

SAFETY DATA SHEET

Solofer

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

SDS Name: Solofer
Synonyms: Iron dextran 200 mg/ml, solution for injection

Product Use: Relevant uses: Medicinal product for veterinary use.

Distributed by: AVL/Solvet
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Calgary, Alberta Canada
T2C5N6

For information, call: (403) 456-2245, 1-877-456-2755
Website: <https://solvet.ca/>
Email: SDS@solvet.ca
Emergency number: (613) 996-6666 (CANUTEC)
1-800 463-5060 OR
(418) 656-8090 (Control Poison Center)

24 Hours: Medical: 1-800-498-5743
Spill/CHEMTREC: 1-800-424-9300

2. COMPOSITION / INFORMATION ON INGREDIENTS

Substances: Non-applicable

Chemical Description: Solution for injection.

Components:

In accordance with Schedule I of the Hazardous Products Regulations (SOR/2015-17), the product contains:

Name	Conc (%w/w)	CAS #	Classification	Note
Iron Dextran	40-60%	CAS No.: 9004-66-4 EC No.: REACH: Index No.:	Skin Sens. 1, H317	
Phenol	<1%	CAS No.: 108-95-2 EC No.: 203-632-7 REACH: Index No.: 604-001-00-2	Acute Tox. 3, H301 Acute Tox. 3, H311 Skin Corr. 1B, H314 (SCL: 3.00 %) Acute Tox. 3, H331 Muta. 2, H341 STOT RE 2, H373 Aquatic Chronic 2, H411	[1]

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


Other information: [1] European occupational exposure limit
The classification of Iron Dextran is based on internal test data.

3. HAZARDS IDENTIFICATION

Classification of the substance or mixture

Classification - GHS	Skin Sens. 1: H317, May cause an allergic skin reaction.
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Label elements

WHMIS 2015 Hazard pictograms	
Hazard Statement	Skin Sens. 1: H317 - May cause an allergic skin reaction.
Precautionary Statement	P261: Avoid breathing mist/vapour. P280: Wear face shield/protective gloves/protective clothing. P362+P364: Take off contaminated clothing and wash it before reuse. P333+P313: If skin irritation or rash occurs: Get medical advice/attention. P501: Dispose of contents/container to an approved waste disposal plant.

Hazardous substances

Iron Dextran

Other hazards

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

4. FIRST AID MEASURES

Description of first aid measures

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.
Eye contact	Upon irritation of the eye: Remove contact lenses and open eyes widely. Flush eyes with water or saline water (20-30°C) for at least 5 minutes. Seek medical assistance and continue flushing during transport.
Skin contact	IF ON SKIN: Wash with plenty of water and soap. Remove contaminated clothing and shoes. Ensure to wash exposed skin thoroughly with water and soap. DO NOT use solvents or thinners. If skin irritation occurs: Get medical advice/attention.

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.
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Most important symptoms and effects, both acute and delayed

Headache, Methaemoglobinaemia (Phenol)

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.

Indication of any immediate medical attention and special treatment needed

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

Information to medic

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

5. FIRE FIGHTING MEASURES**Suitable Extinguishing Media:**

Alcohol-resistant foam, carbon dioxide, powder, water mist.

Unsuitable Extinguishing Media

Waterjets should not be used, since they can spread the fire.

Special hazards arising from the chemical:

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.

Advice for fire-fighters:

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.

6. ACCIDENTAL RELEASE MEASURES**Personal precautions, protective equipment and emergency procedures**

Avoid direct contact with spilled substances.

Environmental precautions

Avoid discharge to lakes, streams, sewers, etc.

Methods and materials for containment and cleaning up

Use sand, 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.

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.

7. HANDLING AND STORAGE**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.

Conditions for safe storage, including any incompatibilities

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

- A. Recommended storage material
Always store in containers of the same material as the original container.
- B. Storage temperature
Should be stored according to conditions described on the label.
- C. Incompatible materials
Strong acids, strong bases, strong oxidizing agents, and strong reducing agents.

