

## Safety Data Sheet

OSHA Hazard Communication Standard (HCS)  
(Subpart Z, Toxic and Hazardous Substances, 29 CFR 1910.1200)

<b>SDS: Fe-200-00</b>	
<b>Product: Uniferon® 200</b>	
<b>Valid from: 06-15-2015</b>	<b>Replaces: 05-28-2015</b>
	<b>Original version: 03-26-2015</b>

### 1 Identification

Substance:	Iron Dextran Complex Injection, 200 mg/mL (each mL contains 200 mg elemental iron)
Synonyms:	Injectable Iron, Ferric Hydroxide Dextran Complex
Cas No.:	9004-66-4 (Phenol: 108-95-2)
NADA No. :	134-708 (approved by FDA)
Supplier:	Pharmacosmos, Inc. 776 Mountain Boulevard Watchung, NJ 07069
Telephone:	(908) 769-7045
Recommended Use:	Iron Dextran Complex Injection, 200 mg/mL is used for the prevention or treatment of baby pig anemia due to iron deficiency.

### 2 Hazard identification

Harmful if swallowed in doses higher than 60 mg Iron/kg body weight, the liberated iron ions will be toxic and dangerous to the health.

Non-flammable liquid mixture.

#### CONFIDENTIAL INFORMATION

This material is the property of Pharmacosmos, Inc. and must not be disclosed or used except as authorized by Pharmacosmos, Inc.

### 3 Composition/information on ingredients

Contains Iron Dextran CAS No. 9004-66-4

Contains Phenol CAS No. 108-95-2

Iron Dextran is a complex of Ferric Hydroxide and low molecular weight hydrogenated Dextran at a concentration that yields a solution of 200 mg/mL of elemental iron. The Ferric Hydroxide and the hydrogenated Dextran components are mixed in water, complexed with heating and stirring and preserved with 0.5% Phenol.

### 4 First aid

If ingested in doses higher than 60 mg Fe/kg body weight, the liberated iron ions will be toxic and cause: nausea/vomiting, stomach pain and subsequently acidosis. If not treated, multiple organ damage may occur.

Transfer to hospital for emptying of stomach and treatment with antidote Deferoxamin.

In case of spill, the solution can cause irritation to skin and mucous membranes. The solution is easily washed away with water.

### 5 Fire fighting measures

The product is dissolved in water and decomposes by fire. The fumes are non-toxic. Non-combustible.

Use extinguishing media appropriate to the surrounding fire conditions.

### 6 Accidental release measures

Personal precautions:	Avoid ingestion of solution; as the limit stated in Item 3 might be exceeded.
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Environmental precautions:	If entering the sewage system, the solution is easily decomposed and has no toxic effect but will cause a strong coloring of the wastewater. Contact the local authorities to explain the coloring.
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The Iron Dextran Complex does not damage the microbial activity in the treatment plant.

Cleaning up methods: Shovel up and collect as much as possible in a container for disposal. Rinse with plenty of water.

## **7 Handling and storage**

Store at an ambient temperature of 15-30°C with a relative humidity of 20-80%.

## **8 Exposure controls/personal protection**

Avoid ingestion.

## **9 Physical and chemical properties**

Appearance: Brown to reddish brown solution.

Odor: Odorless

pH: 5.2 – 6.5

Boiling point/range: Not determined

Melting point/range: Not applicable

Flash point: Not determined

Flammability: Not determined

Auto-ignition temperature: Not determined

Explosive properties: Not determined

Explosion limits: Not determined

Oxidizing properties: Not determined

Vapor pressure: Not applicable

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Density:	1.30 – 1.38 g/mL
Bulk density:	Not determined
Solubility in water:	Not determined
Solubility in organic solvents:	Insoluble
Relative vapor density:	Not applicable
Viscosity (relative):	$\leq 25$

**10 Stability and reactivity**

Stability:	Stable under recommended storage and handling conditions.
Conditions to avoid:	None
Materials to avoid:	None
Hazardous decomposition products:	None

**11 Toxicological information**

Acute toxicity:	
Oral $LD_{50}$	Not determined
Dermal $LD_{50}$	Not determined
Inhalation $LD_{50}$	Not determined
Irritation:	
Skin:	Not determined
Eye:	Not determined
Respiration:	Not determined

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Sensitization:	Not determined
Other toxicological information:	<p>ACUTE TOXICITY: If swallowed in doses higher than 60 mg Iron/kg body weight the liberated iron will be toxic and dangerous to health.</p> <p>POSSIBLE CARCINOGEN: Animal studies (rodents) indicate that repeated intramuscular or subcutaneous injections can produce sarcomas at the site of injection.</p>

## 12 Ecological information

If entering the sewage system, Iron Dextran Complex is easily decomposed and has no toxic effects. Does not damage the microbial activity in the sewage treatment plant.

The waste water becomes colored.

## 13 Disposal considerations

Product:	Incineration, according to local regulations.
Contaminated packaging:	Incineration, according to local regulations.
Other information:	Non-contaminated containers can be treated like domestic garbage. According to local regulations.

## 14 Transport information

### LAND TRANSPORT:

ADR class:	Not applicable
Other information:	Not dangerous goods, according to national and international transport regulations.

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## SEA TRANSPORT:

UN number:	Not applicable
Other information:	Not dangerous goods, according to national and international transport regulations.

## AIR TRANSPORT:

UN number:	Not applicable
Other information:	Not dangerous goods, according to national and international transport regulations.

## 15 Regulatory information

Labeling:	According to own criteria.
Symbols:	None
Risk phrase:	None
Safety phrase:	None

## 16 Other information

The information is correct and complete to the best of our present knowledge and is given in good faith but without warranty. It remains the user's own responsibility to make sure the information is appropriate and complete for his special use of the product.

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