



1. Product and Company Identification

**PRODUCT NAME: FERRLECIT® (sodium ferric gluconate complex in sucrose injection)
62.5 mg elemental iron / 5 mL Sterile Single-use Ampule**

Substance name: Sodium ferric gluconate complex

Supplier:

**Sanofi-aventis U.S. LLC
A SANOFI COMPANY
55 Corporate Drive
Bridgewater, NJ 08807**

**24-Hour Transport Emergency, US (Chemtrec): (800) 424-9300
24-Hour Transport Emergency, outside US (Chemtrec): (703) 527-3887
US Customer Service (800) 207-8049
24-Hour Emergency, sanofi-aventis US: (908) 981-5550**

Product use: Pharmaceutical product.

2. Hazards Identification

2.1 Classification in accordance with 29 CFR 1910.1200

Classification: Sodium ferric gluconate complex in sucrose is not classified as a hazardous substance.

2.2 Label elements in accordance with 29 CFR 1910.1200

Labeling of the finished drug product is not required according to OSHA 29 CFR 1910.1200.

2.3 Hazards Not Otherwise Classified (HNOC)

Not classified.

3. Composition/Information on Ingredients

Chemical Name:	Common Name:	CAS #:	Percentage (w/w)
Sodium ferric gluconate complex (D-Gluconic acid, iron (3 ⁺) sodium salt)	Sodium ferric gluconate complex	34089-81-1	1.2%
Benzyl alcohol	Benzyl alcohol	100-51-6	0.9%
Sucrose	Sucrose	57-50-1	19.5%
Water	Water	7732-18-5	78.4%

4. First Aid Measures

4.1 First aid procedures

Eye contact: In case of contact with product, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses if worn. Get medical attention if irritation develops.

Skin contact: In case of contact with product, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists.

Ingestion: If swallowed, call a poison center or physician if you feel unwell. Do NOT induce vomiting unless directed to do so by a physician. Never give anything by mouth to an unconscious person. Rinse mouth thoroughly with water.

Inhalation: If product is inhaled, remove to fresh air. If breathing is difficult, trained personnel should give oxygen. Get medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Lightheadedness, malaise, fatigue, weakness or severe pain in the chest, back, flanks, or groin.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically and supportively.

5. Fire Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media: All means: water, carbon dioxide, foam or dry chemical.

Unsuitable extinguishing media: Strong water jet.

5.2 Specific hazards arising from the chemical

Hazardous combustion products: Carbon monoxide, carbon dioxide, oxides of nitrogen.

5.3 Special Protective Equipment and Precautions for Fire-fighters

In case of fire, use full firefighting turnout (bunker) gear and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire. Move container from fire area if you can do it without risk. Do not scatter spilled material with high-pressure water streams. Dike fire-control water for later disposal.

6. Accidental Release Measures

6.1 Personal precautions and Protective Equipment:

Eye protection, respiratory protective equipment, and suitable protective clothing should be worn (see Section 8).

6.2 Emergency Procedures:

Follow local workplace procedures. Prevent the product from entering the environment. Avoid discharges to sewers, drains, waterways, or onto the ground.

6.3 Methods for containment:

Absorb spilled liquid with a suitable inert material, place in suitable container for disposal and mop area.

6.4 Methods for clean-up:

Wash the floor with plenty of water, absorb or retain the cleaning water for disposal.

7. Handling and Storage

7.1 Precautions for Safe Handling

Product should be used in a controlled work area. Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Place a disposable absorbent pad under the product preparation area. Do not eat, smoke or drink while handling product. Wash thoroughly after handling.

7.2 Conditions for Safe Storage

Store at 20 – 25°C (68 – 77°F); excursions permitted to 15 – 30°C (59 – 86°F). Do not freeze.

8. Exposure Controls/Personal Protection

8.1 Exposure Limits

Sanofi-aventis occupational exposure limit: Not classified.

ACGIH 8-hour TLV for soluble iron salts: 1 mg/m³.

8.2 Appropriate Engineering Controls

Provide adequate ventilation. No other specific controls are needed under normal handling conditions.

8.3 Individual Protection Measures

Eye/face protection: Safety glasses or safety goggles should be worn if there is a potential for eye contact with the product.

Skin protection: Suitable protective gloves should be worn. Use of a protective or disposable gown or laboratory coat is recommended if there exists a potential for contact with the product.

Respiratory protection: None normally required for routine handling of the product. However, approved respiratory protection should be worn if there is a potential for exposure to the product. A respiratory protection program that meets OSHA 29 CFR 1910.134 and ANSI Z88.2 must be followed whenever workplace conditions warrant respirator usage.

General hygiene considerations: Wash hands before breaks and at the end of the work shift.

9. Physical and Chemical Properties

Appearance: Deep red liquid.

Odor: None.

