

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

CellGenix® GMP rh IL-2

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	04.11.2022	SAG-R0002752	Date of first issue: 04.11.2022

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

1.1 Product identifier

Trade name : CellGenix® GMP rh IL-2

Product code : 1020-050

Substance name : CellGenix® rh IL-2 - Interleukin-2 - recombinant human

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

Use of the Sub-
stance/Mixture : Cell Culture component. For further manufacturing use (GMP grade) or for preclinical ex vivo use (preclinical grade).

Recommended restrictions
on use : Not intended for human in vivo application.

1.3 Details of the supplier of the safety data sheet

Company : Sartorius CellGenix GmbH
Am Flughafen 16
79108 Freiburg
Germany

Telephone : +49 761 888 89-0

Telefax : +49 761 888 89-830

E-mail address of person
responsible for the SDS : CA-FM Department: Environment@sartorius.com

1.4 Emergency telephone number

UK/Europe/Global: +44.1865.407.333 (Sartorius 29003)
United States: +1.866.928.0789 (Toll free), (Sartorius 29003)
Canada: +1.800.579.7421 (Toll free), (Sartorius 29003)
United States & Canada (geographic): +1.202.464.2554 (Sartorius 29003)
Asia-Pacific/East & South East Asia (without China): +65.3158.1074 (Sartorius 29003)
Japan: +81.3.4578.9341 (Sartorius 29003)
Indonesia: 007.803.011.0293 (Toll free Indonesia), (Sartorius 29003)
Malaysia: +60.3.6207.4347 (Sartorius 29003)
Thailand: 001.800.120.666.751 (Toll free Thailand), (Sartorius 29003)
India: 000.800.100.7479 (Toll free India) or +65.3158.1198 (Sartorius 29003)
South Korea: +82.2.3479.8401 (Sartorius 29003)
Australia: +61.2.8014.4558 (Sartorius 29003)
New Zealand: +64.9.929.1483 (Sartorius 29003)

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Middle East/Africa: +44.1235.239671 (Sartorius 29003)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Labelling REGULATION (EC) No 1272/2008

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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 CLP-regulation (EU) No. 1272/2008. However, considering their bioactivity, any unintended exposure should be avoided. Therefore, in the case of any exposure, medical advice should be sought.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : Mixture
powdered form

Hazardous components

Remarks : No dangerous ingredients according to Regulation (EC) No. 1907/2006

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : Show this safety data sheet to the doctor in attendance.

If inhaled : Move out of dangerous area.
If breathed in, move person into fresh air.
Keep respiratory tract clear.

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- Oxygen or artificial respiration if needed.
If symptoms persist, call a physician.
- In case of skin contact : Remove immediately adhering matter.
Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
Get medical attention if irritation develops and persists.
- In case of eye contact : In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Call a physician immediately.
- If swallowed : Thoroughly rinse mouth with water. After rinsing, drink large amounts of water.

If symptoms persist, call a physician.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Water
Carbon dioxide (CO₂)
Dry powder
Foam
- Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

- Specific hazards during fire-fighting : Do not allow run-off from fire fighting to enter drains or water courses.

5.3 Advice for firefighters

- Special protective equipment for firefighters : Wear an approved positive pressure self-contained breathing apparatus in addition to standard fire fighting gear.
- Specific extinguishing meth- : Use extinguishing measures that are appropriate to local cir-

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ods cumstances and the surrounding environment.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Ensure adequate ventilation.
Avoid any contact with the substance.

6.2 Environmental precautions

Environmental precautions : The product should not be allowed to enter drains, water courses or the soil.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Do not create a powder cloud by using a brush or compressed air.

6.4 Reference to other sections

For personal protection see section 8., For disposal considerations see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Avoid creating dust.
Do not breathe vapours/dust.
Avoid contact with skin, eyes and clothing. If syringes are used to handle the product, be careful to avoid injuries with injection needles.

Advice on protection against fire and explosion : The product is flammable but not readily ignited.

Hygiene measures : Keep container tightly closed. When using, do not eat, drink or smoke. Wash hands and face before breaks and immediately after handling the product.

