SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, European Union CLP EC 1272/2008 and the Global Harmonization Standard

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

TRADE/MATERIAL NAME:

INFeD® (IRON DEXTRAN INJECTION, USP) 50 mg/mL 10 x 2 mL

DESCRIPTION: Iron Dextran Complex Solution
OTHER DESIGNATIONS: NDC:52544-931-02
CHEMICAL NAME: Ferric Hydroxide Oxide-Dextran
CHEMICAL FAMILY: Iron-Carbohydrate Mixture
HOW SUPPLIED: 2.0 mL in Single Dose Vials
FORMULA: Unknown; Variable (Contains Iron, Carbon, Oxygen, Hydrogen)

SUPPLIER OF THE SAFETY DATA SHEET

RESPONSIBLE PARTY U.S.: **ALLERGAN**
U.S. ADDRESS: 5 Giralda Farms, Madison, NJ 07940, USA
U.S. BUSINESS PHONE/GENERAL SDS INFORMATION: 1-800-272-5525
RESPONSIBLE PARTY EUROPE:
EUROPEAN ADDRESS:
e-mail: SafetyDataSheets@allergan.com
EUROPEAN BUSINESS PHONE:
EMERGENCY PHONE (U.S./NORTH AMERICA): CHEMTREC: 1-800-424-9300 (24 hours) U.S., Canada, Puerto Rico
EMERGENCY PHONE (OUTSIDE U.S.): CHEMTREC: +1-703-527-3887 (24 hours) Outside North America

NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, Canadian WHMIS [Controlled Products Regulations], EU Directives through EC 1907: 2006, and European Union CLP EC 1272/2008, required information is included in appropriate sections based on the U.S. ANSI Z400.1-2010 format. This product has been classified in accordance with the hazard criteria of the countries listed above.

DATE OF PREPARATION: August 24, 2016 **DATE OF REVISION:** September 24, 2018

2. HAZARD IDENTIFICATION

EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.
Classification: Not Applicable Signal Word: Not Applicable Hazard Statement Codes: Not Applicable

EU LABELING AND CLASSIFICATION 67/548/EEC: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.
Classification: Not Applicable Risk Phrases: Not Applicable Safety Phrases: Not Applicable

See Section 16 for full EU classification information of product and components and full text of hazard and precautionary statements.

EMERGENCY OVERVIEW:

Product Description: INFeD (Iron Dextran Injection, USP) is a dark-brown, slightly viscous liquid complex of Ferric Hydroxide and Dextran.

Health Hazards: The primary health hazard associated with industrial exposure to this material is the potential for mild irritation of contaminated skin or eyes. Iron Dextran is possibly carcinogenic to humans when administered via intravenous injection, especially if injected repeatedly at the same site.

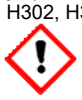
Flammability Hazards: n the event of a fire, this product may emit toxic gases (e.g., carbon oxides and iron compounds).

Reactivity Hazards: This product is not reactive.

Environmental Hazards: Large quantities released to the aquatic and terrestrial environment may have an adverse effect.

Emergency Considerations: Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/v	EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements/Symbol
Iron Dextran	9004-66-4	Unlisted	20-30 (elemental iron concentration is 5.0%)	SELF CLASSIFICATION EU 67/548 Classification: Harmful Risk Phrases: R38& R36; R22 Hazard Symbol:  EU/GHS 1272/2008 Signal word: Warning Classification: Acute Oral Toxicity Category 4, Skin & Eye Irritation Category 2. Hazard Statement Codes: H302, H315, H319 Hazard Symbol/Pictogram: 
Sterile Water and other components which are each present in less than 1 percent concentration (or 0.1% concentration for potential carcinogens, reproductive toxins, respiratory tract sensitizers, and mutagens).			Balance	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable

See Section 16 for full EU classification information of product and components.

4 FIRST-AID MEASURES

Persons who are exposed to this product should seek medical attention if any adverse health effects occur. In the event medical attention is sought, the physician or health care professional should receive a copy of this product's label and this MSDS. The following information is provided for care of persons overexposed to this product.

SKIN EXPOSURE: If adverse skin effects occur, rinse affected area with soap and water. Seek medical attention.

EYE EXPOSURE: If this product contaminates the eyes, open eyes under gently running water. Use sufficient force to open eyelids and then "roll" while flushing eyes. Minimum flushing is for 15 minutes if the exposure has resulted in an adverse effect. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

INHALATION: If mists or sprays of this product are inhaled, remove the contaminated individual to fresh air. Seek medical attention if adverse effect occurs.