Odor threshold: No data available.

pH: 7.7 to 9.7

Melting point/ Freezing point: No data available.

Initial boiling point/boiling point range: No data available.

Flash point: No data available.

Evaporation rate: Not applicable.

Flammability: No data available.

Upper/lower flammability or explosive limits: No data available.

Vapor pressure: No data available.

Vapor density: Not applicable.

Relative density: 1.1 g/mL

Solubility: No data available.

Partition coefficient: n-octanol/water: No data available.

Auto-ignition temperature: No data available.

Decomposition temperature: No data available.

Viscosity: No data available.

10. Stability and Reactivity

10.1 Reactivity

Not a reactive material under normal handling conditions.

10.2 Chemical Stability

Stable under normal handling conditions.

10.3 Possibility of hazardous reactions

None known.

10.4 Conditions to Avoid

Keep away from heat, sparks and flames.

10.5 Incompatible materials

Strong oxidizing and reducing agents.

10.6 Hazardous decomposition products

Carbon monoxide, carbon dioxide, oxides of nitrogen.

11. Toxicological Information

The following information is for the active ingredient sodium ferric gluconate complex unless otherwise noted:

Information on likely routes of exposure: Not expected under normal handling conditions. Unintended spills or releases could result in exposure to eyes, skin and respiratory tract.

Symptoms related to the physical, chemical and toxicological characteristics:
Lightheadedness, malaise, fatigue, weakness or severe pain in the chest, back, flanks, or groin. Nausea, vomiting and/or diarrhea.

Effects of short-term (acute) exposure: Hypotension.

Effects of long-term (chronic) exposure: Excess storage of iron with the possibility of iatrogenic hemosiderosis.

Acute toxicity (LD50):

Oral route, rat: No data available.

Skin corrosion/irritation: No data available.

Serious eye damage/irritation: No data available.

Sensitization: No data available.

Specific target organ toxicity – single exposure (STOT-SE): No data available.

Specific target organ toxicity – repeated exposure (STOT-RE): No data available.

Carcinogenicity: Long term carcinogenicity studies of sodium ferric gluconate in animals were not performed.

Not listed by NTP, not found to be a potential carcinogen by IARC or OSHA.

Reproductive toxicity and teratogenicity: Studies to assess the effects of sodium ferric gluconate on fertility were not conducted. Reproduction studies have been performed in mice at doses up to 100 mg/kg/day (300 mg/m²/day) and in rats at up to 20 mg/kg/day (120 mg/m²/day). The doses in mice and rats are 4 and 1.5 times the human dose of 125 mg/day (77 mg/m²/day) on a body surface area basis and have revealed no evidence of harm to the fetus due to Ferrlecit®.

Ferrlecit contains benzyl alcohol as a preservative. There are no known adverse outcomes associated with fetal exposure to the preservative benzyl alcohol through maternal drug administration; however, the preservative benzyl alcohol can cause serious adverse events and death when administered intravenously to neonates and infants. Consult the Package Insert for additional information.

Mutagenicity: Sodium ferric gluconate was not genotoxic in the Ames test or the rat micronucleus test. Sodium ferric gluconate produced a clastogenic effect in an in vitro chromosomal aberration assay in Chinese hamster ovary cells.

Aspiration hazard: Not applicable.

12. Ecological Information

12.1. Ecotoxicity

No data available.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Other adverse effects

No data available.

13. Disposal Considerations

13.1 Disposal of product waste

Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

13.2 Disposal of packaging waste

Dispose of in a safe manner in accordance with federal, state and local environmental regulations. Empty packages, containers or liners may contain product residue.

14. Transport Information

14.1 Basic shipping information, finished product

U.S. DOT	Not a regulated material.
ICAO/IATA	Not a regulated material.
IMDG	Not a regulated material.

15. Regulatory Information

US Regulations

CERCLA Hazardous Substance List (40 CFR 302.4): Not listed.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): Not listed.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): Not listed.

SARA Title III:

Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): Not listed.

Section 313 Toxic Release Inventory (40 CFR 372): Not listed.

State Regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): Not listed.

Massachusetts Right-To-Know List: Not listed.

New Jersey Right-To-Know List: Not listed.

Pennsylvania Right-To-Know List: Not listed.

16. Other Information

Other Information: The information contained herein is based upon data considered true and accurate. Sanofi-aventis U.S. LLC. 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.

Abbreviations and Acronyms

CAS: Chemical Abstracts Service

DOT: U.S. Department of Transportation

EST: Eastern standard time (U.S.)

IATA: International Air Transport Association

IMDG: International Maritime Dangerous Goods Code

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

OEL: Occupational Exposure Limit

PPE: Personal Protection Equipment

SDS: Safety Data Sheet

STEL: Short-term exposure limit

TWA: Time-weighted average

U.S.: United States

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Second version.