



1. Product and Company Identification

**PRODUCT NAME: LEUKINE® sargramostim injection, lyophilized powder, for solution
250 mcg/vial (1.4×10^6 IU/Vial)
Recombinant GM-CSF-Yeast-Expressed**

Substance name: Sargramostim

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 of the finished drug product is not required according to OSHA 29 CFR 1910.1200. The following information is provided for the drug substance, sargramostim:

Classification: Not classified as a hazardous substance or mixture.

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. The following information is provided for the drug substance, sargramostim:

Signal Word: None required.

Hazard Statement(s): None required.

Symbol(s): None required. Precautionary Statement(s):

Prevention: None required.

Response: None required.

Storage: None required.

Disposal: None required.

2.3 Hazards Not Otherwise Classified (HNOC)

None known.

3. Composition/Information on Ingredients

<u>Chemical name:</u>	<u>Common Name:</u>	<u>CAS #:</u>	<u>Percentage or concentration range</u>
Sargramostim (yeast derived recombinant human granulocyte-macrophage colony stimulating factor)	Sargramostim	123774-72-1	0.49 %
Tris(hydroxymethyl) methylamine	Tromethamine	77-86-1	2.33 %
Sucrose	Sucrose	57-50-1	19.44 %
(2R,3R,4R,5R)-hexane-1,2,3,4,5,6-hexol	Mannitol	69-65-8	77.74 %

4. First Aid Measures

4.1 First aid procedures

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

Skin contact: In case of contact with dust, 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 immediately. 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 dust 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

Not significantly absorbed orally or by inhalation. Reversible variable increases in white blood cells and platelet counts have been observed when administered by injection.

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 if significant dust emissions are generated.

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:

Vacuum or scoop up, moisten any dust with water before collection with a shovel or broom.

6.4 Methods for clean-up:

Place material in suitable container for disposal. 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

Use with adequate ventilation. Avoid breathing dust. Do not get dust in eyes or on skin. Wash thoroughly after handling.

7.2 Conditions for Safe Storage

Keep container tightly closed. Protect from light. Store in a cool, well-ventilated area.

8. Exposure Controls/Personal Protection

8.1 Exposure Limits

Sanofi-aventis occupational exposure limit, sargramostim: Not established.

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 dust exposure.

Skin protection: Suitable protective gloves should be worn if handling the unfinished product.

Respiratory protection: None normally required. Approved respiratory protection should be worn if there is a potential for exposure to dust from handling operations.

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

9. Physical and Chemical Properties

Appearance: White solid powder.

Odor: No data available.

Odor threshold: No data available.

pH: 7.1 – 7.7 when reconstituted.

Melting point/ Freezing point: Not applicable.

Initial boiling point/boiling point range: Not applicable.

Flash point: Not applicable.

Evaporation rate: Not applicable.

Flammability: Not applicable.

Upper/lower flammability or explosive limits: Not applicable.

Vapor pressure: Not applicable.

Vapor density: Not applicable.

Relative density: No data available.

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 sargramostim 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: None identified.

Effects of short-term (acute) exposure: Variable increases in white blood cells and platelet counts

Effects of long-term (chronic) exposure: No data available.

Acute toxicity (LD₅₀):

Sargramostim: No data. Not significantly absorbed orally. Oral administration of sargramostim in humans did not increase concentrations of free GM-CSF in the bloodstream. Since sargramostim is a glycoprotein, a toxic effect is not expected after oral uptake due to rapid metabolism and denaturation.

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): Sargramostim can induce reversible variable increases in white blood cells and platelet counts by injection, with the spleen, bone marrow and lymph nodes (lymphohematopoietic system) as target organs.

Carcinogenicity: Animal studies have not been conducted to evaluate the carcinogenic potential.

Sargramostim is not listed by NTP, and are not found to be potential carcinogens by IARC or OSHA.

Reproductive toxicity and teratogenicity: Animal reproduction and fertility studies have not been conducted.

Mutagenicity: No data available.

Aspiration hazard: No data available.

12. Ecological Information

The following information is for the active ingredient sargramostim unless otherwise noted:

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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Third version.