

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: STIMUFEND® (pegfilgrastim-fpgk) injection, for subcutaneous use

Synonyms: Pegfilgrastim 6 mg/0.6 mL

1.2. Intended Use of the Product

Pharmaceutical Product

1.3. Name, Address, and Telephone of the Responsible Party

Distributor

Fresenius Kabi USA, LLC

Three Corporate Drive

Lake Zurich, IL 60047

General Phone Number: (847) 550-2300

Customer Service Phone Number: (888) 386-1300

Health Issues Information: (800) 551-7176

<http://www.fresenius-kabi.com/us/>

Co-Manufacturer

Merck Serono S.p.A

Via delle Magnolie, 15

70026 Modugno Z.I, Bari, Italy

1.4. Emergency Telephone Number

Emergency Number : ChemTel LLC
 (800)255-3924 (North America)
 +1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US/CA Classification

Reproductive toxicity Category 2

H361

2.2. Label Elements

GHS-US/CA Labeling

Hazard Pictograms (GHS-US/CA) :



GHS08

Signal Word (GHS-US/CA) :

Warning

Hazard Statements (GHS-US/CA) :

H361 - Suspected of damaging fertility or the unborn child.

Precautionary Statements (GHS-US/CA) :

P201 - Obtain special instructions before use.
 P202 - Do not handle until all safety precautions have been read and understood.
 P280 - Wear protective gloves, protective clothing, and eye protection.
 P308+P313 - If exposed or concerned: Get medical advice/attention.
 P405 - Store locked up.
 P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US/CA)

No additional information available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

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3.2. Mixture

Name	Synonyms	Product Identifier	% *	GHS Ingredient Classification
Water	AQUA / water	(CAS-No.) 7732-18-5	94.031	Not classified
D-Glucitol	Sorbitol / D-Sorbitol / Sorbitol, D- / SORBITOL / sorbitol	(CAS-No.) 50-70-4	4.912	Comb. Dust
Pegfilgrastim	Colony-stimulating factor (human), 3-hydroxypropyl-N-methionyl-, 1-ether with .alpha.-methyl-omega.-hydroxypoly(oxy-1,2-ethanediyl) / pegfilgrastim	(CAS-No.) 208265-92-3	0.982	Repr. 2, H361
Acetic acid	Acetic acid, glacial / Ethanoic acid / Ethylic acid / Vinegar acid / ACETIC ACID / Acetic acid solution / Acetic acid ...% / acetic acid	(CAS-No.) 64-19-7	0.052	Flam. Liq. 3, H226 Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402
Sodium acetate	Acetic acid, sodium salt / Acetic acid, sodium salt (1:1) / Sodium acetate, anhydrous / SODIUM ACETATE / Sodium acetate anhydrous	(CAS-No.) 127-09-3	0.02	Comb. Dust
Polyoxyethylene sorbitan monolaurate	Polysorbate 20 / Sorbitan monolaurate, ethoxylated / Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivatives / Polyoxyethylene (20) sorbitan monolaurate / PEG-10 SORBITAN LAURATE / PEG sorbitan laurate / Ethoxylated sorbitan monolaurate / Polyethylene glycol sorbitan monolaurate / PEG-80 sorbitan laurate / Polysorbate 21 / PEG-10 sorbitan laurate / PEG-40 sorbitan laurate / PEG-75 sorbitan laurate / PEG-44 sorbitan laurate / Sorbitan monolaurate, ethoxylate / Bioactivator NN-21 / PEG-40 SORBITAN LAURATE / PEG-44 SORBITAN LAURATE / PEG-75 SORBITAN LAURATE / PEG-80 SORBITAN LAURATE / POLYSORBATE 21 / POLYSORBATE 20	(CAS-No.) 9005-64-5	0.003	Not classified

Full text of H-statements: see section 16

*Percentages are listed in weight by weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume by volume percentage (v/v%). The delivered 0.6 mL dose from the prefilled syringe contains 6 mg pegfilgrastim-fpgk (based on protein weight) in a sterile, clear, colorless, preservative-free solution (pH 4.0) containing acetate (0.35 mg), polysorbate 20 (0.02 mg), sodium (0.02 mg), and sorbitol (30 mg) in Water for Injection, USP.

