

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Product form	: Mixture
Trade name	: CellGenix® Interleukin-2 – recombinant human (rh IL-2)
Product code	: 1020 (GMP grade); 1420 (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 1020, GMP grade) or for preclinical ex vivo use (product code 1420, preclinical grade).
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**1.2.2. Uses advised against**

Restrictions on use	: Not intended for human in vivo application.
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**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@ubsplus.de

**1.4. Emergency telephone number**

Emergency number	: +49 761 19240 (Vergiftungs-Informationen-Zentrale Freiburg, 24 h, German & English)
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**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.
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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<sub>2</sub>), 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.

**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.

**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.
- 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 1020, GMP grade) or for preclinical ex vivo use (product code 1420, 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.

## 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 : 16.3 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 Interleukin-2 (rh IL-2)	
Persistence and degradability	Bioaccumulation unlikely.

**12.3. Bioaccumulative potential**

Recombinant Human Interleukin-2 (rh IL-2)	
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 Interleukin-2 (rh IL-2)**

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
<b>14.1. UN number</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>				
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.*