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

1.1. Product identifier

Product form: Mixture
Trade name: CellGenix® Transforming Growth Factor-beta 1 - recombinant human (TGF-β1)
Product code: 1026 (GMP grade); 1426 (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 1026 GMP grade) or for preclinical ex vivo use (product code 1426, 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: 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-Informations-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]

Not classified

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

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 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.

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


Unsuitable extinguishing media: Not known.

5.2. Special hazards arising from the substance or mixture

Fire hazard: Combustible solids.

Explosion hazard: Not known.


5.3. Advice for firefighters

Firefighting instructions: Do not allow run-off from fire fighting to enter drains or water courses.


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 to -20 °C (Shipping at ambient temperature.)
Information on mixed storage: SECTION 15.

7.3. Specific end use(s)

Cell Culture component. For further manufacturing use (product code 1026, GMP grade) or for preclinical ex vivo use (product code 1426, 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: No data available
pH solution: Not determined
Relative evaporation rate (butylacetate=1): Not applicable
Melting point: Not determined
Freezing point: No data available
Boiling point: Not applicable
Flash point: No data available
Auto-ignition temperature: Not determined
Decomposition temperature: Not determined
Flammability (solid, gas): Not determined
Vapour pressure: Not applicable
Relative vapour density at 20 °C: No data available
Relative density: Not determined
Solubility: Water: Soluble
Log Pow: No data available
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 : ca. 25.6 kDa (Homodimer).

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)
Serious eye damage/irritation : Not classified (Based on available data, the classification criteria are not met)
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
Transforming Growth Factor-beta 1 - recombinant human (TGF-β1)
Persistence and degradability : Bioaccumulation unlikely.

12.3. Bioaccumulative potential
Transforming Growth Factor-beta 1 - recombinant human (TGF-β1)
Log Kow : Not determined

12.4. Mobility in soil
No additional information available
12.5. Results of PBT and vPvB assessment

<table>
<thead>
<tr>
<th>Substance/Mixture</th>
<th>PBT criteria</th>
<th>vPvB criteria</th>
</tr>
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<td>Transforming Growth Factor-beta 1 - recombinant human (TGF-β1)</td>
<td>This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII</td>
<td>This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII</td>
</tr>
</tbody>
</table>

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

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<thead>
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<th>IMDG</th>
<th>IATA</th>
<th>ADN</th>
<th>RID</th>
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</thead>
<tbody>
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<td>14.2. UN proper shipping name</td>
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<td>14.4. Packing group</td>
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<tr>
<td>14.5. Environmental hazards</td>
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<td>Not regulated</td>
<td>Not regulated</td>
<td>Not regulated</td>
</tr>
</tbody>
</table>

14.6. Special precautions for user

- Overland transport
  Not regulated

- Transport by sea
  Not regulated

- Air transport
  Not regulated

- Inland waterway transport
  Not regulated

- Rail transport
  Not regulated

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.
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 does not 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.