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). In the event of accidental injection, immediately call a poison center or seek medical advice. If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 5 minutes. If exposed or concerned: Get medical advice/attention. If product is biologically contaminated, seek medical advice and follow all insitutional protocols concerning bodily contact with biological specimens.

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Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

General: Suspected of damaging fertility or the unborn child.

Inhalation: Prolonged exposure may cause irritation.

Skin Contact: Prolonged exposure may cause skin irritation.

Eye Contact: May cause slight irritation to eyes.

Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂).

5.4. Reference to Other Sections

Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing. Do not breathe vapor, mist or spray.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Collect spilled material with absorbant material.

Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

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SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes, on skin, or on clothing. Do NOT breathe (dust, vapor, mist, gas). Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store refrigerated between 36°F to 46°F (2°C to 8°C) in the carton to protect from light. Do not shake. Discard syringes stored at room temperature for more than 72 hours. Do not freeze. Discard syringe if frozen. Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Pharmaceutical Product

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

Acetic acid (64-19-7)		
USA ACGIH	ACGIH OEL TWA [ppm]	10 ppm
USA ACGIH	ACGIH OEL STEL [ppm]	15 ppm
USA OSHA	OSHA PEL (TWA) [1]	25 mg/m ³
USA OSHA	OSHA PEL (TWA) [2]	10 ppm
USA NIOSH	NIOSH REL (TWA)	25 mg/m ³
USA NIOSH	NIOSH REL TWA [ppm]	10 ppm
USA NIOSH	NIOSH REL (STEL)	37 mg/m ³
USA NIOSH	NIOSH REL STEL [ppm]	15 ppm
USA IDLH	IDLH [ppm]	50 ppm
Alberta	OEL STEL	37 mg/m ³
Alberta	OEL STEL [ppm]	15 ppm
Alberta	OEL TWA	25 mg/m ³
Alberta	OEL TWA [ppm]	10 ppm
British Columbia	OEL STEL [ppm]	15 ppm
British Columbia	OEL TWA [ppm]	10 ppm
Manitoba	OEL STEL [ppm]	15 ppm
Manitoba	OEL TWA [ppm]	10 ppm
New Brunswick	OEL STEL	37 mg/m ³
New Brunswick	OEL STEL [ppm]	15 ppm
New Brunswick	OEL TWA	25 mg/m ³
New Brunswick	OEL TWA [ppm]	10 ppm
Newfoundland & Labrador	OEL STEL [ppm]	15 ppm
Newfoundland & Labrador	OEL TWA [ppm]	10 ppm
Nova Scotia	OEL STEL [ppm]	15 ppm
Nova Scotia	OEL TWA [ppm]	10 ppm
Nunavut	OEL STEL [ppm]	15 ppm
Nunavut	OEL TWA [ppm]	10 ppm
Northwest Territories	OEL STEL [ppm]	15 ppm

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Northwest Territories	OEL TWA [ppm]	10 ppm
Ontario	OEL STEL [ppm]	15 ppm
Ontario	OEL TWA [ppm]	10 ppm
Prince Edward Island	OEL STEL [ppm]	15 ppm
Prince Edward Island	OEL TWA [ppm]	10 ppm
Québec	VECD (OEL STEL)	37 mg/m ³
Québec	VECD (OEL STEL) [ppm]	15 ppm
Québec	VEMP (OEL TWA)	25 mg/m ³
Québec	VEMP (OEL TWA) [ppm]	10 ppm
Saskatchewan	OEL STEL [ppm]	15 ppm
Saskatchewan	OEL TWA [ppm]	10 ppm
Yukon	OEL STEL	43 mg/m ³
Yukon	OEL STEL [ppm]	25 ppm
Yukon	OEL TWA	25 mg/m ³
Yukon	OEL TWA [ppm]	10 ppm

8.2. Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Glass syringe with a stainless steel needle
Odor	: No data available
Odor Threshold	: No data available
pH	: 4
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Lower Flammable Limit	: No data available
Upper Flammable Limit	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Specific Gravity	: No data available
Solubility	: No data available

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Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity:

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability:

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

10.4. Conditions to Avoid:

Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials:

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products:

Not expected to decompose under ambient conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects - Product

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

LD50 and LC50 Data:

No additional information available

Skin Corrosion/Irritation: Not classified

pH: 4

Eye Damage/Irritation: Not classified

pH: 4

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Reproductive Toxicity: Suspected of damaging fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child

Potential Adverse human health effects and symptoms: Based on available data, the classification criteria are not met.

