

Safety Data Sheet

1. Identification

Product name	Japanese Pharmacopoeia Lenograstim Reference Standard
Supplier Name	Pharmaceutical and Medical Device Regulatory Science Society of Japan
Address	2-12-15, Shibuya, Shibuya-ku, Tokyo 150-0002, Japan
Tel	+81-3-3400-5634
Emergency contact	Pharmaceutical and Medical Device Regulatory Science Society of Japan, Pharmaceutical Reference Standards Center
Tel	+81-6-6221-3444
Fax	+81-6-6221-3445
Recommended use	This product is analytical reagent.
Restrictions on use	It is not a medicine or clinical diagnostic agent, so it can not be used for human or animals.

2. Hazard Identification

GHS Classification of chemicals													
Physicochemical hazards	Not classified.												
Health hazards	Not classified.												
Environmental hazards	Not classified.												
Label elements	<table> <tr> <td>Label</td><td>Pictograms</td><td>No symbol.</td></tr> <tr> <td>elements</td><td>Signal word</td><td>None.</td></tr> <tr> <td></td><td>Hazard statement</td><td>—</td></tr> <tr> <td></td><td>Precautionary statement</td><td>—</td></tr> </table>	Label	Pictograms	No symbol.	elements	Signal word	None.		Hazard statement	—		Precautionary statement	—
Label	Pictograms	No symbol.											
elements	Signal word	None.											
	Hazard statement	—											
	Precautionary statement	—											

3. Composition / Information on Ingredients

Substance / Mixture	Substance.
Chemical name	Lenograstim.
Synonym / common name	—
CAS No.	135968-09-1
Component and concentration or concentration range	100%
Reference Number in Gazetted List in Japan	ENCS : — ISHL : —
Component contributing to GHS classification	No data available.

4. First-Aid Measures

Inhalation	Remove victim to fresh air and keep comfortable for breathing. Get medical attention if irritation develops and persists.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If ingestion of a large amount dose occur, call a doctor/physician immediately. No data available.
Most important symptoms/effects, acute and delayed	No data available.
Protection of first-aiders	Wear personal protective equipment as required.
Indication of immediate medical attention and special treatment needed	Provide the symptomatic treatment.

5. Fire-Fighting Measures

Suitable extinguishing media	Water spray, foam, dry chemical, carbon dioxide.
Unsuitable extinguishing media	No data available.
Specific hazards arising from the chemical product	Irritating, toxic or corrosive gases may be generated by a fire.
Special extinguishing method	Use standard firefighting procedures and consider the hazards of other involved materials.

As with all fires, evacuate personnel to a safe area.
 Use water spray to cool unopened containers.
 Wear suitable protective equipment.

Protection of fire-fighters

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Ensure adequate ventilation. Avoid inhalation of dust or vapor etc from the spilled material. See section 8 of the SDS, wear suitable protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
Environmental precautions	Avoid release to the environment.
Methods and materials for containment and cleaning up	Collect spillage in an appropriate way. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

7. Handling and Storage

Handling	Technical measures	See section 8 of the SDS, perform engineering controls and wear protective equipment. See section 8 of the SDS, perform local ventilation or general ventilation.
	Safety handling precautions	When handling Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wear personal protective equipment. After removing gloves, wash hands and other exposed skin thoroughly.
	Contact avoidance	See section 10 of the SDS.
Storage	Safe storage conditions	Keep container tightly closed.
	Safe packaging material	Store in an appropriate container according to applicable laws and regulations.

8. Exposure Controls/Personal Protection

Administrative Control Levels	Not set up.
Occupational Exposure Limits	No data available.
Engineering controls	Install an eyewash facility and a safety shower in the workplace where this material is stored or handled. Install general ventilation system and local exhaust ventilation. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.
Personal protective equipment	
Respiratory protection	Wear appropriate respiratory protection (e.g., dust mask, gas mask).
Hand protection	Wear appropriate protective gloves (e.g., chemically compatible gloves).
Eye protection	Wear appropriate eye protection/face protection (e.g., safety glasses with side shields, goggle-type protective glasses).
Skin and body protection	Wear appropriate protective clothing (e.g., lab coat, long sleeve work clothes).

9. Physical and Chemical Properties and Safety Characteristics

Physical state	Loquid: Clear liquid.
Colour	Colorless.
Odor	No data available.
Melting point/Freezing point	No data available.
Flammability	No data available.
Boiling point or initial boiling point and boiling range	No data available.
Lower and upper explosion limit/ flammability limit	
Lower limit(%)	No data available.
Upper limit (%)	No data available.
Flash point	No data available.
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.
pH	No data available.
Kinematic viscosity	No data available.
Solubility	Water No data available.

Other	No data available.
Partition coefficient n-octanol/water (log value)	No data available.
Vapor pressure	No data available.
Density and/or relative density	No data available.
Relative vapor density	No data available.
Particle characteristics	No data available.
Other information	No data available.

1 0 . Stability and Reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction under conditions of normal use.
Conditions to avoid	No data available.
Incompatible materials	No data available.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

1 1 . Toxicological Information

Acute toxicity	No data available.
Skin corrosion / irritation	No data available.
Serious eye damage / eye irritation	No data available.
Respiratory sensitization	No data available.
Skin sensitization	No data available.
Germ cell mutagenicity	No data available.
Carcinogenicity	No data available.
Reproductive toxicity	No data available.
Specific target organ toxicity - Single exposure	No data available.
Specific target organ toxicity - Repeated exposure	No data available.
Aspiration hazard	No data available.
Other information	No data available.

1 2 . Ecological Information

Ecotoxicity	No data available.
Persistence and degradability	No data available.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Hazard to the ozone layer	This substance is not listed in the Annex to the Montreal Protocol.

1 3 . Disposal Considerations

Information on safe and environmentally desirable disposal or recycling of chemicals, contaminated containers and packaging.

Dispose in a safe manner in accordance with national and local regulations.

When empty containers are discarded, contents should be completely removed.

1 4 . Transport Information

UN Number	Not regulated.
Proper shipping name	
Hazard class	
Subsidiary hazard class	
Packing group	
Domestic restriction	Rail and road
	Not regulated.
Marine	Not regulated.
Aviation	Not regulated.

1 5 . Regulatory Information

Japanese regulations

Pollutant Release and Transfer Register	Not regulated.
Poisonous and Deleterious Substances Control Act	Not regulated.
Industrial Safety and Health Act	Not regulated.
Fire Service Act	Not regulated.

16. Other Information

Issued date	LEN-01 : Jun. 19, 2019
Revision date	LEN-02 : Apr. 01, 2021
References	
Ministry of Health, Labour and Welfare : GHS model SDS information	
Japan Science and Technology Agency. : J-GLOBAL	
National Institute of Technology and Evaluation: NITE Chemical Risk Information Platform (NITE-CHRIP)	
etc.	

The information in this Safety Data Sheet is designed only as a guidance for safe handling, and is not to be considered a warranty or quality specification of this product. The information provided is correct to the best of our knowledge, information and belief at the date of its publication and so on. However, any warranty shall not be given regarding the data contained and the assessment of hazards and toxicity.