SECTION 1: IDENTIFICATION

1.1. Product Identifier
Product Form: Colloidal Solution
Product Name: Venofer® (Iron Sucrose Injection, USP)
Product Codes: 0517-2340-01; 0517-2340-10; 0517-2340-25; 0517-2325-10; 0517-2310-05; 0517-2340-99

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
Company
American Regent, Inc.
5 Ramsey Road
P.O. Box 9001
Shirley, NY
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

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification (GHS-US)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water for Injection</td>
<td>(CAS No) 7732-18-5</td>
<td>qs</td>
<td>Not classified</td>
</tr>
<tr>
<td>Saccharated iron oxide</td>
<td>(CAS No) 8047-67-4</td>
<td>2% w/v Iron (Fe)</td>
<td>Not classified</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>(CAS No) 1310-73-2</td>
<td>Used to adjust pH</td>
<td>Met. Corr. 1, H290, Acute Tox. 4 (Dermal), H312, Skin Corr. 1A, H314, Eye Dam. 1, H318, Aquatic Acute 3, H402</td>
</tr>
</tbody>
</table>

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.
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 asphyxiating. 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.
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 carton at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Do not freeze.

7.3. Specific End Use(s) Pharmaceutical

SECTION 8: EXPOSURE CONTROLS/PERSOAL PROTECTION
8.1. Control Parameters

<table>
<thead>
<tr>
<th>Substance</th>
<th>ACGIH Ceiling (mg/m³)</th>
<th>NIOSH REL (ceiling) (mg/m³)</th>
<th>US IDLH (mg/m³)</th>
<th>OSHA PEL (TWA) (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide (1310-73-2)</td>
<td>2 mg/m³</td>
<td>2 mg/m³</td>
<td>10 mg/m³</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

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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 protective clothing. 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: Approx. 1.15

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: TOXICOCLOGICAL 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
**Venofer® Iron Sucrose Injection, USP**

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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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

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**SECTION 12: ECOLOGICAL INFORMATION**

**12.1. Toxicity**

<table>
<thead>
<tr>
<th>Sodium hydroxide (1310-73-2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 Fish 1</td>
</tr>
</tbody>
</table>

**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.

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**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.

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**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

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**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. - 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:**

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

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

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SDS US (GHS HazCom)