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## CellGenix® GMP rh TNF-alpha

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: -           |
| 1.0     | 04.11.2022     | SAG-R0002740 | Date of first issue: 04.11.2022 |

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

#### 1.1 Product identifier

Trade name : CellGenix® GMP rh TNF-alpha

Product code : 1006-050

Substance name : CellGenix® rh TNF-alpha - Tumor Necrosis Factor-alpha - recombinant human

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

Use of the Substance/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)

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New Zealand: +64.9.929.1483 (Sartorius 29003)  
Middle East/Africa: +44.1235.239671 (Sartorius 29003)

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### 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.

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### 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

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### 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.

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- Keep respiratory tract clear.  
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.

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## 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 (CO<sub>2</sub>)  
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.

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Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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### 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.

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### 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)

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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<br>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 |

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### 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 |

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Relative vapour density : No data available

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 : 17,5 kg/mol

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## 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.

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## 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 |
|------------------|---|----------------------------|

#### 12.3 Bioaccumulative potential

No data available

#### 12.4 Mobility in soil

**Product:**

|          |   |                            |
|----------|---|----------------------------|
| Mobility | : | Remarks: No data available |
|----------|---|----------------------------|

#### 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.. |
|------------|---|---|

#### 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.<br>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.<br>Empty the packaging completely prior to disposal. Handle uncleaned empty containers as full ones. |
| Contaminated packaging | : Clean container with water.<br><br>Retain and dispose of contaminated wash water.   |

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### 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.

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### 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<br>Remarks: (own classification) |
|------------------------------|--|

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### 15.2 Chemical safety assessment

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

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## 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 does'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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