

Safety Data Sheet

oriented at regulation (EC) No. 1907/2006 (REACH) and US 1910.1200 App D - Safety Data Sheets

Revision date: 07/07/2022

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Date of issue: 13/07/2020

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Trade name : CellGenix® Granulocyte-Macrophage Colony-Stimulating Factor – recombinant human (rh GM-CSF)
Product code : 1012 (GMP grade); 1412 (preclinical grade)

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Cell Culture component. For further manufacturing use (product code 1012, GMP grade) or for preclinical ex vivo use (product code 1412, preclinical grade).

1.2.2. Uses advised against

Restrictions on use : Not intended for human in vivo application.

1.3. Details of the supplier of the safety data sheet

Supplier
Sartorius CellGenix GmbH
Am Flughafen 16
79108 Freiburg
T +49 761 888 89-0
F +49 761 888 89-830

E-mail address of competent person responsible for the SDS
info@ubspplus.de

1.4. Emergency telephone number

Emergency number : +49 761 19240
(Vergiftungs-Informationen-Zentrale Freiburg, 24 h, German & English)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP] and 29 CFR § 1910.1200, Appendix A and B

Not classified

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] and 29 CFR § 1910.1200, Appendix C

No labelling applicable

2.3. Other hazards

Other hazards not contributing to the classification : Cytokines and growth factors are highly bioactive proteins involved in cell signaling. Up to now, there are no test data available which would allow to classify them into one of the hazard classes according to the UN-GHS classification criteria. However, considering their bioactivity, any unintended exposure should be avoided. Therefore, in the case of any exposure, medical advice should be sought.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Move the affected person away from the contaminated area. Fresh air, rest. Prevent cooling by covering the victim (no warming up). If unconscious place in recovery position and seek medical advice. Do not give an unconscious person anything to drink. Remove soiled clothing promptly.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Artificial respiration if indicated. If symptoms persist, call a physician.
First-aid measures after skin contact	: Immediately remove contaminated clothing or footwear. Rinse and then wash skin thoroughly with water and soap. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Wash with plenty of water (during 20 minutes minimum) with eyes wide open after taking off soft contact lenses and immediately take medical advice.
First-aid measures after ingestion	: Rinse mouth. Drink plenty of water. If you feel unwell, seek medical advice.

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

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: water, carbon dioxide (CO ₂), powder and foam. Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: Not known.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Combustible solids.
Explosion hazard	: Not known.
Hazardous decomposition products in case of fire	: Nitrogen oxides. Carbon monoxide. Carbon dioxide.

5.3. Advice for firefighters

Firefighting instructions	: Do not allow run-off from fire fighting to enter drains or water courses.
Protection during firefighting	: Evacuate the danger area. Keep public away from danger area. Extra personal protection: complete protective clothing including self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Do not breathe Dust. Avoid contact with skin and eyes. Ventilate spillage area. In case of insufficient ventilation, wear suitable respiratory equipment.
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6.1.1. For non-emergency personnel

Protective equipment	: Avoid exposure. Wear personal protective equipment.
Measures in case of dust release	: Do not breathe dust.

6.1.2. For emergency responders

Protective equipment	: Avoid exposure. Wear personal protective equipment.
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6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment	: Dike and contain spill. Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible.
Methods for cleaning up	: Clean with water.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed	: Avoid dust formation. Do not breathe dust.
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CellGenix® Granulocyte-Macrophage Colony-Stimulating Factor – recombinant human (rh GM-CSF)

Safety Data Sheet

oriented at regulation (EC) No. 1907/2006 (REACH) and US 1910.1200 App D - Safety Data Sheets

Precautions for safe handling	: Avoid contact with skin, eyes and clothing. If syringes are used to handle the product, be careful to avoid injuries with injection needles.
Hygiene measures	: Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep container tightly closed.
Storage temperature	: -80 - -20 °C (Shipping at ambient temperature.)

7.3. Specific end use(s)

Cell Culture component. For further manufacturing use (product code 1012, GMP grade) or for preclinical ex vivo use (product code 1412, preclinical grade). Not intended for human in vivo application.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls	: Ensure good ventilation of the work station.
Materials for protective clothing	: Wear proper protective equipment
Hand protection	: Chemically resistant protective gloves. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. . Material : Latex (0,1 mm). Nitrile rubber (0,1 mm)
Eye protection	: Sealed safety goggles. (EN 166).
Respiratory protection	: No respiratory protection needed under normal use conditions



Other information	: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.
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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Powder
Colour	: white
Odour	: odourless
Odour threshold	: Not applicable
pH	: Not determined
pH solution	: Not determined
Relative evaporation rate (butylacetate=1)	: Not applicable
Melting point	: Not determined
Freezing point	: Not determined
Boiling point	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not determined
Decomposition temperature	: Not determined
Flammability (solid, gas)	: Not determined
Vapour pressure	: Not determined
Relative vapour density at 20 °C	: Not determined
Relative density	: Not determined
Solubility	: Water: Soluble
Log Pow	: Not determined

Log Kow	: Not determined
Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: Not applicable
Explosive properties	: Not known.
Oxidising properties	: Not known.
Explosive limits	: No data available

9.2. Other information

Other properties	: Molecular weight : 14.5 kDa
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SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: Not determined
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: Not determined
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Ecological problems are not known or expected under normal use.
Acute aquatic toxicity	: Not classified
Chronic aquatic toxicity	: Not classified

12.2. Persistence and degradability

Recombinant Human Granulocyte-Macrophage Colony-Stimulating Factor (rh GM-CSF)

Persistence and degradability	Bioaccumulation unlikely.
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12.3. Bioaccumulative potential

Recombinant Human Granulocyte-Macrophage Colony-Stimulating Factor (rh GM-CSF)	
Log Pow	Not determined
Log Kow	Not determined

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Recombinant Human Granulocyte-Macrophage Colony-Stimulating Factor (rh GM-CSF)	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste)	: This material and its container must be disposed of in a safe way, and as per local legislation.
Sewage disposal recommendations	: Do not allow to enter drains or water courses.
Additional information	: Empty the packaging completely prior to disposal. Handle uncleaned empty containers as full ones.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

- Overland transport

Not applicable

- Transport by sea

Not applicable

- Air transport

Not applicable

- Inland waterway transport

Not applicable

- Rail transport

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

IBC code : Not applicable.

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Other information, restriction and prohibition regulations : Export and import of dangerous chemicals: Not subject to Regulation (EC) No 649/2012. Ozone layer depleting substances: Not subject to Regulation (EC) No 1005/2009. Persistent organic pollutants (POPs): Not subject to Regulation (EC) No 850/2004. Control of major-accident hazards (COMAH, Seveso III): Not subject to Directive 2012/18/EC.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

Not specifically applicable

Mixtures

SECTION 16: Other information

Other information : For this mixture, a safety data sheet is legally not required, neither due to REACH art. 31(1) nor due to REACH art. 31(3). Therefore, the compilation of this safety data sheet is done voluntarily and the safety data sheet doesn't have to fit the requirements of REACH annex II to the full extent.

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.