

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



CellGenix® GMP TCM (500ml Bottle)

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	27.04.2023	SAG-R0002793	Date of first issue: 27.04.2023

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

1.1 Product identifier

Trade name : CellGenix® GMP TCM (500ml Bottle)

Product code : 20814-0500

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

Use of the Substance/Mixture : Cell Culture component. For preclinical ex vivo use.

Recommended restrictions on use : Not intended for therapeutic use.

1.3 Details of the supplier of the safety data sheet

Company : Sartorius CellGenix GmbH
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Göttingen

Telephone : +49 761 888 89-0
+49551308049

E-mail address of person responsible for the SDS : EHS-SDS@sartorius.com

1.4 Emergency telephone number

UK/Europe/Global: +44.1865.407.333 (Sartorius 29003)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) Middle East/Africa:
+44.1235.239671 (Sartorius 29003)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : Aqueous solution

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.
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

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immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Call a physician immediately.

If swallowed : Clean mouth with water and drink afterwards plenty 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 firefighting : 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 methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Ensure adequate ventilation.
Do not inhale vapour and aerosols.

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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 : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).

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 formation of aerosol.
Avoid inhalation of vapour or mist.
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 not flammable.

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. Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

Further information on storage conditions : Keep in the refrigerator (2-8°C / 36-46 °F). Shipping at ambient temperature

Protect from light.

7.3 Specific end use(s)

Specific use(s) : Cell Culture component. For preclinical ex vivo use.
Not intended for therapeutic use.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

No data available

Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
CellGenix® GMP T Cell Medium (TCM) - Serum-free - Xeno-free				
Remarks: 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
Material : Latex gloves
Skin and body protection : Lab coat
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 : Aqueous solution
Colour : yellowish
Odour : odourless
pH : 6.9

to ≤ 7.3
Ph. Eur. 2.2.3

Melting point/freezing point : No data available

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Boiling point/boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Vapour pressure : No data available

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : not determined

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

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

None known.

10.2 Chemical stability

No decomposition if stored and applied as directed.

10.3 Possibility of hazardous reactions

Hazardous reactions : None reasonably foreseeable.

10.4 Conditions to avoid

Conditions to avoid : Protect from frost, heat and sunlight.

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

Stable under recommended storage conditions.

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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

Genotoxicity in vivo : Remarks: No data available

Germ cell mutagenicity-Assessment : Remarks: No data available

Carcinogenicity

Product:

Remarks : This information is not available.

Carcinogenicity - :

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toxicity)
Toxicity to daphnia and other : Remarks: No data available
aquatic invertebrates
(Chronic toxicity)
Toxicity to microorganisms :
Remarks: No data available

Toxicity to soil dwelling : Remarks: No data available
organisms
Sediment toxicity : Remarks: No data available

12.2 Persistence and degradability

Product:

Biodegradability : Remarks: No data available

12.3 Bioaccumulative potential

Product:

Bioaccumulation : Remarks: No data available

12.4 Mobility in soil

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:

Endocrine disrupting : The substance/mixture does not contain components
potential considered to have endocrine disrupting properties according
to REACH Article 57(f) or Commission Delegated regulation
(EU) 2017/2100 or Commission Regulation (EU) 2018/605 at
levels of 0.1% or higher.

Additional ecological : No data available
information

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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 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

Relevant EU provisions transposed through retained EU law

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Other regulations:

15.2 Chemical safety assessment

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

SECTION 16: Other information

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

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