Specific end use(s)

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

8. EXPOSURE CONTROLS/ PERSONAL PROTECTION**Control parameters**

Phenol

Long term exposure limit (8 hours) (ppm):	2
Long term exposure limit (8 hours) (mg/m ³):	7,8
Short term exposure limit (15 minutes) (ppm):	4
Short term exposure limit (15 minutes) (mg/m ³):	16

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. EH40/2005 Workplace exposure limits (Fourth Edition 2020):.

DNEL

No data available

PNEC

No data available

Exposure controls:

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

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

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

Appropriate technical measures

The formation of vapours must be kept at a minimum and below current limit values (see above). Installation of a local 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.


A. Respiratory protection

Pictogram	PPE	Standards
-	-	No specific requirements


B. Specific protection for the hands

Pictogram	PPE	Standards
 Mandatory hand protection	Nitrile gloves	EN374-2

C. Ocular and facial protection

Pictogram	PPE	Standards
 Mandatory face protection	Wear face shield alternatively safety glasses with side shields.	EN166

D. Bodily protection

Pictogram	PPE	Standards
 Mandatory complete body protection	Dedicated work clothing should be worn.	-

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties:

Physical state:	Liquid
Color:	Brown
Odor/ Odor threshold:	Characteristic
pH:	5.2-6.5
Density (g/cm³):	1.1-1.8
Kinematic viscosity:	No data available
Particle characteristics:	Does not apply to liquids.
Melting point/freezing point (°C):	No data available
Softening point/range (waxes and pastes) (°C)	Does not apply to liquids.
Boiling point:	No data available
Vapor pressure:	No data available
Relative vapour density:	No data available
Decomposition temperature (°C):	No data available
Flash Point (°C):	No data available
Ignition (°C):	No data available
Auto flammability (°C):	No data available
Upper and lower explosion limit (%w/v)	No data available
Solubility in water:	Soluble
n-octanol/water coefficient	No data available
Solubility in fat (g/L)	No data available
Evaporation rate (n-butylacetate = 100)	No data available
Other physical and chemical parameters	No data available

10. STABILITY AND REACTIVITY

Reactivity:
No data available.

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

Possibility of hazardous reactions:

No special.

Conditions to Avoid:

No special.

Incompatible Materials:

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

Hazardous decomposition products:

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

11. TOXICOLOGICAL INFORMATION**Information on hazard classes as defined in Regulation (EC) No 1272/2008:****Acute toxicity**

Product/substance	Iron Dextran
Test method	-
Species	Rat
Route of exposure	Oral
Test	LOEC
Result	60.00 mg/kg
Other information	-

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

May cause an allergic skin reaction.

Germ cell mutagenicity

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

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

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.

Information on other hazards**Long term effects**

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

Endocrine disrupting properties

No special

Other information

Iron Dextran has been classified by IARC as a group 2B carcinogen.

Phenol has been classified by IARC as a group 3 carcinogen.

12. ECOLOGICAL INFORMATION

Toxicity:

No data available

Persistence and degradability:

No data available

Bioaccumulative potential:

No data available

Mobility in soil:

No data available

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.

Endocrine disrupting properties

No special

Other adverse effects:

No special

13. DISPOSAL CONSIDERATIONS

Waste treatment methods:

Product is covered by the regulations on hazardous waste.

HP 13 – Sensitising

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

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.

14. TRANSPORT INFORMATION**Not dangerous goods according to ADR, IATA and IMDG.****ADR/RID**

Not applicable

IMDG

Not applicable

MARINE POLLUTANT

No

IATA

Not applicable

Environmental hazards

Not applicable

Special precautions for user

Not applicable

Maritime transport in bulk according to IMO instruments

No data available

15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture****Restrictions for application**

Restricted to professional users.

People under the age of 18 shall not be exposed to this product.

Demands for specific education

No specific requirements

SEVESO - Categories / dangerous substances

Not applicable

Additional information

Not applicable

Sources

The Management of Health and Safety at Work Regulations 1999
 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

Chemical safety assessment

No

16. OTHER INFORMATION

<p>Full text of H-phrases</p>	<p>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.</p>
<p>Abbreviations and Acronyms</p>	<p>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</p>

	<p>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</p>
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Additional information

The classification of the substance/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

Morten Givard / Sikma Consult / www.sikma.dk

Other

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

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Revision Date: 2024-09-26