Releuko®

Material Safety Data Sheet

Revision Number: 01 Date Issued: 24 FEB 2022

SECTION 1 – PRODUCT AND COMPANY INFORMATION

Product Name: Releuko
Common Name: Filgrastim
Chemical Name: Not applicable
Synonyms: Filgrastim, recombinant granulocyte colony stimulating factor, G-CSF, rHuG-CSF

Recommended Use: Pharmaceutical
Uses advised against: No information available

Manufacturer:
Kashiv BioSciences, LLC
3440 S. Dearborn St., Suite300
Chicago, IL 60616
312-620-1500

Emergency Telephone Number:
Chemtrec
North America: 1-800-424-9300
International: 1-703-527-3887

SECTION 2 – HAZARD IDENTIFICATION

Emergency Overview

Pharmaceutical product intended for research and development, clinical and manufacturing purposes only. Product contains filgrastim, a recombinant for of human granulocyte colony stimulating factor. Dosage form contents may pose a health hazard only if exposure occurs to contents, e.g. after a spill or leak. Repeated overexposure in manufacturing or from a significant spill may potentially cause effects seen in patients administered the drug such as increased neutrophil count, increased lactic dehydrogenase (LDH) and alkaline phosphatase (AP) levels. This material may induce blood disorders and/or aggravate pre-existing blood disorders. Avoid inhalation, skin contact, eye contact, and ingestion.

Classification of the drug substance or mixture (drug product in final form, not applicable)
Regulation (EC) No 1272/2008: Not Classified

Classification according to EU Directives 67/548/EEC or 1999/45/EC
For the full text of the R phrases mentioned in this Section, see Section 16

Label Elements: Not Classified

SECTION 3 – COMPOSTION / INFORMATION ON INGREDIENTS

Substances

Ingredients: Proprietary information
Chemical Name: Not application
CAS-No: 121181-53-1

Syringes containing 300 mcg/0.5mL syringe

	CAS Number	Amount
Filgrastim	121181-53-1	300 µg
Acetate	127-09-3	0.295 mg
Sorbitol	50-70-4	25 mg
Polysorbate 80	9005-65-6	0.02 mg
Sodium	7647-14-5	0.0175 mg
Water for Injection, USP	7732-18-5	0.5 mL

Syringes containing 480 mcg/0.8mL syringe

	CAS Number	Amount
Filgrastim	121181-53-1	480 µg
Acetate	127-09-3	0.47 mg
Sorbitol	50-70-4	40 mg
Polysorbate 80	9005-65-6	0.03 mg
Sodium	7647-14-5	0.03 mg
Water for Injection, USP	7732-18-5	0.8 mL

Vials containing 300 mcg/1.0mL vial

	CAS Number	Amount
Filgrastim	121181-53-1	300 µg
Acetate	127-09-3	0.59 mg
Sorbitol	50-70-4	50 mg
Polysorbate 80	9005-65-6	0.04 mg
Sodium	7647-14-5	0.035 mg
Water for Injection, USP	7732-18-5	1.0 mL

Vials containing 480 mcg/1.6mL vial

	CAS Number	Amount
Filgrastim	121181-53-1	480 µg
Acetate	127-09-3	0.94 mg
Sorbitol	50-70-4	80 mg
Polysorbate 80	9005-65-6	0.064 mg
Sodium	7647-14-5	0.056 mg
Water for Injection, USP	7732-18-5	1.6 mL

SECTION 4 – FIRST AID MEASURES

Description of first-aid measures

Eye Contact: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Consult a physician if necessary.

Inhalation: Move to fresh air. If symptoms persist, call a physician.

Ingestion: If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

SECTION 5 – FIRE-FIGHTING MEASURES

Extinguishing media

Flammable Properties: Not applicable/aqueous solution
Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Special hazards arising from the substance or mixture

Hazardous Combustion Products: No information available

Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, NIOSH (approved) and full protective gear.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Spill Procedures: If material is spilled or released, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment in cleaning up a spill. Soak up material with absorbent e.g. paper towels, and wash spill area thoroughly with appropriate cleaning materials. Dispose of collected material in accordance with applicable waste disposal regulations. Avoid release to the environment.

SECTION 7 – HANDLINE AND STORAGE

Precautions for Safe Handling

Handling and Storage: Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke in work areas. Use adequate ventilation to minimize exposure. Wash hands, face and other potentially exposed areas immediately after handling this material. Remove contaminated clothing prior to entering eating areas. Clean protective equipment thoroughly after each use. Store in a well ventilated area.

