ignition (°C)
-	-	-

Explosion limits (Vol %)	Oxidizing properties
-	-

Solubility

Solubility in water	n-octanol/water coefficient
Soluble	-

9.2. Other information

Solubility in fat	Additional information
-	N/A

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 on "Handling and storage".

10.3. Possibility of hazardous reactions

No special

10.4. Conditions to avoid

Do not expose to heat (e.g. sunlight), because it can lead to excess pressure.

10.5. Incompatible materials

Strong acids, strong bases, strong oxidizing agents, and strong reductants 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

Substance	Species	Test	Route of exposure	Result
Iron Dextran	Rat	LOEC	Oral	60 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

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

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

Neurotoxic effect: This product contains organic solvents, which can have an effect on the nervous system. Symptoms of neurotoxicity can be: loss of appetite, headache, dizziness, whistling in the ears, tingling sensations in the skin, sensitivity to the cold, cramps, difficulty in concentrating, tiredness, etc.

Repeated exposure to solvents can result in the breaking down of the skin's natural fat layer. The skin will then be more prone to absorb dangerous substances, e.g. allergens.

Sensitivity effects: This product contains substances which can give an allergic reaction on contact with skin. The allergic reaction will typically set in 12-72 hours after exposure as the substance penetrates the skin and reacts with proteins in the outer skin. The body's immune system sees the chemically changed protein as a foreign body and will try to destroy it.

SECTION 12: Ecological information

12.1. Toxicity

Substance	Species	Test	Test duration	Result
No data available.				

12.2. Persistence and degradability

Substance	Biodegradability	Test	Result
No data available.			

12.3. Bioaccumulative potential

Substance	Potential bioaccumulation	LogPow	BFC
No data available.			

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

No data available

12.6. Other adverse effects

This product contains ecotoxic substances which can have damaging effects on water-organisms. This product contains substances which can cause undesirable long-term effects in the water environment, due to its poor biodegradability.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

The product is covered by the regulations on dangerous waste.

Waste

EWC code

-

Specific labelling

-

Contaminated packing

Packaging which contains leftovers from the product must be disposed of in the same way as the product.

SECTION 14: Transport information

Not listed as dangerous goods under ADR and IMDG regulations.

14.1 – 14.4

ADR/RID	14.1. UN number	14.2. UN proper shipping name	14.3. Transport hazard class(es)	14.4. Packing group	Notes
IMDG	UN-no.	Proper Shipping Name	Class	PG*	EmS MP** Hazardous constituent
IATA/ICAO	UN-no.	Proper Shipping Name	Class	PG*	

14.5. Environmental hazards

This product contains substances which can cause undesirable long-term effects in the water environment, due to its poor biodegradability.

14.6. Special precautions for user

-

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

No data available

(*) Packing group

(**) Marine pollutant

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 must not be exposed to this product cf. Council Directive 94/33/EC. Only for industrial use.

Demands for specific education

-

Additional information

-

Sources

EC regulation 1907/2006 (REACH)

Directive 2000/532/EC

EC Regulation 1272/2008 (CLP)

15.2. Chemical safety assessment

No

SECTION 16: Other information

Full text of H/R-phrases as mentioned in section 3

R34 - Causes burns.

R43 - May cause sensitisation by skin contact.

R68 - Possible risk of irreversible effects.

R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.

R48/20/21/22 - Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.

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.

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

H411 - Toxic to aquatic life with long lasting effects.

The full text of identified uses as mentioned in section 1

-

Other symbols mentioned in section 2

-

Other

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.
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.

The safety data sheet is validated

10-03-2015