



MATERIAL SAFETY DATA SHEET

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1. PRODUCT IDENTIFICATION

Product Name(s): Ferrlecit[®]
Synonyms: Sodium ferric gluconate complex in sucrose injection

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2. HAZARDS IDENTIFICATION

Emergency Overview No hazards expected. Supplied as colorless glass ampules. Each ampule contains 62.5 mg (12.5 mg/mL) of elemental iron in 5 mL of aqueous sucrose solution.

Eye No data for determination of unusual hazard to the eyes is available at this time.

Skin Contact No adverse dermal effects are known.

Skin Absorption Not expected.

Ingestion Not intended for oral use but expected to be non-toxic by ingestion.

Inhalation Not an expected route of exposure.

Chronic Effects/ Carcinogenicity None known.

Medical Conditions Aggravated by Exposure Previous sensitivity to iron dextran.

3. COMPOSITION / INFORMATION ON INGREDIENTS

CHEMICAL IDENTITY	CAS#
Sodium ferric gluconate complex	34089-81-1
Water for Injection	7732-18-5
Sucrose	57-50-1
Benzyl alcohol	100-51-6

None of the components are listed as carcinogens by IARC, NTP or OSHA.

4. FIRST AID MEASURES

Eyes Flush with water for 15 minutes. If irritation develops, seek medical attention.

Skin Wash with soap and water. If irritation develops, seek medical attention.

Ingestion If accidentally swallowed, seek medical attention and show the physician the package insert.

Inhalation Not an expected route of exposure.

Note to Physician Common adverse effects include hypotension, nausea, vomiting, musculoskeletal cramps, flushing, pruritus and rash.

5. FIRE FIGHTING MEASURES

General Hazards Only potential fire hazard would involve packaging material.

Fire Fighting Extinguishing Media In case of fire use waterspray, foam or dry chemical.

Fire Fighting Instructions In case of fire, use full firefighting turnout (bunker) gear and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire.

Hazardous Combustion Products Packaging material fires may produce carbon monoxide and other gaseous asphyxiants plus airborne particulate matter, soot and smoke.

6. ACCIDENTAL RELEASE MEASURES

Large Spill Contain spill. Absorb on suitable medium and deposit in container for disposal. Mop area with soap and water.

Small Spill Absorb on paper towels. Deposit in suitable container for disposal. Broken glass requires additional caution.

7. HANDLING AND STORAGE

Special Handling Prevent physical damage to package.

Special Storage Product can be stored at 68 – 77 ° F (20 to 25° C). Excursions permitted to 59 – 86 ° F (15 – 30° C). Do not freeze.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Eye Protection Clean-up, manufacturing and packaging operations may require safety glasses or goggles if there is a potential for splashing.

Skin Protection Nitrile gloves or gloves of equal or greater protection are recommended for spill clean-up, manufacturing and packaging operations.

Respiratory Protection None normally required.

Engineering Controls Clean-up, manufacturing and packaging operations should be required so as to offer no significant exposure to the ingredients.

Exposure Limits ACGIH 8-hour TLV for soluble Iron salts: 1 mg/m³.

9. PHYSICAL AND CHEMICAL PROPERTIES

Color:	Brown to dark brown
Physical State:	Liquid
pH:	7.7 to 9.7 (usually 8.5)
Odor:	None
Density:	1.1 g/mL

10. STABILITY AND REACTIVITY

Incompatibility No known incompatibilities.

Hazardous Decomposition Products No known hazardous decomposition products.

Hazardous Polymerization Hazardous polymerization has not been reported to occur under normal temperatures and pressures.

11. TOXICOLOGICAL INFORMATION

General Iron Toxicity: Iron is not easily eliminated from the body and accumulation can be toxic.

Genotoxicity: Not mutagenic in the Ames test and the rat micronucleus test. Produced a clastogenic effect in the in vitro chromosomal aberration assay in Chinese hamster ovary cells.

Carcinogenicity: Long-term carcinogenicity studies in animals were not performed.

Teratogenicity: Not teratogenic at doses of elemental iron up to 100 mg/kg/day in mice and 20 mg/kg/day in rats. There are no adequate and well-controlled studies in pregnant women.

Fertility: Studies have not been conducted.

Adverse effects form overexposure: Hypotension, nausea, vomiting, musculoskeletal cramps, flushing, pruritus and rash.

12. ECOLOGICAL INFORMATION

Ecological Information No information for determination of unusual environmental fate or toxicity is available at this time.

13. DISPOSAL CONSIDERATIONS

Disposal Information This material and its container must be disposed of in a safe way.

Waste Disposal Methods Wastes must be disposed of in accordance with federal, state and local environmental regulations.

14. TRANSPORT INFORMATION

DOT/IATA Not a regulated material.

15. REGULATORY INFORMATION

TSCA Inventory Status: This product is a pharmaceutical agent and as such is regulated by the United States Food and Drug Administration (FDA).

16. OTHER INFORMATION

Other Information The information contained herein is based upon data considered true and accurate. Sanofi-aventis makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.