

# Kit SDS Cover Sheet

## STD POWERCHO2 POWDER KIT 10L

Version 4.0

Revision Date 01.05.2024

Print Date 09.09.2024

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### Product Information

Product name : STD POWERCHO2 POWDER KIT 10L

Material number : BE15-771ND

### Components

STD PowerCHO2 W/O FECITR,INS,LIPIDS,PEG	SDS attached
(STD) CHO 7 LIPIDS 2X CONCENTRATE	SDS attached
Recombinant human insulin 0.5%	SDS attached
Polyethylene Glycol	SDS attached
Fe Citrate concentrated solution (100x)	SDS attached

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according to Regulation (EC) No. 1907/2006

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

Product name : STD PowerCHO2 W/O FECITR,INS,LIPIDS,PEG  
Unique Formula Identifier (UFI) : E58Y-P86Y-000Y-6RY3

**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)**

Eye irritation, Category 2 H319: Causes serious eye irritation.  
Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.

**2.2 Label elements****Labelling (REGULATION (EC) No 1272/2008)**

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Hazard pictograms

:



Signal word

: Warning

Hazard statements

: H317 May cause an allergic skin reaction.  
H319 Causes serious eye irritation.

Precautionary statements

:  
**Prevention:**  
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.  
P280 Wear protective gloves/ eye protection/ face protection.  
**Response:**  
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
P337 + P313 If eye irritation persists: Get medical advice/ attention.  
P362 + P364 Take off contaminated clothing and wash it before reuse.  
**Disposal:**  
P501 Dispose of contents/container in accordance with local regulation.

Hazardous components which must be listed on the label:

Sodium pyruvate

**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 combustible dust concentrations in air.

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## 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)
Sodium pyruvate	113-24-6 204-024-4 01-2120767047-50-XX XX	Eye Irrit. 2; H319 Skin Sens. 1; H317	>= 1 - < 10
Tyrosine disodium salt dihydrate	122666-87-9	Eye Dam. 1; H318	>= 1 - < 3

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

- If inhaled : If breathed in, move person into fresh air.  
Consult a physician after significant exposure.
- In case of skin contact : After contact with skin, wash immediately with plenty of soap  
and water.  
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 : If swallowed, do not induce vomiting - seek medical advice.  
Immediately give large quantities of water to drink.  
Never give anything by mouth to an unconscious person.

### 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

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

- Suitable extinguishing media : Dry powder  
Water spray

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Foam

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

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

**5.3 Advice for firefighters**

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

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.  
Avoid dust formation.

**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 : 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).  
Non-sparking tools should be used.

**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 : 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

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to the friction of transfer and mixing operations.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Advice on protection against fire and explosion : Avoid dust formation. During processing, dust may form explosive mixture in air.

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**

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.

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).

Use only appropriately classified electrical equipment and powered industrial trucks.

**Personal protective equipment**

Eye protection : Safety glasses with side-shields

Hand protection

Material : Nitrile rubber

Rate of permeability : > 480 min

Skin and body protection : No special protective equipment required.

Respiratory protection : Dust safety masks are recommended when the dust concentration is more than 10 mg/m<sup>3</sup>.

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**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties**

Physical state	:	solid
Appearance	:	powder
Colour	:	white, to, tan
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	:	Not applicable
Lower explosion limit / Lower flammability limit	:	Not applicable
Flash point	:	No data available Not applicable
Auto-ignition temperature	:	Not applicable
Decomposition temperature Decomposition temperature	:	No data available
pH	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable
Solubility(ies) 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

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Relative vapour density : Not applicable  
Particle characteristics : No data available

**9.2 Other information**

No data available

**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.

**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



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**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

**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.

**The following toxicological data refer to:****Tyrosine disodium salt dihydrate** (CAS-No.: 122666-87-9)**Acute toxicity**Acute oral toxicity : LD50 (Rat, female): > 2 000 mg/kg  
Method: OECD Test Guideline 420**Serious eye damage/eye irritation**Species: Bovine cornea  
Exposure time: 4 h  
Method: OECD Test Guideline 437  
Result: Causes serious eye damage.

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Test substance: Information given is based on data obtained from similar substances.

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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 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**

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.

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.

**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

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**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) : Calcium chloride  
2-Hydroxy-N,N,N-trimethylethanamium chloride

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

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Not applicable

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

**15.2 Chemical safety assessment**

not required

**SECTION 16: Other information****Classification of the mixture:**

Eye Irrit. 2 H319

Skin Sens. 1 H317

**Classification procedure:**

Calculation method

Calculation method

**Full text of H-Statements**

H317 : May cause an allergic skin reaction.  
H318 : Causes serious eye damage.  
H319 : Causes serious eye irritation.

**Full text of other abbreviations**

Eye Dam. : Serious eye damage  
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 -

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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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Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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

Product name : (STD) CHO 7 LIPIDS 2X CONCENTRATE

**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**

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EUH210 Safety data sheet available on request.

