



AMERICAN REGENT, INC.

**MATERIAL SAFETY DATA SHEET**

<b>Section 1: PRODUCT AND COMPANY INFORMATION</b>	
Luitpold Pharmaceuticals, Inc. P.O. Box 9001 Shirley, New York 11967 (800) 645-1706 (631) 924-4000	Chemtrec 24/7 Emergency Telephone Number Domestic North America: (800) 424-9300 International: +1 703-527-3887
<b>PRODUCT NAME:</b>	<b>Venofer® (Iron Sucrose Injection, USP)</b>
<b>PRODUCT CODE (NDC):</b>	<b>20 mg Elemental Iron/mL: 0517-2340-10, 0517-2340-25, 0517-2310-05</b>
<b>Section 2: HAZARDS IDENTIFICATION</b>	
<b>EMERGENCY OVERVIEW</b>	
Appearance / Odor	Brown, viscous, aqueous solution.
<b>WARNING!</b>	
Skin, eye and respiratory and gastrointestinal irritant	Causes slight irritation of the eyes, skin and respiratory and gastrointestinal tracts.
Toxicity to fish/aquatic organisms	Product is not known to be toxic to fish.
<i>Potential Health Effects: See Section 11 for more information</i>	
Likely Routes of Exposure	Eye contact, skin contact, inhalation and ingestion.
Eye	Causes slight irritation of the eye.
Skin	Causes slight irritation of the skin.
Inhalation	May cause irritation of the upper and lower respiratory tract.
Ingestion	May cause irritation of the gastrointestinal tract.
Skin Absorption	Not absorbed through the skin.
Medical Conditions Aggravated by Exposure	Personnel with sensitivity to this product. Workers with iron overload and impaired kidney functions should minimize their exposure to this product.
Target Organs	Eyes, skin, kidneys, gastrointestinal tract and respiratory tract.

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<b>Section 2: HAZARDS IDENTIFICATION (continued)</b>	
<i>Potential Environmental Effects: See Section 12 for more information</i>	This product is not known to be toxic to fish.
This product <b>does</b> contain a possible carcinogen listed by IARC but not by OSHA and NTP.	
This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).	

<b>Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS</b>		
Component	CAS Number	Percentage (%) by Weight
Iron Sucrose (Venofer)	8047-67-4	2.0 percent
Sodium Hydroxide	1310-73-2	used for pH adjustment
Water for Injection	7732-18-5	98.0 percent

<b>Section 4: FIRST AID MEASURES</b>	
Eye Contact	Causes irritation. Flush for 15 minutes with copious quantities of water. Seek medical attention.
Skin Contact	May cause irritation. Remove contaminated clothing. Flush area with copious quantities of water for 15 minutes. Seek medical attention.
Inhalation	May cause irritation of respiratory tract. Remove person to fresh air. Remove contaminated clothing. Seek medical attention.
Ingestion	May cause abdominal pain, nausea, vomiting and diarrhea. Flush mouth out with water. Seek medical attention.
Injection	See prescribing information.
Note to Physicians	Exposure to this product may result in headache, dizziness and hypotension. Cardiac collapse and hemosiderosis have been observed following overdose. See prescribing information.

<b>Section 5: FIRE FIGHTING MEASURES</b>	
Suitable Extinguishing Media	Water spray, foam, dry chemical or Carbon Dioxide (CO <sub>2</sub> ). <b>Caution:</b> CO <sub>2</sub> will displace air in confined spaces and may cause an Oxygen deficient atmosphere.
Unsuitable Extinguishing Media	None.

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**Section 5: FIRE FIGHTING MEASURES (cont'd)**

Hazardous Combustion Products	When heated, Venofer® (Iron Sucrose Injection) thermally decomposes to form toxic vapors. (i.e. Carbon Monoxide, Carbon Dioxide and oxides of Nitrogen, Sulfur and Iron).
<u>Protection for Firefighters:</u> Venofer® (Iron Sucrose Injection) thermally decomposes to form toxic vapors. Vapors may be irritating to eyes and skin and toxic to respiratory tract. Firefighters are to wear self-contained breathing apparatus (SCBA) and full turn out gear (Bunker gear). Cool containers with water spray and use caution when approaching.	

**Section 6: ACCIDENTAL RELEASE MEASURES**

Personnel Precautions	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
Environmental Precautions	This material is not considered a water pollutant. However, it is recommended to prevent spilled or leaking material from entering waterways. Minimize the use of water to prevent environmental contamination.
Methods of Containment	Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions.
Methods of Clean 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 material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.
Other Information	A spill of this material does not need to be reported to the National Response Center.

**Section 7: HANDLING AND STORAGE**Handling:

As a general rule, when handling pharmaceutical products, avoid all contact and inhalation of mists or vapors associated with the product. Avoid contact with skin, eyes or clothing. Do not mix with other drugs.

Use in a well ventilated area. Wash thoroughly after handling.

Storage:

Store in a well ventilated area. Keep containers closed when not in use. Product residue may remain in empty containers. Observe all label precautions until container is cleaned, discarded or destroyed.

