SAFETY DATA SHEET

1. Identification

Product identifier **High Molecular Weight Filgrastim**

Other means of identification

Catalog number 1270457

Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Company name U. S. Pharmacopeia

Address 12601 Twinbrook Parkway
Rockville
MD
20852-1790
US

Telephone RS Technical Services 301-816-8129

Website www.usp.org

E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & Canada 1-800-424-9300
CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Sensitization, respiratory Category 1
Sensitization, skin Category 1

OSHA hazard(s) Not classified.

Label elements

Signal word Danger

Hazard statement May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statement

Prevention Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves. In case of inadequate ventilation wear respiratory protection.

Response If on skin: Wash with plenty of water/. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor.

Storage Not available.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) Not classified.

3. Composition/information on ingredients

Mixture

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Filgrastim		121181-53-1	0.94
Polysorbate 20		9005-64-5	0.13

Non-hazardous components

Chemical name	Common name and synonyms	CAS number	%
Mannitol		69-65-8	53.98
Sucrose		57-50-1	38.59
Trehalose		6138-23-4	4.29
Glutamic Acid		56-86-0	1.99
Sodium Acetate		127-09-3	0.07
Other components below reportable levels			0.01

4. First-aid measures

Inhalation
If dust from the material is inhaled, remove the affected person immediately to fresh air. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Skin contact
Wash off with soap and plenty of water. For minor skin contact, avoid spreading material on unaffected skin. If skin irritation or rash occurs: Get medical advice/attention.

Eye contact
Rinse with water. Get medical attention if irritation develops and persists.

Ingestion
Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed
May cause allergic skin reaction. May cause allergic respiratory reaction.

Indication of immediate medical attention and special treatment needed
Symptoms may be delayed. Provide general supportive measures and treat symptomatically.

General information
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media
Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters
Wear suitable protective equipment.

Fire-fighting equipment/instructions
Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe handling
As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

Conditions for safe storage, including any incompatibilities
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	REL	5 mg/m3	Respirable.
		10 mg/m3	Total

US. ACGIH Threshold Limit Values

Components	Type	Value
Sucrose (CAS 57-50-1)	TWA	10 mg/m3

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection

Hand protection Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory protection Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Thermal hazards Not available.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance Powder.

Physical state Solid.

Form Powder.

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point 206.6 °F (97 °C) estimated

Initial boiling point and boiling range Not available.

Flash point 199.94 °F (93.30 °C) estimated

Evaporation rate Not available.

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	0.000011 hPa estimated
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	860 °F (460 °C) estimated
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Density	1.55 g/cm3 estimated
Flammability class	Combustible IIIB estimated
Specific gravity	1.545245835 estimated

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	None known.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Based on available data, the classification criteria are not met.
Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin contact	May cause an allergic skin reaction.
Eye contact	Due to lack of data the classification is not possible.
Symptoms related to the physical, chemical, and toxicological characteristics	Not available.

Acute toxicity

Product	**Species**	**Test Results**
High Molecular Weight Filgrastim (CAS Mixture)		
Acute		
Oral		
LD50	Mouse	40.7558 g/kg, estimated
	Rat	18804.6093 mg/kg, estimated
Components	**Species**	**Test Results**
Glutamic Acid (CAS 56-86-0)		
Oral		
LD50	Rabbit	> 2300 mg/kg
	Rat	> 30 g/kg
Mannitol (CAS 69-65-8)		
Acute		
Oral		
LD50	Mouse	22 g/kg
	Rat	13500 mg/kg
Polysorbate 20 (CAS 9005-64-5)		
Oral		
LD50	Mouse	> 33 g/kg

Components	Species	Test Results
	Rat	36700 µliters/kg
Sodium Acetate (CAS 127-09-3)		
Inhalation		
LC50	Rat	> 30000 mg/kg
Oral		
LD50	Mouse	6891 mg/kg, (anhydrous)
	Rat	3530 mg/kg, (anhydrous)
Sucrose (CAS 57-50-1)		
Acute		
Oral		
LD50	Rat	29700 mg/kg
Trehalose (CAS 6138-23-4)		
Oral		
LD50	Mouse	> 5000 mg/kg
	Rat	> 5000 mg/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Due to lack of data the classification is not possible.

Serious eye damage/eye irritation Due to lack of data the classification is not possible.

Local effects

Polysorbate 20	15 ml Irritancy test Result: Irritant. Species: Human Organ: Skin. Test Duration: 3 days Severity: Mild.
Sodium Acetate	500 mg Irritation test Result: Irritant. Species: Rabbit Organ: Eye. Severity: Mild. 500 mg Irritation test Result: Irritant. Species: Rabbit Organ: Skin. Test Duration: 24 hours Severity: Mild.
Trehalose	Irritancy test Result: Non-irritant. Species: Rabbit Organ: Eye.
Glutamic Acid	Irritancy test Result: Non-irritant. Species: Rabbit Organ: Eyes Irritancy test Result: Non-irritant. Species: Rabbit Organ: Skin

Respiratory sensitization May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitization May cause an allergic skin reaction.

Sensitization

Glutamic Acid	Guinea pig maximization test Result: Non-sensitizing. Species: Guinea pig Organ: Skin
Polysorbate 20	Magnussan-Kligman sensitization test Result: Sensitizer. Species: Guinea pig Severity: Moderate to strong.

Germ cell mutagenicity Due to lack of data the classification is not possible.

Mutagenicity

Sodium Acetate	Chinese hamster fibroblast cytogenic assay Result: Negative.
Trehalose	Chinese hamster ovary cell chromosomal aberration Result: Negative (with and without activation).
Sucrose	Chromosomal aberrations in CHO-WBL cells Result: Positive (with and without activation). Mouse lymphoma test Result: Negative (witih and without activation).
Trehalose	Mouse micronucleus formation Result: Negative (with and without activation).
Glutamic Acid	S. typhimurium Ames assay Result: Negative.
Sodium Acetate	S. typhimurium Ames assay Result: Negative.
Trehalose	S. typhimurium reverse mutation assay Result: Negative (with and without activation).
Sodium Acetate	Sister chromatid chromosomal aberration (in vitro) Result: Negative. Testicular DNA synthesis inhibition test (in vivo) Result: Negative.

Carcinogenicity Due to lack of data the classification is not possible.

Mannitol	50000 ppm Carcinogenicity study, dietary doses Result: No evidence of carcinogenicity. Species: Mouse Test Duration: 103 weeks 50000 ppm Carcinogenicity study, dietary doses Result: No evidence of carcinogenicity. Species: Rat Test Duration: 103 weeks

Reproductive toxicity Due to lack of data the classification is not possible.

Reproductivity

Polysorbate 20	0 - 5000 mg/kg/day Reproductivity test Result: No developmental toxicity was observed. Species: Mouse
Trehalose	< 5 g/kg Reproductivity study Result: No reproductive effects were seen. Species: Rat < 6.9 g/kg Reproductivity study Result: No evidence of developmental toxicity. Species: Rat <= 2.8 g/kg Reproductivity study Result: No evidence of developmental toxicity. Species: Rabbit

Specific target organ toxicity - single exposure Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure Due to lack of data the classification is not possible.

Aspiration hazard Due to lack of data the classification is not possible.

12. Ecological information

Ecotoxicity No ecotoxicity data noted for the ingredient(s).

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential Not available.

Mobility in soil Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations Not available.

Hazardous waste code Not available.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

15. Regulatory information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

Issue date 05-29-2015

Version # 01

Further information Not available.

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