INGESTION: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain immediate medical attention.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Conditions that may be aggravated can include anemias not associated with iron deficiency, impaired liver function, Infectious kidney disease, : Cardiovascular disease, persons with pre-existing, hemoglobinopathies and other refractory anemias, **r**heumatoid arthritis.

RECOMMENDATIONS TO PHYSICIANS: This product should only be used by persons experienced in management of patients receiving the type of therapy intended for this product. In the event of an occupational overexposure, treat symptoms and eliminate overexposure. When administered therapeutically, readiness for anaphylactic allergic reaction must be planned for. Immediate administration of Epinephrine should be used in the event of acute hypersensitivity reactions.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not applicable.

AUTOIGNITION TEMPERATURE: Not established.

FLAMMABLE LIMITS (in air by volume, %):

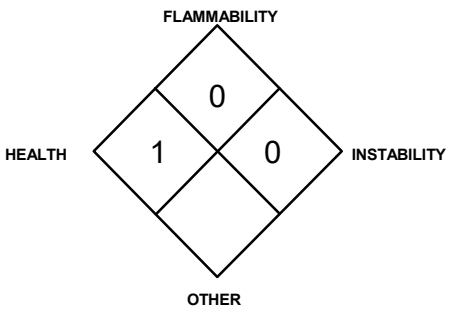
Lower (LEL): Not applicable.
Upper (UEL): Not applicable.

FIRE EXTINGUISHING MATERIALS: Use extinguishing media appropriate for surrounding fire.

Water Spray: OK Carbon Dioxide: OK Foam: OK
Dry Chemical: OK Halon: OK Other: Any "ABC" Class

UNUSUAL FIRE AND EXPLOSION HAZARDS: This product may is not flammable. At extremely high temperatures this product will decompose to produce irritating vapors and toxic gases (e.g., carbon oxides, iron compounds).

NFPA RATING



Hazard Scale: **0** = Minimal **1** = Slight
2 = Moderate **3** = Serious **4** = Severe

5. FIRE-FIGHTING MEASURES (Continued)

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

SPECIAL FIRE-FIGHTING PROCEDURES: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

6. ACCIDENTAL RELEASE MEASURES

SPILL RESPONSE: For small releases of this compound (1 vial), wear double latex or butyl rubber gloves and safety glasses. Clean-up solution with a damp sponge, polypad, or other appropriate material for small spills and place in a bag and hold for waste disposal. Avoid producing sprays or mists of this product during cleanup. In case of a large spill, clear the affected area and protect people. Large or uncontrolled releases should be responded to by trained personnel using pre-planned procedures. Proper protective equipment should be used, including double butyl rubber gloves, full body gown, and full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator in event of a large spill. Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Dispose of in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of the EC and its member states or Canada and its Provinces.

7. HANDLING and USE

NOTE: Consistent with the OSHA Bloodborne Pathogen regulation (29 CFR 1910.1030), observe Universal Precautions while using this product. Place used or product-contaminated hypodermic needles and syringes in a rigid “Sharps” container. Do not recap or clip used or product-contaminated hypodermic needles.

WORK AND HYGIENE PRACTICES: As with all chemicals, avoid getting this material ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling this product or equipment and containers of this compound. Follow SPECIFIC USE INSTRUCTIONS supplied with compound. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Operations of high risk associated with the use of this product include:

- Manual manipulation (measuring, transferring, etc.) of reconstituted drug product; and
- Opening ampoules.

Use of this product should meet the following provisions:

- Work should be performed in a designated area for working with hazardous drugs or potent compounds;
- Containment devices, such as a Biological Safety Cabinet, Ventilated Enclosures should be used;
- Contaminated waste must be properly handled; and

Work areas must be regularly decontaminated.

STORAGE AND HANDLING PRACTICES: Employees must be trained to properly use this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Operations associated with the use of this product when dissolved in water include withdrawal of needles from drug vials, drug transfers using syringes and needles, and expulsion of air from drug-filled syringes. Use of this product should be performed in a designated area for working with drugs. Contaminated waste must be properly handled. Work areas must be regularly decontaminated. Ensure vials are properly labeled. Store this product away from incompatible materials (see Section 10, Stability and Reactivity). Store this product in original container, at controlled room temperature of 15-30°C (59-86°F). Avoid freezing and excessive heat. Protect from light.

PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials, and other disposable items contaminated with this product should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this MSDS.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/GUIDELINES:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR									
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	AIHA WEELs		OTHER
		TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	IDLH mg/m^3	TWA mg/m^3	STEL mg/m^3	$\mu g/m^3$
Iron Dextran	9004-66-4	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Sterile Water and other components which are each present in less than 1 percent concentration (or 0.1% concentration for potential carcinogens, reproductive toxins, respiratory tract sensitizers, and mutagens).		None of the other components contribute significant additional hazards at the concentrations present in this product. All pertinent hazard information has been provided in this document, per the requirements of the Federal Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards; Canadian Workplace Hazardous Materials Identification System Standards (CPR 4); and the applicable Council Directives of the European Community.									

NE = Not Established. See Section 16 for Definitions of Terms Used.

INTERNATIONAL OCCUPATIONAL EXPOSURE LIMITS: Currently there are no international exposure limits for the components of this product.

RESPIRATORY PROTECTION: A respirator is not required for routine conditions of use of this product.

EYE PROTECTION: For situations in which excessive splashes or sprays may be generated, wear chemical splash goggles, or regular splash goggles.

HAND PROTECTION: For situations in which prolonged skin contact is anticipated, double glove, using latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. Gloves should cover the gown cuff.

BODY PROTECTION: Use appropriate protective clothing for the task (e.g., lab coat, etc.)

9. PHYSICAL and CHEMICAL PROPERTIES

BOILING POINT: ≈ 0°C (32°F)

FREEZING/MELTING POINT: ≈ 100°C (≈ 212°F)

EVAPORATION RATE (nBuAc = 1): Similar to water.

SOLUBILITY IN WATER: Soluble.

VAPOR PRESSURE (air = 1): Not determined.

SPECIFIC GRAVITY (water = 1): 1.013

ODOR THRESHOLD: Not established.

pH: 5.2-6.5

MOLECULAR WEIGHT: ~ 165,000 g/mole $\pm$ 10%

COEFFICIENT WATER/OIL DISTRIBUTION: Not determined.

APPEARANCE, ODOR and COLOR: This product is dark-brown, odorless, slightly viscous solution.

HOW TO DETECT THIS SUBSTANCE (warning properties): The color of this solution is a distinguishing characteristic.

10. STABILITY and REACTIVITY

STABILITY: This product is stable when properly stored (see Section 7, Handling and Storage).

DECOMPOSITION PRODUCTS: When heated to decomposition temperatures, this product will emit carbon dioxide, carbon monoxide, nitrogen oxides, and sulfur and nitrogen compounds.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. Acids, caustics, and other chemicals that could affect its performance should be avoided. This product is incompatible with material incompatible with water and strong oxidizers.

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Heat may cause this product to decompose, destroying the compound and producing irritating vapors and toxic gases. Avoid contact with incompatible chemicals.

11. TOXICOLOGICAL INFORMATION

GENERAL TOXICITY INFORMATION: The following is general toxicity effects reported from therapeutic use of Iron Dextran Complex.

Cardiovascular Effects: Chest pain, chest tightness, shock, cardiac arrest, hypotension, hypertension, tachycardia, bradycardia, flushing and arrhythmias (flushing and hypotension can occur from too rapid of intravenous injection).

Dermatologic Effects: Urticaria, pruritus, purpura rash and cyanosis.

Gastrointestinal Effects: Abdominal pain, nausea, vomiting and diarrhea.

Hematological/Lymphatic Effects: Leukocytosis, lymphadenopathy.

Musculoskeletal/Soft Tissue Effects: Arthralgia, arthritis (may activate previously dormant rheumatoid arthritis), myalgia, backache, sterile abscesses, atrophy/fibrosis at intramuscular injection site, brown skin and/or underlying tissue, discoloration, cellutitis, swelling, inflammation, local phlebitis at or near injection site.

Neurologic Effects: Convulsions, seizures, syncope, headache, weakness, unresponsiveness, paresthesia, febrile episodes, chills, dizziness, disorientation, numbness, unconsciousness.

Respiratory Effects: Respiratory arrest, dyspnea, bronchospasms, wheezing.

Urologic Effects: Hematuria.

