

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

TheraPRO® CHO Production Medium

Version 3.0

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

Product name : TheraPRO® CHO Production Medium

Material number : BESP1571B

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

Use of the Substance/Mixture : Suitable for GMP manufacturing.

Recommended restrictions on use : Not for human or animal in vivo or diagnostic use.

1.3 Details of the supplier of the safety data sheet

Company : **Lonza Ltd**
Muenchensteinerstrasse 38
CH-4002 Basel, Switzerland
Business Telephone: +41 61 316 81 11

Lonza Verviers Sprl
Parc Industriel de Petit-Rechain
BE-4800 Verviers, Belgium
Business Telephone: +32 8732 1611

Lonza Cologne GmbH
Nattermannallee 1
DE-50829 Köln, Germany
Business Telephone: + 49 221 99 1990

E-mail address / Responsible/issuing person : sds@lonza.com

1.4 Emergency telephone number

Emergency telephone number : Lonza Ltd, CH-4002 Basel, Switzerland
Telephone: +41 61 313 94 94 (24h)

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.

Additional Labelling

EUH210 Safety data sheet available on request.
EUH208 Contains Sodium pyruvate. May produce an allergic reaction.

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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.

Ecological information: The substance/mixture does not contain components 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.

Toxicological information: The substance/mixture does not contain components 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.

May form explosible dust-air mixture if dispersed.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. REACH Registration Number	Classification	Concentration (% w/w)
L-Cysteine	52-90-4 200-158-2	Acute Tox. 4; H302	$\geq 1 - < 3$
Sodium pyruvate	113-24-6 204-024-4 01-2120767047-50-XX XX	Eye Irrit. 2; H319 Skin Sens. 1; H317	$\geq 0,3 - < 0,5$

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- | | |
|-------------------------|---|
| If inhaled | : Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician. |
| In case of skin contact | : Wash with water and soap as a precaution.
If on clothes, remove clothes.
In the case of skin irritation or allergic reactions see a physician. |
| In case of eye contact | : Flush eyes with water as a precaution.
Remove contact lenses.
Keep eye wide open while rinsing.
Protect unharmed eye.
If eye irritation persists, consult a specialist. |
| If swallowed | : Clean mouth with water and drink afterwards plenty of water.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician. |

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4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

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 : Water spray
Alcohol-resistant foam
Dry chemical

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Heating or fire can release toxic gas.

Hazardous combustion products : Carbon oxides (COx)
Sodium oxides
Hydrogen chloride (HCl)
Nitrogen oxides (NOx)
Potassium oxides
Sulphur oxides (SOx)

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Further information : Use a water spray to cool fully closed containers.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Avoid dust formation.

6.2 Environmental precautions

Environmental precautions : Try to prevent the material from entering drains or water courses.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Pick up and arrange disposal without creating dust.
Non-sparking tools should be used.
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).

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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 : No special precautions required.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Minimize dust generation and accumulation.
Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces.
Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations.
For personal protection see section 8.
- Advice on protection against fire and explosion : During processing, dust may form explosive mixture in air.
Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed. Take precautionary measures against static discharges.
- Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep container tightly closed. Keep in a well-ventilated place.
Electrical installations / working materials must comply with the technological safety standards. To maintain product quality, do not store in heat or direct sunlight.
- Further information on storage conditions : Avoid moisture.
- Advice on common storage : No special restrictions on storage with other products.
- Further information on storage stability : Keep in a dry place. No decomposition if stored and applied as directed.

7.3 Specific end use(s)

- Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Contains no substances with occupational exposure limit values.

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Calcium chloride	Workers	Inhalation	Acute local effects	10 mg/m3

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	Workers	Inhalation	Long-term local effects	5 mg/m3
	Consumer use	Inhalation	Acute local effects	5 mg/m3
	Consumer use	Inhalation	Long-term local effects	2,5 mg/m3

8.2 Exposure controls

Engineering measures

It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment.

Use only appropriately classified electrical equipment and powered industrial trucks.

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

Personal protective equipment

Eye protection : Safety glasses

Hand protection
Remarks : Wear protective gloves. Break through time : > 480 min

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Lightweight protective clothing

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.

Filter type : Particulate type (P1/N95) (P1-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : solid

Appearance : powder

Colour : No data available

Odour : No data available

Melting point/freezing point : No data available

Boiling point/boiling range : Not applicable

Flammability : No data available

Upper explosion limit / Upper flammability limit : Not applicable

Lower explosion limit / Lower flammability limit : Not applicable

Flash point : Not applicable

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Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	Not applicable
Viscosity	:	Not applicable
Viscosity, kinematic	:	Not applicable
Solubility(ies)	:	No data available
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	Not applicable
Particle characteristics	:	No data available
Particle size	:	No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No decomposition if stored and applied as directed.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under recommended storage conditions.
No hazards to be specially mentioned.

Dust may form explosive mixture in air.

10.4 Conditions to avoid

Conditions to avoid : Heat

10.5 Incompatible materials

Materials to avoid : Oxidizing agents
Strong acids and strong bases

10.6 Hazardous decomposition products

No decomposition if used as directed.

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SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Acute oral toxicity : Acute toxicity estimate: > 2 000 mg/kg
Method: Calculation method

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Remarks: No data available

Serious eye damage/eye irritation

Remarks: No data available

Respiratory or skin sensitisation

Remarks: No data available

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: No data available

Carcinogenicity

Remarks: No data available

Reproductive toxicity

Effects on fertility : Remarks: No data available

STOT - single exposure

Remarks: No data available

STOT - repeated exposure

Remarks: No data available

Aspiration toxicity

No aspiration toxicity classification

11.2 Information on other hazards

Endocrine disrupting properties

Assessment : The substance/mixture does not contain components 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.

Further information

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Remarks: No data available

SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish : Remarks: No data available

12.2 Persistence and degradability

Biodegradability : Remarks: No data available

12.3 Bioaccumulative potential

Bioaccumulation : Remarks: No data available

12.4 Mobility in soil

Distribution among environmental compartments : Remarks: No data available

12.5 Results of PBT and vPvB assessment

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 Endocrine disrupting properties

Endocrine disrupting potential : The substance/mixture does not contain components 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.

12.7 Other adverse effects

Additional ecological information : No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of contents/container in accordance with local regulation.
Contact waste disposal services.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

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SECTION 14: Transport information

IATA Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class(es) : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

IMDG Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class(es) : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : Marine pollutant: no

ADR Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class(es) : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

RID Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class(es) : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

DOT Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class(es) : Not applicable
 14.4 Packing group : Not applicable

TDG Not dangerous goods

14.1 UN number : Not applicable
 14.2 Proper shipping name : Not applicable
 14.3 Transport hazard class(es) : Not applicable
 14.4 Packing group : Not applicable
 14.5 Environmental hazards : no

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation

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classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	2-Hydroxy-N,N,N-trimethylethanaminium chloride Calcium chloride
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REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
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REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
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Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	:	Not applicable
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Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Water hazard class (Germany)	:	WGK 1 slightly hazardous to water
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15.2 Chemical safety assessment

No data available

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SECTION 16: Other information

Full text of H-Statements

H302	: Harmful if swallowed.
H317	: May cause an allergic skin reaction.
H319	: Causes serious eye irritation.

Full text of other abbreviations

Acute Tox.	: Acute toxicity
Eye Irrit.	: Eye irritation
Skin Sens.	: Skin sensitisation

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; 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; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

Other information	: This Safety Data Sheet is a generic European Safety Data Sheet and therefore does not contain all specific information for each European country.
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Date format	: dd.mm.yyyy
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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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