Luitpold Pharmaceuticals

AMERICAN REGENT, INC.

MATERIAL SAFETY DATA SHEET

Section 1: PRODUCT AND COMPANY INFORMATION

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

PRODUCT NAME: **Dexferrum® (Iron Dextran Injection, USP)**

PRODUCT CODE (NDC): **50 mg Elemental Iron/mL: 0517-0134-10, 0517-0234-10**

Section 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Appearance / Odor	Dark brown, slightly viscous solution.
WARNING!	
Skin, eye and respiratory irritant	Causes slight irritation of the eyes, skin and respiratory tract.
Toxicity to fish/aquatic organisms	Product is not known to be toxic to fish.
Potential Health Effects: See Section 11 for more information	
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	Workers with impaired liver function should minimize their exposure to this product. Personnel with sensitivity to this product.
Target Organs	Eyes, skin, kidneys, mucous membranes, upper and lower respiratory tract.

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Section 2: HAZARDS IDENTIFICATION (continued)	
Potential Environmental Effects: See Section 12 for more information	This product is not known to be toxic to fish.
This product **does** 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).	

Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS		
Component	CAS Number	Percentage (%) by Weight
Iron Dextran (Dexferrum)	9004-66-4	5.0 percent
Sodium Chloride	7647-14-5	0.9 percent
Sodium Hydroxide	1310-73-2	used for pH adjustment
Hydrochloric Acid	7647-01-0	used for pH adjustment
Water for Injection	7732-18-5	94.1 percent

Section 4: FIRST AID MEASURES	
Eye Contact	Causes irritation. Flush for 15 minutes with copious quantities of water. Seek medical attention.
Skin Contact	May cause irritation, rash, or urticaria (hives). Remove contaminated clothing. Flush area with copious quantities of water for 15 minutes. Seek medical attention.
Inhalation	May cause irritation of respiratory tract. Rhinitis, dyspnea, wheezing and respiratory arrest are possible with inhalation exposures. Remove person to fresh air. Remove contaminated clothing. Seek medical attention.
Ingestion	May cause abdominal pain, nausea, vomiting and diarrhea. Soluble iron salts can damage the walls of the stomach and small intestine. 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. Hemosiderosis may be observed following large exposures. Anaphylactic-type reactions, including fatalities have followed the parenteral administration of iron dextran injection. See prescribing information.

Section 5: FIRE FIGHTING MEASURES	
Suitable Extinguishing Media	Water spray, foam, dry chemical or Carbon Dioxide (CO_2). **Caution:** CO_2 will displace air in confined spaces and may cause an Oxygen deficient atmosphere.
Unsuitable Extinguishing Media	None.
Hazardous Combustion Products	When heated, Dexferrum® solution thermally decomposes to form toxic vapors. (i.e. Carbon Monoxide, Carbon Dioxide, Nitrogen oxides and oxides of Sulfur).

Protection for Firefighters: Dexferrum® solution 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.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION			
Exposure Guidelines	OSHA PEL	ACGIH TLV	OTHER
Iron Dextran	Not listed	Not listed	
Sodium Chloride	Not listed	Not listed	
Hydrochloric Acid	5 parts per million - Ceiling	2 parts per million - Ceiling	
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, use latex or nitrile gloves. Use Tyvek™ SL or equivalent coveralls, PVC booties and nitrile gloves for clean up activities.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES	
Color	Dark brown, slightly viscous solution.
Odor / Odor Threshold	Odorless
Physical State	Liquid
pH	4.5 to 7.0
Freezing Point	Highest known value is 32 degrees Fahrenheit (Water for Injection)
Boiling Point	Lowest known value is 212 degrees Fahrenheit (Water for Injection)
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 1.1
Solubility (water)	Freely soluble in water, ethanol
Partition Coefficient	Not applicable
Auto-ignition Temperature	Not applicable
Percent Volatile	0 percent
Volatile Organic Compounds (%)	0 percent

Section 10: STABILITY AND REACTIVITY	
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, Nitrogen oxides and oxides of Sulfur may be released by thermal decomposition.
Possibility of Hazardous Reactions	Hazardous polymerization will not occur.

Section 11: TOXICOLOGY INFORMATION		
Acute Effects		
Oral (LD_{50})	LD_{50}:	1000 mg/kg oral - mouse
Subcutaneous (LD_{50})	No data available	
Intravenous (LD_{50}/LD_{Lo})	LD_{50}: LD_{Lo}:	Not less than 500 mg/kg intravenous - mouse 500 mg/kg intravenous - rabbit
Intramuscular (LD_{Lo})	LD_{Lo}:	1617 mg/kg intramuscular - rat
Intraperitoneal (LD_{50})	LD_{50}:	3000 mg/kg intraperitoneal - rat
Dermal (LD_{50})	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.	
Chronic Effects		
Organ Systems	Prolonged or repeated exposure may lead to hemosiderosis.	
Carcinogenicity	Iron Dextran is considered possibly carcinogenic by IARC. No adequate and well controlled studies in humans have been conducted.	
Mutagenicity	One animal cell study classified iron dextran as mutagenic. No adequate and well controlled studies in humans regarding the mutagenic affects of Iron Dextran. Sodium Chloride is considered mutagenic for mammalian somatic cells, bacteria and yeast.	

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Section 11: TOXICOLOGY INFORMATION (continued)	
Reproductive Effects	No adequate and well controlled studies in humans have been conducted to determine whether Iron Dextran is a reproductive toxin. Iron Dextran passes into breast milk of nursing mothers.
Developmental Effects	Iron Dextran was found to be teratogenic in animal studies. No adequate and well controlled studies in humans. Classified as Pregnancy Category C.

Section 12: ECOLOGICAL INFORMATION	
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.

Section 13: DISPOSAL CONDITIONS	
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.

Section 14: TRANSPORTATION INFORMATION	
Regulatory Agency	**Shipping Description**
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.

Section 15: REGULATORY INFORMATION	
STATE RIGHT TO KNOW	Refer to the applicable state to determine applicability.
California Safe Drinking Water & Toxic Enforcement Act (Prop 65)	Iron Dextran (Dexferrum) is currently listed as a carcinogen under California Proposition 65.
RTECS Number	NI2200000
TSCA	8b Inventory - Iron Dextran
NFPA Rating	Health - 1, Fire - 1, Reactivity - 0
WHMIS (Canada)	D-2A - Causes other toxic effects.

Section 16: OTHER INFORMATION

Dexferrum® **(**Iron Dextran Injection, USP) is indicated for treatment of patients with documented iron deficiency in whom oral administration is unsatisfactory or impossible.

Refer to Luitpold / American Regent's prescribing information for further information at http://www.americanregent.com/product_index.asp

Prepared By: Christopher Seniuk CIH CSP

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.