Delayed Reactions: Arthralgia, backache, chills, dizziness, fever, headache, malaise, myalgia, nausea, vomiting

Miscellaneous Effects: Febrile episodes, sweating, shivering, chills, malaise, altered taste.

11. TOXICOLOGICAL INFORMATION (Continued)

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees using this product in an occupational setting. This product is designed to be administered via intravenous or intramuscular injections. The following paragraphs describe the symptoms of exposure, via route of entry, for relatively high doses of this product.

INHALATION: Inhalation of mists or sprays containing this product may mildly irritate the mucous membranes and upper respiratory tract. Symptoms of such overexposure may include coughing and sneezing.

CONTACT WITH SKIN or EYES: Skin or eye contact with this product may be irritating. Symptoms of eye contact may include redness, pain, and watering. Symptoms of skin contact may include redness, itching, and numbness of contaminated area. Prolonged, repeated skin contact with product may cause persistent irritation.

SKIN ABSORPTION: Skin absorption is not reported to contribute significantly to overall exposure for Iron Dextran.

INGESTION: Ingestion is not a likely route of occupational exposure for this product. Should this product be swallowed, as a result of poor hygiene, symptoms of such exposure may include nausea, vomiting, and diarrhea.

INJECTION: Depending on the dose of injection, this product may cause reddening, local swelling, and symptoms described under "Other Potential health Effects". Therapeutic injection of this Iron Dextran Complex has resulted in severe allergic-type reactions, including anaphylactic shock and fatality in certain susceptible people. Accidental arterial injection of this product may be life-threatening. If injection of therapeutic doses occur, symptoms described under "Other Potential Health Effects" may develop.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	1
FLAMMABILITY HAZARD	(RED)	0
PHYSICAL HAZARD	(YELLOW)	0

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate
3 = Serious **4** = Severe * = Chronic hazard

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: Employees administering the product should not experience adverse effects if handled properly. Severe, allergic anaphylactic reactions have been reported with the use of Iron Dextran Injection; on occasion, the reaction has been fatal. Symptoms which may be experienced by individuals receiving therapeutic doses of this product include the following: chest pains, chest tightness, shock, hypotension, tachycardia, flushing, arrhythmias, rashes, welts, joint and muscle pain, back pain, brown skin and/or underlying tissue discoloration, headache, weakness, fever, chills, dizziness, nausea, vomiting, sweating, shivering, chills, malaise, and altered taste.

Large IV doses, such as used with total dose infusions, associated with an increased incidence of adverse effects. Such adverse effects frequently are delayed (1-2 days) reactions typified by one or more of the following: arthralgia, backache, chills, dizziness, moderate to high fever, headache, malaise, myalgia, nausea, and vomiting. Onset usually is 24-48 hours after administration, and symptoms generally subside within 3-4 days. Symptoms also reported following intramuscular injection and generally subside within 3-7 days. Etiology of reactions is not known. See Section 11 (Toxicological Information) for more detailed description of general toxicity information for this product.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Overexposure to this product may cause the following health effects:

ACUTE: Slight irritation of contaminated skin and eyes is the primary health effect anticipated for occupational exposures to this product. Overexposure to this product may cause coughing, sneezing, skin irritation, eye irritation, and gastric distress.

CHRONIC: There is a risk of carcinogenesis associated with intramuscular injection of iron-carbohydrate complexes, especially when the same injection site is used repeatedly. Use of this product may create the onset of dormant rheumatoid arthritis in persons with this disease. This product has produced embryotoxic and teratogenic toxicity effects in animal tests. See Section 11 (Toxicological Information) for additional information.

TARGET ORGANS: ACUTE: Industrial Exposure: Skin, eyes. Therapeutic Doses: Central nervous system and blood. CHRONIC: Industrial Exposure: Skin. Therapeutic Doses: Blood, cardiovascular system, liver, kidneys, joints.

IRRITANCY OF PRODUCT: This product may be slightly irritating to contaminated tissue.

SENSITIZATION OF PRODUCT: Therapeutic injection of this Iron Dextran Complex has resulted in severe allergic-type reactions, including anaphylactic shock and fatality in certain susceptible people. Accidental arterial injection of this product may be life-threatening.

TOXICITY DATA: This MSDS presents Human and LD_{50} Oral-Mouse, LD_{50} Intraperitoneal-Mouse and LD_{50} Intravenous-Mouse toxicity data currently available for the active component, Iron Dextran Complex. Additional data are available for the components of this product, but are not presented in this MSDS. Contact Allergan

Pharmaceuticals for more information.