7.2 Conditions for safe storage, including any incompatibilities

Further information on storage conditions : -80 - -20 °C (Shipping at ambient temperature.)

Storage class (TRGS 510) : 10-13, German Storage Class 10 to 13

7.3 Specific end use(s)

Specific use(s) : Cell Culture component. For further manufacturing use (GMP grade) or for preclinical ex vivo use (preclinical grade).

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

No data available

8.2 Exposure controls

Engineering measures

none

Personal protective equipment

Eye protection	:	Safety glasses with side-shields conforming to EN166
Hand protection	:	
Material	:	Nitrile rubber Latex gloves
Skin and body protection	:	Change working clothes after each workshift.
Respiratory protection	:	No personal respiratory protective equipment normally required.
Protective measures	:	Personal protective equipment comprising: suitable protective gloves, safety goggles and protective clothing

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	powder
Colour	:	white
Odour	:	odourless
Odour Threshold	:	No data available
pH	:	not determined
Melting point/range	:	No data available
Boiling point/boiling range	:	Not applicable
Flash point	:	No data available
Evaporation rate	:	Not applicable
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available

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Relative density : No data available

Density : No data available

Bulk density : No data available

Solubility(ies)

Water solubility : soluble

Solubility in other solvents : not determined

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : not determined

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : Not applicable

Viscosity, kinematic : Not applicable

Flow time : Not applicable

Explosive properties : Not applicable

Oxidizing properties : No data available

9.2 Other information

Self-heating substances : No data available

Impact sensitivity : Not applicable

Molecular weight : 16,3 kg/mol

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : None known.

Stable under recommended storage conditions.
No decomposition if used as directed.

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10.4 Conditions to avoid

Conditions to avoid : Not applicable

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if stored and applied as directed.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product:

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : Remarks: No data available

Skin corrosion/irritation

Product:

Remarks: No data available

Serious eye damage/eye irritation

Product:

Remarks: No data available

Respiratory or skin sensitisation

Product:

Remarks: No data available

Germ cell mutagenicity

Product:

Genotoxicity in vitro : Remarks: No data available

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Genotoxicity in vivo : Remarks: No data available

Carcinogenicity

Product:

Remarks: This information is not available.

Reproductive toxicity

Product:

Effects on fertility : Remarks: No data available

STOT - single exposure

Product:

Remarks: No data available

STOT - repeated exposure

Product:

Remarks: No data available

Repeated dose toxicity

Product:

Remarks: This information is not available.

Experience with human exposure

Product:

General Information	: Remarks: No data available
Inhalation	: Remarks: This information is not available.
Skin contact	: Remarks: This information is not available.
Eye contact	: Remarks: This information is not available.
Ingestion	: Remarks: This information is not available.

Neurological effects

Product:

Remarks: No data available

Further information

Product:

Remarks: No data available

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SECTION 12: Ecological information

12.1 Toxicity

Product:

Toxicity to fish	:	Remarks: No data available
Toxicity to daphnia and other aquatic invertebrates	:	Remarks: No data available
Toxicity to algae	:	Remarks: No data available
Toxicity to fish (Chronic toxicity)	:	Remarks: No data available
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	Remarks: No data available
Toxicity to bacteria	:	Remarks: No data available
Sediment toxicity	:	Remarks: No data available

12.2 Persistence and degradability

Product:

Biodegradability	:	Remarks: No data available
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12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

Product:

Mobility	:	Remarks: No data available
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12.5 Results of PBT and vPvB assessment

Product:

Assessment	:	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher..
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12.6 Other adverse effects

Product:

Further information	:	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation
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Additional ecological information	: (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher. Remarks: No data available
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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	: In accordance with local and national regulations. Empty the packaging completely prior to disposal. Handle uncleaned empty containers as full ones.
Contaminated packaging	: Clean container with water. Retain and dispose of contaminated wash water.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Water hazard class (Germany)	: WGK 3 highly hazardous to water Remarks: (own classification)
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15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this mixture.

SECTION 16: Other information

Further 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.

These safety instructions also apply to empty packaging which may still contain product residues.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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