



SAFETY DATA SHEET

Revision date 10-Jun-2020

Version 1

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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Pegfilgrastim Injection (Hospira, Inc.)

Product Code(s) PZ03525

Trade Name: NYVEPRIA™

Chemical Family: Not determined

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company

275 North Field Drive

Lake Forest, Illinois 60045

1-800-879-3477

Hospira UK Limited

Horizon

Honey Lane

Hurley

Maidenhead, SL6 6RJ

United Kingdom

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

E-mail address pfizer-MSDS@pfizer.com

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Reproductive toxicity Category 2

2.2. Label elements

Signal word Warning

Hazard statements H361d - Suspected of damaging the unborn child

Precautionary Statements P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood

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P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
Compound, not fully tested, additional hazards may exist.

Supplemental Hazard



2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Hazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Pegfilgrastim	Not Listed	208265-92-3	0.1 - 1	Repr. 2 (H361d)	
ACETIC ACID	200-580-7	64-19-7	< 1	Skin Corr. 1A (H314) Flam. Liq. 3 (H226)	

NonHazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Water	231-791-2	7732-18-5	*	Not Listed	
Sorbitol solution	200-061-5	50-70-4	*	Not Listed	
Sodium acetate trihydrate	Not Listed	6131-90-4	*	Not Listed	
Polysorbate 20	Not Listed	9005-64-5	*	Not Listed	

Full text of H- and EUH-phrases: see section 16

Additional information

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: FIRST AID MEASURES

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4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately. It is considered unlikely that, if swallowed, significant amounts of this material would be absorbed into the blood circulation.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	None.
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Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media	Dry chemical, CO ₂ , alcohol-resistant foam or water spray.
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5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Fine particles (such as mists) may fuel fires/explosions.
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Hazardous combustion products	Formation of toxic gases is possible during heating or fire.
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5.3. Advice for firefighters

Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
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Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
For emergency responders	Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
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6.3. Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Prevention of secondary hazards	Clean contaminated objects and areas thoroughly observing environmental regulations.

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6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Avoid breathing vapor or mist. Use appropriate engineering controls to maintain exposures below the B-OEB taking all applicable routes of exposure into consideration. A change area to facilitate 'good laboratory/manufacturing' decontamination practices is recommended. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

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

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

Sorbitol solution

Russia

MAC: 10 mg/m³

ACETIC ACID

ACGIH TLV

STEL: 15 ppm

Austria

10 ppm

10 ppm

25 mg/m³

STEL: 20 ppm

STEL: 50 mg/m³

STEL: 50 mg/m³

STEL: 20 ppm

25 mg/m³

10 ppm

25 mg/m³

Ceiling: 50 mg/m³

Bulgaria

10 ppm

Czech Republic

25 mg/m³

10 ppm

25 mg/m³

STEL: 10 ppm

STEL: 25 mg/m³

Denmark

5 ppm

Estonia

13 mg/m³

10 ppm

25 mg/m³

Finland

STEL: 10 ppm

STEL: 25 mg/m³

Germany

10 ppm

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Germany	25 mg/m ³ Ceiling / Peak: 20 ppm Ceiling / Peak: 50 mg/m ³ 10 ppm 25 mg/m ³ 25 mg/m ³ STEL: 50 mg/m ³
Hungary	10 ppm 25 mg/m ³ 25 mg/m ³ STEL: 50 mg/m ³
Ireland	10 ppm 25 mg/m ³ STEL: 20 ppm STEL: 50 mg/m ³
Latvia	10 ppm 25 mg/m ³ STEL: 50 mg/m ³ STEL: 20 ppm
Netherlands	25 mg/m ³ STEL: 50 mg/m ³ STEL: 50 mg/m ³ 25 mg/m ³
Poland	25 mg/m ³ STEL: 50 mg/m ³ STEL: 50 mg/m ³ 10 ppm
Romania	10 ppm 25 mg/m ³ STEL: 20 ppm STEL: 50 mg/m ³
Russia	MAC: 5 mg/m ³ Skin 10 ppm 25 mg/m ³
Slovakia	10 ppm 25 mg/m ³ 10 ppm 25 mg/m ³
Spain	10 ppm 25 mg/m ³ STEL: 20 ppm STEL: 50 mg/m ³
Switzerland	10 ppm 25 mg/m ³ STEL: 20 ppm STEL: 50 mg/m ³
OSHA PEL	10 ppm 25 mg/m ³ (vacated) TWA: 10 ppm (vacated) TWA: 25 mg/m ³
United Kingdom	TWA: 10 ppm TWA: 25 mg/m ³ STEL: 20 ppm STEL: 50 mg/m ³

Pfizer OEB Statement:

The Biotherapeutic Occupational Exposure Band (B-OEB) is an acceptable daily intake (ADI) range, based on available hazard data with appropriate safety factors applied. Engineering control measures should be utilized to bring exposures into the relevant B-OEB; supplementary administrative controls and personal protective equipment are to be used to achieve exposure control to the bottom of the band.