11. TOXICOLOGICAL INFORMATION (Continued)

TOXICITY DATA (Continued):

IRON DEXTRAN:
TD (Intramuscular-Woman) 52 mg (Fe)/kg/6 weeks-intermittent: Tumorigenic: Carcinogenic by RTECS criteria, tumors at site of application

IRON DEXTRAN (continued):
TDLo (Intramuscular-Woman) 20 mg/kg/3 years-intermittent: Tumorigenic: neoplastic by RTECS criteria; Tumorigenic: tumors at site of application

IRON DEXTRAN (continued):
LD_{50} (Intraperitoneal-Rat) 3 gm (Fe)/kg
LD_{50} (Oral-Mouse) 1 gm (Fe)/kg
LD_{50} (Intravenous-Mouse) 460 mg(Fe)/kg

SUSPECTED CANCER AGENT: A risk of carcinogenesis may attend the intramuscular injection of iron-carbohydrate complexes. Such Complexes have been found under experimental conditions to produce sarcoma when large doses or small doses, injected repeatedly at the same site, were given to rats, mice, rabbits, and possibly hamsters. The long latent period between the injection of a potential carcinogen and the appearance of a tumor makes it impossible to measure accurately the risk in man. There have, however, been several reports in the literature describing tumors at the injection site in humans who have previously received intramuscular injections of iron-carbohydrate complexes. Iron Dextran is listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

IARC-2B (Possibly Carcinogenic to Humans); NTP-R (Reasonably Anticipated to Be a Human Carcinogen)

The remaining components of this product are not found on the following lists: FEDERAL OSHA Z LIST, NTP, IARC, and CAL/OSHA and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

REPRODUCTIVE TOXICITY INFORMATION: Iron Dextran Complex is rated Pregnancy Category C (Risk Cannot Be Ruled Out). Listed below is information concerning the effects Iron Dextran Complex on human and animal reproductive systems.

Mutagenicity: This product is not reported to be mutagenic in therapeutic doses.

Embryotoxicity: The components of this product are not reported to be mutagenic to humans in therapeutic doses. Iron Dextran has been shown to be embryotoxic and teratogenic in studies with mice, rats, rabbits, dogs and monkeys in doses that are approximately 3 times the maximum human dose. No consistent adverse fetal effects were observed in mice, rats, rabbits, dogs and monkeys at doses of 50 mg iron/kg or less.

Teratogenicity: The components of this product are not reported to be teratogenic to humans in therapeutic doses. Fetal and maternal toxicity has been reported in monkeys at a total intravenous dose of 90 mg iron/kg over a 14 day period. Similar effects were observed in mice and rats on administration of single doses of a single dose of 125 mg/kg. Fetal abnormalities in rats and dogs were observed at doses of 250 mg iron/kg and higher.

Reproductive Toxicity: This product is not reported to cause reproductive toxicity effects in humans. Non-metabolized iron can be found in breast milk of mothers using the medication. This product should be used with caution in nursing women. Various animal studies and studies involving pregnant women have demonstrated inconclusive results with respect to placental transfer of Iron Dextran. In studies it appears that some iron reaches the fetus, but it is unclear the form of iron that crosses the placenta.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, there are no ACGIH Biological Exposure Indices (BEIs) have been determined for the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

ENVIRONMENTAL STABILITY: This product should decompose over time in the environment. There are no environmental stability data currently available for the active component of this product.

EFFECT OF MATERIAL ON PLANTS or ANIMALS: No specific information is currently available on the effect of Iron Dextran Complex on plants or animals in the environment. This compound may be harmful or fatal to contaminated plant and animal life.

EFFECT OF CHEMICAL ON AQUATIC LIFE: No information is currently available on the effect of this product on aquatic plants or animals in the environment. Release of this product to an aquatic environment may be harmful to aquatic plant and animal life in contaminated bodies of water, especially in large quantities.

13. DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of the EC and its member states or Canada and its Provinces. This product, if unaltered by handling, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All gowns, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. Handle as if capable of transmitting infectious agents. Incineration is recommended. Reusable equipment should be cleaned with soap and water.

U.S. EPA WASTE NUMBER: Not applicable to wastes consisting only of this product.