<b>Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION</b>			
Exposure Guidelines	OSHA PEL	ACGIH TLV	OTHER
Iron Sucrose	Not Listed	Not Listed	
Sodium Hydroxide	2 milligrams / cubic meter - 8 hour TWA	2 milligrams / cubic meter - Ceiling	
Water for Injection	Not Listed	Not Listed	
Personal Protective Equipment		Description	
Ventilation		Local exhaust or general ventilation is recommended.	
Respiratory Protection		Under normal conditions of product use, respiratory protection is not required. When required, use a NIOSH approved air purifying respirator with combination P-100 / organic vapor cartridges.	
Eye Protection		Wear ANSI approved chemical splash goggles or safety glasses.	
Skin Protection		When administering this product to patients, wear nitrile or latex gloves. Use Tyvek™ SL or equivalent coveralls, PVC booties and nitrile gloves for clean up activities.	

<b>Section 9: PHYSICAL AND CHEMICAL PROPERTIES</b>	
Color	Dark Brown
Odor / Odor Threshold	Odorless
Physical State	Viscous Liquid
pH	10.5 to 11.1
Freezing Point	Approximately 32 degrees Fahrenheit
Boiling Point	Approximately 212 degrees Fahrenheit
Flash Point	Not applicable
Evaporation Rate	Not applicable
Flammability	Nonflammable, noncombustible
Upper Flammable Limit	Not applicable
Lower Flammable Limit	Not applicable
Vapor Pressure	Not applicable
Vapor Density	Not applicable
Specific Gravity	Approximately 1.2
Solubility (water)	Freely soluble in water
Partition Coefficient	Not applicable
Auto-ignition Temperature	Not applicable
Percent Volatile	0 percent
Volatile Organic Compounds (%)	0 percent

<b>Section 10: STABILITY AND REACTIVITY</b>	
Stability	Stable.
Conditions to Avoid	Do not mix with other drugs. Avoid heat, light and humidity. Keep away from flames, thermally decomposes to form toxic vapors.
Incompatible Materials	Reactive with oxidizers.
Hazardous Decomposition Products	Carbon Monoxide, Carbon Dioxide, oxides of Nitrogen, Iron and Sulfur may be released by thermal decomposition.
Possibility of Hazardous Reactions	Hazardous polymerization will not occur.
<b>Section 11: TOXICOLOGY INFORMATION</b>	
<b>Acute Effects</b>	
Oral (LD <sub>50</sub> )	No data available
Intraperitoneal (LD <sub>50</sub> )	No data available
Intravenous (LD <sub>50</sub> )	No data available
Dermal (LD <sub>50</sub> )	No data available
Inhalation	Respiratory irritation is possible.
Eye Irritation	Eye irritation is possible.
Skin Irritation	Skin irritation is possible.
Sensitization	Some personnel may have sensitivity to this product.
<b>Chronic Effects</b>	
Organ Systems	Prolonged or repeated exposure may lead to hemosiderosis.
Carcinogenicity	Iron complexes such as Iron Sucrose are considered possibly carcinogenic by IARC. No adequate and well controlled studies in humans have been conducted.
Mutagenicity	No adequate and well controlled studies in humans regarding the mutagenic effects of Iron Sucrose. Sodium Chloride is considered mutagenic for mammalian somatic cells, bacteria and yeast.
Reproductive Effects	No adequate and well controlled studies in humans have been conducted to determine whether Iron Sucrose is a reproductive toxin. In laboratory animals, Iron Sucrose passes into breast milk of nursing mothers.
Developmental Effects	No adequate and well controlled studies in humans have been conducted to determine whether Iron Sucrose is a teratogen. Classified as Pregnancy Category B.

<b>Section 12: ECOLOGICAL INFORMATION</b>	
Ecotoxicity	No data available.
Persistence / Degradability	Short term products of biodegradation are not likely. Long term degradation products may arise but are not as toxic as the product itself.
Bioaccumulation / Accumulation	No applicable bioaccumulation is expected in the environment.
Mobility in Environment	Appreciable volatilization is not expected into the air.

<b>Section 13: DISPOSAL CONDITIONS</b>	
Disposal	Do not mix with other substances. Dispose of in accordance with Federal, state and local regulations. Contact your state or local government environmental and / or sanitation department for guidance on disposal.

<b>Section 14: TRANSPORTATION INFORMATION</b>	
<b>Regulatory Agency</b>	<b>Shipping Description</b>
US DOT (ground)	Not considered a DOT regulated material - Non hazardous for shipment.
Canadian TDG (ground)	See US DOT.
IATA (air)	Not considered a DOT regulated material - Non hazardous for shipment.

<b>Section 15: REGULATORY INFORMATION</b>	
STATE RIGHT TO KNOW	Refer to the applicable state to determine applicability.
California Safe Drinking Water & Toxic Enforcement Act (Prop 65)	This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins under California Proposition 65.
RTECS Number	No data available
TSCA	8b Inventory - Not listed
NFPA Rating	Health - 1, Fire - 0, Reactivity - 0
WHMIS (Canada)	Not controlled

**Section 16: OTHER INFORMATION**

Venofer® (Iron Sucrose Injection, USP) is indicated in the treatment of iron deficiency anemia in the following patients:

- non-dialysis dependent-chronic kidney disease (NDD-CKD) patients receiving an erythropoietin
- non-dialysis dependent-chronic kidney disease (NDD-CKD) patients not receiving an erythropoietin
- hemodialysis dependent-chronic kidney disease (HDD-CKD) patients receiving an erythropoietin
- peritoneal dialysis dependent-chronic kidney disease (PDD-CKD) patients receiving an erythropoietin.

Refer to Luitpold / American Regent's prescribing information for further information at [http://www.americanregent.com/product\\_index.asp](http://www.americanregent.com/product_index.asp)

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*The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall Luitpold, its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if Luitpold has been advised of the possibility of such damages.*