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Occupational Exposure Limit: No exposure guidelines established by ACGIH, NIOSH or OSHA. Kashiv recommends an occupational exposure limit (OEL) of 6 $\mu g/m^3$ as an 8-hour time weighted average over a 40-hour work week. The OEL is designed as an acceptable airborne concentration of a substance for which it is believed that workers may be repeatedly exposed day after day without adverse health effects.

Engineering Controls: When practicable, handle material in enclosed processes or in processes with effective local exhaust ventilation or within a chemical hood.

Exposure controls

Personal Protective Equipment

Eye/face Protection: Wear safety glasses with side shields, chemical splash goggles, or safety glasses with side shields and a full-face shield to prevent contact with eyes. The choice of protection should be based on the job activity and potential for exposure to the eyes and face.

Skin Protection: Use gloves or other appropriate personal protective equipment if skin contact with formulation is possible. Wear lab coat or other protective over garment if splashing is possible. The choice of protection should be based on the job activity and potential for skin contact.

Respiratory Protection: When possible, handle material in enclosed processes or containers. If it is properly handled with effective local exhaust ventilation or containment, respiratory protection may not be needed. For procedures involving larger quantities or dust/aerosol generating procedures such as weighing or a large transfer of liquids, an air-purifying respirator with NIOSH approval for dusts and mists may be needed.

Other: Wash hands, face and other potentially exposed areas after handling material (especially before eating, drinking or smoking). Clean protective equipment thoroughly after each use.

Environmental Exposure Controls

Environmental exposure controls Avoid release to the environment

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Appearance (at 20°C):	Clear colorless liquid
Molecular Weight:	18,800±1 Daltons
Odor:	No information available
Odor Threshold:	No information available
pH:	4.0
Melting Point:	Not applicable
Boiling Point:	100°C
Flash Point:	Not applicable
Evaporation Rate:	No information available
Lower explosive limit:	No information available
Upper explosive limit:	No information available
Vapor Pressure:	No information available
Vapor Density (air = 1):	Not applicable
Relative density:	No information available
Water Solubility:	No information available
Partition Coefficient (log Kow):	No information available
Viscosity:	No information available

SECTION 10 – STABILITY AND REACTIVITY

Reactivity:	No information available
Chemical stability:	Stable
Possibility of hazardous reactions:	No information available
Conditions to avoid:	No information available
Incompatible materials:	No information available
Hazardous decomposition products:	No information available
Other information:	None

SECTION 11 – TOXICOLOGICAL INFORMATION

Acute Toxicity:	No information available
Skin corrosion/irritation:	No information available
Serious eye damage/eye irritation:	No information available
Respiratory or skin sensitization:	No information available
Germ cell mutagenicity:	No information available
Carcinogenicity:	No information available
Reproductive toxicity:	No information available
STOT-single exposure:	Even through this does not meet GHS classification, the following data is available: Releuko single-dose administration by subcutaneous (SC) route resulted in no significant toxicity in rats.
STOT - repeated exposure:	Does not meet GHS classification
Aspiration Hazard:	No information available

SECTION 12 – ECOLOGICAL INFORMATION

No information available

SECTION 13 – DISPOSAL CONSIDERATIONS

Waste Disposal Method: Dispose of any waste according to prescribed federal, state, local and competent authority guidelines.

SECTION 14 – TRANSPORTATION INFORMATION

DOT Not regulated by U.S. DOT or IATA
TDG (Canada): Not regulated

SECTION 15 – REGULATORY INFORMATION

International Inventories

TSCA: -
EINECS/ELINCS: -
DSL/NDSL: -
PICCS: -
ENCS: -
CHINA: -
AICS: -
KECL: -

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
AICS - Australian Inventory of Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

State Regulations

California Proposition 65: The active ingredient, filgrastim is listed as a developmental toxicant.

Chemical Safety Assessment: No CSA has been conducted

SECTION 16 – OTHER INFORMATION

R Phrases mentioned in Section 2	No information available
S-Phrases	S 36/37: Wear suitable protective clothing and gloves S 53: Avoid exposure - -obtain special instructions before use
Revision Number	2

The information contained herein is based on data considered accurate and is offered solely for information, consideration and investigation. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Company shall not be liable for any claims, losses or damages of any third party or any lost profits or any special, indirect, incidental consequential or exemplary damages however they might arise, even if the Company is advised of the possibility of such damages. The data on this Material Safety Data Sheet relates only to this product and does not relate to use with any other material or in any process. All chemical products should be used only under the direction of technically qualified personnel who are aware of the hazards involved and the necessity for reasonable care in handling. Hazard communication regulations require that employees must be trained how to use a Material Safety Data Sheet as a source for Hazard information. Caution should be used in the handling and use of the material because it may be biologically active.