14. TRANSPORTATION INFORMATION

THIS PRODUCT IS NOT HAZARDOUS AS DEFINED BY 49 CFR 172.101 BY THE U.S. DEPARTMENT OF TRANSPORTATION.

PROPER SHIPPING NAME: Not Regulated
HAZARD CLASS NUMBER and DESCRIPTION: Not Applicable
UN IDENTIFICATION NUMBER: Not Applicable
PACKING GROUP: Not Applicable
DOT LABEL(S) REQUIRED: Not Applicable
EMERGENCY RESPONSE GUIDEBOOK NUMBER (2000): Not Applicable

MARINE POLLUTANT: No component of this product is classified by the U.S. DOT as a Marine Pollutant

14. TRANSPORTATION INFORMATION (Continued)

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not considered as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is not considered as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is not considered by the United Nations Economic Commission for Europe to be dangerous goods.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for any component of this product. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. SARA EXTREMELY HAZARDOUS REPORTABLE QUANTITY: Not applicable.

U.S. CERCLA REPORTABLE QUANTITIES (RQ): Phenol = 1000 lb (454 kg)

U.S. TSCA INVENTORY STATUS: This product is regulated under Food and Drug Administration standards; it is not subject to requirements under TSCA.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): The Iron Dextran Complex component of this product is on the California Proposition 65 lists. WARNING! Contains a chemical known to the state of California to cause cancer.

OTHER U.S. FEDERAL REGULATIONS: Based on this compound's use, the requirements of the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) are applicable.

CANADIAN REGULATIONS:

CANADIAN DSL INVENTORY STATUS: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it excepted from requirements of the DSL/NDSL Inventory.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: The components of this product are not on the CEPA Priorities Substances Lists.

OTHER CANADIAN REGULATIONS: Not applicable.

CANADIAN WHMIS CLASSIFICATION AND SYMBOL: Class D2B (Materials Causing Other Toxic Effects)

16. OTHER INFORMATION

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): CAUTION! MAY BE HARMFUL IF INHALED, INGESTED, OR ACCIDENTALLY INJECTED. MAY CAUSE SKIN AND EYE IRRITATION. CAN CAUSE SEVERE ALLERGIC REACTIONS. CONTAINS A CHEMICAL WHICH IS POSSIBLY CARCINOGENIC TO HUMANS. Risk of cancer depends on dose of exposure and duration of contact. Do not taste or swallow. Do not get on skin, in eyes, or on clothes. Avoid prolonged or repeated skin contact. Avoid breathing mists or sprays. Keep container closed. Use only with adequate ventilation. Wash thoroughly after handling. If necessary, wear gloves, goggles, and appropriate body protection. Store containers in a cool location, tightly closed, away from direct light. **FIRST-AID:** In case of contact, immediately flush skin or eyes with plenty of water. If inhaled, remove to fresh air. If ingested, do not induce vomiting. Get medical attention if necessary. **IN CASE OF FIRE:** Use water fog, dry chemical, CO_2, or “alcohol” foam. **IN CASE OF SPILL:** Absorb spill with polypads and place in suitable container. Consult Safety Data Sheet for additional information.

EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU LABELING AND CLASSIFICATION 67/548/EEC: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

16. OTHER INFORMATION (Continued)

COMPONENT GLOBAL HARMONIZATION, EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION FULL TEXT:

Iron Dextran:

Signal Word: Warning

Classification: Acute Oral Toxicity Category 4; Skin and Eye Irritation Category 2

Hazard Statements: H302; H315; H319

Precautionary Statements: P280: Wear protective gloves/protective clothing/eye protection/face protection; P260: Do not breathe dust; P262: Do not get in eyes, on skin, or on clothing

Hazard Symbol/Pictograms: 

ALL OTHER COMPONENTS:

These components do not meet the criteria for classification of hazardous.

COMPONENT EU 67/548/EEC LABELING AND CLASSIFICATION FULL TEXT:

Iron Dextran:

Hazard Classification: Harmful

Risk Phrases: R38; R36; R22

Hazard Symbol: 

EU Safety Phrases: NA

ALL OTHER COMPONENTS:

EU Classification: An official classification for these substances has not been published in Commission Directives.

REFERENCES AND DATA SOURCES: Contact the supplier for information.

METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

REVISION DETAILS: Updated with GHS

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DATE OF PRINTING: September 24, 2018