11.2. Information on Toxicological Effects - Ingredient(s)

LD50 and LC50 Data:

Sodium acetate (127-09-3)	
LD50 Oral Rat	3530 mg/kg
LD50 Dermal Rabbit	> 10 g/kg
LC50 Inhalation Rat	> 30 g/m ³ (Exposure time: 1 h)
Acetic acid (64-19-7)	
LD50 Oral Rat	3310 mg/kg
D-Glucitol (50-70-4)	
LD50 Oral Rat	15.9 g/kg
Polyoxyethylene sorbitan monolaurate (9005-64-5)	
LD50 Oral Rat	> 18000 mg/kg
LC50 Inhalation Rat	> 5.1 mg/l/4h

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SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General: Not classified.

Sodium acetate (127-09-3)	
LC50 Fish 1	> 100 mg/l (Exposure time: 96 h - Species: Danio rerio [semi-static])
EC50 - Crustacea [1]	> 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
Acetic acid (64-19-7)	
LC50 Fish 1	79 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 - Crustacea [1]	65 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
LC50 Fish 2	75 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

12.2. Persistence and Degradability

STIMUFEND® (pegfilgrastim-fpgk) injection, for subcutaneous use	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

STIMUFEND® (pegfilgrastim-fpgk) injection, for subcutaneous use	
Bioaccumulative Potential	Not established.
Sodium acetate (127-09-3)	
BCF Fish 1	< 10
Acetic acid (64-19-7)	
Partition coefficient n-octanol/water (Log Pow)	-0.31 (at 20 °C)

12.4. Mobility in Soil

No additional information available

12.5. Other Adverse Effects

Other Information: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Not regulated for transport

14.2. In Accordance with IMDG

Not regulated for transport

14.3. In Accordance with IATA

Not regulated for transport

14.4. In Accordance with TDG

Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

STIMUFEND® (pegfilgrastim-fpgk) injection, for subcutaneous use	
SARA Section 311/312 Hazard Classes	Health hazard - Reproductive toxicity
Sodium acetate (127-09-3)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
Acetic acid (64-19-7)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	

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CERCLA RQ	5000 lb
D-Glucitol (50-70-4)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
Polyoxyethylene sorbitan monolaurate (9005-64-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	

15.2. US State Regulations

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State or local regulations
Acetic acid (64-19-7)
U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

15.3. Canadian Regulations

Sodium acetate (127-09-3)
Listed on the Canadian DSL (Domestic Substances List)
Acetic acid (64-19-7)
Listed on the Canadian DSL (Domestic Substances List)
D-Glucitol (50-70-4)
Listed on the Canadian DSL (Domestic Substances List)
Polyoxyethylene sorbitan monolaurate (9005-64-5)
Listed on the Canadian DSL (Domestic Substances List)
Water (7732-18-5)
Listed on the Canadian DSL (Domestic Substances List)

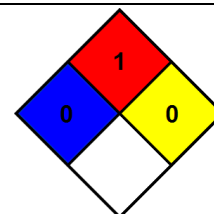
SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision	: 07/29/2022
Other Information	: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada's Hazardous Products Regulations (HPR) SOR/2015-17.

GHS Full Text Phrases:

H226	Flammable liquid and vapor
H290	May be corrosive to metals
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H361	Suspected of damaging fertility or the unborn child
H402	Harmful to aquatic life

NFPA Health Hazard	: 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.
NFPA Fire Hazard	: 1 - Materials that must be preheated before ignition can occur.
NFPA Reactivity Hazard	: 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS III Rating Health	: 0 Minimal Hazard - No significant risk to health
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Flammability : 1 Slight Hazard
Physical : 0 Minimal Hazard

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

NA GHS SDS 2015 (Can, US)