

**SAFETY DATA SHEET**

according to Regulation (EC) No. 1907/2006

**TheraPEAK™ ProFreeze™ CDM (2x)**

Version 3.0

Revision Date 26.04.2024

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

Product name : TheraPEAK™ ProFreeze™ CDM (2x)  
Material number : BEBP12-769E

**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.

**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.

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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.

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### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

##### Components

Remarks : No hazardous ingredients

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### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

If inhaled : No special precautions required.

In case of skin contact : Wash with water and soap as a precaution.  
If skin irritation persists, call a physician.

In case of eye contact : Immediately flush eye(s) with plenty of water.  
If eye irritation persists, consult a specialist.

If swallowed : Immediately give large quantities of water to drink.  
Do not induce vomiting without medical advice.  
Never give anything by mouth to an unconscious person.

#### 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 : No information available.

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### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Dry powder  
Foam

#### 5.2 Special hazards arising from the substance or mixture

Hazardous combustion products : No hazardous combustion products are known

#### 5.3 Advice for firefighters

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

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Further information : Use water spray to cool unopened containers.

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**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.

**6.2 Environmental precautions**

Environmental precautions : Prevent product from entering drains.

**6.3 Methods and material for containment and cleaning up**

Methods for cleaning up : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

**6.4 Reference to other sections**

For personal protection see section 8.

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**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

Advice on safe handling : No special precautions required.

Advice on protection against fire and explosion : 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 : No special storage conditions required.

**7.3 Specific end use(s)**

Specific use(s) : No information available.

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**SECTION 8: Exposure controls/personal protection****8.1 Control parameters****Occupational Exposure Limits**

Contains no substances with occupational exposure limit values.

**8.2 Exposure controls****Engineering measures**

Avoid splashes.

**Personal protective equipment**

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Eye protection	:	Tightly fitting safety goggles
Hand protection	:	
Material	:	Nitrile rubber
Rate of permeability	:	> 480 min
Skin and body protection	:	Choose body protection according to the amount and concentration of the dangerous substance at the work place. No special protective equipment required.
Respiratory protection	:	No personal respiratory protective equipment normally required.

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Appearance	:	Aqueous solution
Colour	:	No data available
Odour	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	No data available
		No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	No data available

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Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	No data available
Particle characteristics	:	No data available

**9.2 Other information**

No data available

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**SECTION 10: Stability and reactivity****10.1 Reactivity**

Stable under recommended storage conditions.

**10.2 Chemical stability**

Stable under normal conditions.

**10.3 Possibility of hazardous reactions**

Hazardous reactions : Stable under normal conditions.

**10.4 Conditions to avoid**

Conditions to avoid : No data available

**10.5 Incompatible materials**

Materials to avoid : Strong oxidizing agents

**10.6 Hazardous decomposition products**

No decomposition if stored normally.

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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 : Remarks: No data available

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

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### 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

Remarks: No data available

## 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

Remarks: No data is available on the product itself.

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## SECTION 12: Ecological information

### 12.1 Toxicity

Toxicity to fish : Remarks: No data available

### 12.2 Persistence and degradability

Biodegradability : Result: 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

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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

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

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

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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

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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 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.

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## SECTION 15: Regulatory information

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable

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



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Water hazard class (Germany) : WGK 1 slightly hazardous to water

### 15.2 Chemical safety assessment

not required

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**SECTION 16: Other information****Full text of other abbreviations**

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**

Date format : dd.mm.yyyy

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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