

Venofer® Iron Sucrose Injection, USP

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations
Revision Date: 01/10/2019 Date of issue: 08/26/2014

Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Brown, sterile, aqueous solution

Product Name: Venofer® Iron Sucrose Injection, USP

Product Codes: NDC-49230-534-10, NDC-49230-534-25, NDC-49230-530-10, NDC-49230-530-25

1.2. Intended Use of the Product

Use of the substance/mixture: An iron replacement product indicated for the treatment of iron deficiency anemia in patients with chronic kidney disease (CKD).

1.3. Name, Address, and Telephone of the Responsible Party

Distributor

Fresenius Medical Care NA
Waltham, MA 02451
1-800-323-5188

Manufacturer

American Regent, Inc.
5 Ramsey Road
Shirley, NY 11967
1-800-645-1706

www.americanregent.com

1.4. Emergency Telephone Number

Emergency Number : CHEMTREC 1-800-424-9300

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification (GHS-US)

Not classified

2.2. Label Elements

GHS-US Labeling

No labeling applicable

2.3. Other Hazards

Other Hazards: Exposure may aggravate individuals with iron overload. The most common adverse reactions are diarrhea, nausea, vomiting, headache, dizziness, hypotension, pruritus, pain in extremity, arthralgia, back pain, muscle cramp, chest pain, and peripheral edema. Hemosiderosis has been observed following overdosage. Refer to package insert for more information.

2.4. Unknown Acute Toxicity (GHS-US) No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance Not applicable

3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
Water for Injection	(CAS No) 7732-18-5	98	Not classified
Saccharated iron oxide	(CAS No) 8047-67-4	2	Not classified
Sodium hydroxide	(CAS No) 1310-73-2	Used to adjust pH	Met. Corr. 1, H290 Acute Tox. 4 (Dermal), H312 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: Go into open air and ventilate suspected area. Seek medical attention.

First-aid Measures After Skin Contact: Remove contaminated clothing. Flush affected area with water for at least 15 minutes. Seek medical attention.

First-aid Measures After Eye Contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Seek medical attention.

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

Symptoms/Injuries: May cause an allergic reaction in sensitive individuals. Exposure may aggravate individuals with iron overload. The most common adverse reactions are diarrhea, nausea, vomiting, headache, dizziness, hypotension, pruritus, pain in extremity, arthralgia, back pain, muscle cramp, chest pain, and peripheral edema. Hemosiderosis has been observed following overdosage. Refer to package insert for more information.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, dry chemical, foam, carbon dioxide.

Unsuitable Extinguishing Media: A heavy water stream may spread burning liquid. CAUTION: Carbon dioxide is an asphyxiant. Lack of oxygen can be fatal.

5.2. Special Hazards Arising From the Substance or Mixture

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Firefighting Instructions: Exercise caution when fighting any chemical fire. Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Firefighters must use full bunker gear including NIOSH-approved positive-pressure self-contained breathing apparatus (SCBA) to protect against potential hazardous combustion and decomposition products.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid all unnecessary exposure. Do not breathe vapour or mist.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE) as identified in section 8.

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection. Refer to section 8: "Exposure controls/personal protection"

Emergency Procedures: Isolate the hazard area. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up

Methods for Cleaning Up: Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.

6.4. Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store in original container. Store in a dry, well-ventilated place.

Incompatible Products: Strong acids. Strong oxidizers.

Storage Temperature: 20 - 25 °C (68 - 77 °F) Excursions permitted to 15 to 30 °C.

7.3. Specific End Use(s) Pharmaceutical.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	2 mg/m ³
USA IDLH	US IDLH (mg/m ³)	10 mg/m ³
USA OSHA	OSHA PEL (TWA) (mg/m ³)	2 mg/m ³

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8.2. Exposure Controls

Appropriate Engineering Controls

: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Gloves. Safety glasses.



Hand Protection

: Wear chemically resistant protective gloves.

Eye Protection

: Chemical goggles or safety glasses.

Skin and Body Protection

: Wear suitable protective clothing. Wash contaminated clothing before reuse.

Respiratory Protection

: In case of inadequate ventilation wear respiratory protection.

Consumer Exposure Controls

: Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Brown Viscous, Aqueous
Odor	: Odorless
Odor Threshold	: No data available
pH	: 10.5 - 11.1
Relative Evaporation Rate (butylacetate=1)	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: 100 °C (212 °F)
Flash Point	: Approx. to water
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: nonflammable, noncombustible liquid
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Specific Gravity	: 1.2
Solubility	: Soluble in water
Partition coefficient: n-octanol/water	: No data available
Viscosity	: No data available

9.2. Other Information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1 Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2 Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3 Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4 Conditions to Avoid:** Direct sunlight. Extremely high or low temperatures.
- 10.5 Incompatible Materials:** Strong acids. Strong oxidizers.
- 10.6 Hazardous Decomposition Products:** Carbon oxides (CO, CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Water (7732-18-5)	
LD50 Oral Rat	> 90000 mg/kg
Sodium hydroxide (1310-73-2)	
LD50 Dermal Rabbit	1350 mg/kg

Skin Corrosion/Irritation: Not classified (pH: 10.5 - 11.1)

Serious Eye Damage/Irritation: Not classified (pH: 10.5 - 11.1)

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

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Saccharated iron oxide (8047-67-4)	
IARC group	3

Reproductive Toxicity: Not classified

Developmental: US FDA Pharmaceutical Pregnancy Category B: Iron sucrose passes into breast milk of nursing animals.

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

12.2. Persistence and Degradability

Venofer®	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Venofer®	
Bioaccumulative Potential	Not established.

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: TRANSPORT INFORMATION

14.1 In Accordance with DOT Not regulated for transport

14.2 In Accordance with IMDG Not regulated for transport

14.3 In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2 US State Regulations

Sodium hydroxide (1310-73-2)	
U.S. - Massachusetts - Right To Know List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	
U.S. - Pennsylvania - RTK (Right to Know) List	

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision date : 01/10/2019

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
H290	May be corrosive to metals
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H402	Harmful to aquatic life

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Refer to American Regent prescribing information for further information at: <http://www.americanregent.com/AllProducts.aspx>

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