Pegfilgrastim

Pfizer Occupational Exposure Band (OEB):

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, biosafety cabinet, or other engineering controls to maintain airborne levels within the B-OEB range. It is recommended that all large scale operations should be fully enclosed. Air recirculation is not recommended.

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Environmental exposure controls	No information available.
Personal protective equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Eye/face protection	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).
Hand protection	Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).
Skin and body protection	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).
Respiratory protection	Under normal conditions of use, if the applicable Biotherapeutic Occupational Exposure Band (B-OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the B-OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).

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

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Solution
Color	Clear to colorless
Molecular formula (MF):	Mixture
Molecular weight	Mixture
Odor	No data available.
Odor threshold	No data available
Property	Values
pH	
Melting point / freezing point	No data available
Boiling point / boiling range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available

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Explosive properties No data available
Oxidizing properties No data available

9.2. Other information

Liquid Density No data available
Bulk density No data available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

General Information:

Short term

Toxicological properties have not been investigated. May be harmful if inhaled. Not determined, however, there may be potential for adverse reactions associated with administration of antibodies to humans, including potential systemic allergic reactions. This substance, based on the composition, may also cause eye irritation, skin irritation, and may produce allergic reactions following direct contact. This material is a novel research formulation intended to be pharmacologically active, and is assumed to be harmful if injected.

Known Clinical Effects:

Based on clinical trials in humans, common possible adverse effects following exposure to this compound may include: headache, nausea, musculoskeletal pain and injection site pain.

Acute Toxicity: (Species, Route, End Point, Dose)

Sorbitol solution

Rat Oral LD50 15,900 mg/kg

Mouse Oral LD50 17,800 mg/kg

Pegfilgrastim

Rat Subcutaneous NOAEL 10 mg/kg

Non-human Primate Subcutaneous NOAEL 7.5 mg/kg

ACETIC ACID

Mouse Sub-tenon injection (eye) LC 50 5620 ppm/1H

Rat Oral LD 50 3310 mg/kg

Rabbit Dermal LD 50 1060 uL/kg

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
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Water	> 90 mL/kg (Rat)	-	-
Sorbitol solution	= 15900 mg/kg (Rat)	-	-
ACETIC ACID	= 3310 mg/kg (Rat)	= 1060 mg/kg (Rabbit)	= 11.4 mg/L (Rat) 4 h
Polysorbate 20	= 37000 mg/kg (Rat) = 36700 µL/kg (Rat)	-	-

Irritation / Sensitization Comments: **Eye Irritation:** Not determined, however, based on the composition may cause irritation.
Skin Irritation: Not determined, however, based on the composition, may be harmful, may cause irritation and may be a potential allergen.
Skin Sensitization: Not determined, however, based on the characteristics of this substance may have the potential to be a skin sensitizer.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

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4 Week(s) Rat Subcutaneous 1.8 mg/kg/week NOAEL None identified
4 Week(s) Monkey Subcutaneous 1.5 mg/kg/week NOAEL None identified
13 Week(s) Rat Subcutaneous 0.3 mg/kg/week NOAEL Bone Marrow, Spleen, Kidney
13 Week(s) Monkey Subcutaneous 1 mg/kg/week NOAEL None identified
26 Week(s) Rat Subcutaneous 0.3 mg/kg/week NOAEL Kidney, Gastrointestinal system

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Pegfilgrastim

Embryo / Fetal Development Rabbit Subcutaneous 0.01 mg/kg/day NOAEL Maternal toxicity, Developmental toxicity

Carcinogenicity

Not listed as a carcinogen by IARC, NTP or US OSHA.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. Environmental properties of the formulation have not been thoroughly investigated.

12.1. Toxicity

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

ACETIC ACID

Fathead Minnow NPDES LC-50 96 hours 88 mg/l
Bluegill Sunfish NPDES LC-50 96 hours 75 mg/L
Goldfish NPDES LC-50 24 hours 423 mg/l

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

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Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

Chemical Name	PBT and vPvB assessment
ACETIC ACID	The substance is not PBT / vPvB PBT assessment does not apply
Polysorbate 20	The substance is not PBT / vPvB PBT assessment does not apply

12.6. Other adverse effects

Other adverse effects No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-791-2
AICS	Present

Sorbitol solution

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-061-5
AICS	Present

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CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed

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EINECS	Not Listed
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4
ACETIC ACID	
CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-580-7
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5
Sodium acetate trihydrate	Schedule 6
CERCLA/SARA Section 313 de minimus %	Schedule 2
California Proposition 65	
EINECS	
AICS	
Polysorbate 20	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	Not Listed
AICS	Present

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child. Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage. Flammable liquids-Cat.3; H226 - Flammable liquid and vapor.

Data Sources:	Pfizer proprietary drug development information.
Reason for revision	New data sheet.
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Prepared By	Product Stewardship Hazard Communication Pfizer Global Environment, Health, and Safety Operations

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