#### 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.

## 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)
Ethanol	64-17-5 200-578-6 603-002-00-5 01-2119457610-43-XX XX	Flam. Liq. 2; H225 Eye Irrit. 2; H319  specific concentration limit Eye Irrit. 2; H319 > 50 %	>= 1 - < 3

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 breathed in, move person into fresh air.
- 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.



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- 
- Remove contaminated clothing. If irritation develops, get medical attention.
- 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 : Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
- 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 : Do not induce vomiting without medical advice.  
Never give anything by mouth to an unconscious person.  
Gently wipe or rinse the inside of the mouth with water.  
If symptoms persist, call a physician or Poison Control Centre immediately.
- 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.

**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.

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**SECTION 5: Firefighting measures****5.1 Extinguishing media**

- Suitable extinguishing media : Water spray  
Dry powder  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)
- Water spray
- Unsuitable extinguishing media : High volume water jet

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

Specific hazards during firefighting : Heating or fire can release toxic gas.

Hazardous combustion products : Carbon oxides (COx)

**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.

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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 : No special environmental precautions required.  
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 : Dispose of in accordance with local regulations.  
Pick up and transfer to properly labelled containers.  
Remove all sources of ignition.

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.

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 : Wear personal protective equipment.

No special precautions required.  
For personal protection see section 8.

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Advice on protection against fire and explosion : Take precautionary measures against static discharges.

Normal measures for preventive fire protection.

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 : Store in original container. Remove all sources of ignition.

Store at room temperature.

Keep container tightly closed. Keep in a well-ventilated place. To maintain product quality, do not store in heat or direct sunlight.

Advice on common storage : No special restrictions on storage with other products.

Further information on storage stability : 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

Countries not listed may have their own country specific values.

#### Occupational Exposure Limits

##### Switzerland

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ethanol	64-17-5	TWA	500 ppm 960 mg/m <sup>3</sup>	CH SUVA
		STEL	1 000 ppm 1 920 mg/m <sup>3</sup>	CH SUVA

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Ethanol	Consumers	Oral	Long-term systemic effects	87 mg/kg

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	Consumers	Dermal	Long-term systemic effects	206 mg/kg
	Consumers	Inhalation	Long-term systemic effects	114 mg/m3
	Workers	Inhalation	Long-term systemic effects	950 mg/m3
	Workers	Dermal	Long-term systemic effects	343 mg/kg

#### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Ethanol	Fresh water	0,96 mg/l
	Soil	0,63 mg/kg
	Fresh water sediment	3,6 mg/kg
	Marine water	0,79 mg/l
	Sewage treatment plant	580 mg/l
	Marine sediment	2,9 mg/kg
	Oral	380 mg/kg

## 8.2 Exposure controls

### Engineering measures

Use only in area provided with appropriate exhaust ventilation.

### 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

: No personal respiratory protective equipment normally required.

No personal respiratory protective equipment normally required.

In the case of vapour formation use a respirator with an approved filter.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state : liquid

Appearance : Aqueous solution

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Colour	:	No data available
Odour	:	No data available
Melting point/freezing point	:	ca. 0 °C
Initial boiling point and boiling range	:	ca. 97 °C
Flammability	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	does not flash
Auto-ignition temperature	:	No data available
Decomposition temperature Decomposition temperature	:	No data available
pH	:	ca. 6,7 - 7,5
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
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**

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.

**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.

**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

**Germ cell mutagenicity**

Genotoxicity in vitro : Remarks: No data available

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#### 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

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

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**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**

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.

Additional ecological information : No data available

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**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

Product : Dispose of in accordance with local regulations.

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

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<b>TDG</b>	:	Not dangerous goods
<b>14.1 UN number</b>	:	Not applicable
<b>14.2 Proper shipping name</b>	:	Not applicable
<b>14.3 Transport hazard class(es)</b>	:	Not applicable
<b>14.4 Packing group</b>	:	Not applicable
<b>14.5 Environmental hazards</b>	:	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 - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable

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

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) : nwg not water endangering

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**15.2 Chemical safety assessment**

not required

**SECTION 16: Other information****Full text of H-Statements**

H225 : Highly flammable liquid and vapour.  
H319 : Causes serious eye irritation.

**Full text of other abbreviations**

Eye Irrit. : Eye irritation  
Flam. Liq. : Flammable liquids

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

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**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.

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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Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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

Product name : Recombinant human insulin 0.5%

**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.

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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.

Insulin: may cause hypoglycaemia.

Insulin is inactivated in the gastro-intestinal tract when ingested.

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**SECTION 3: Composition/information on ingredients****3.2 Mixtures****Components**

Remarks : No hazardous ingredients

---

**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.

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**SECTION 5: Firefighting measures****5.1 Extinguishing media**

Suitable extinguishing media : Water spray

Unsuitable extinguishing media : High volume water jet

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

Specific hazards during firefighting : Heating or fire can release toxic gas.

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.  
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.

**6.2 Environmental precautions**Environmental precautions : No special environmental precautions required.  
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 : Use neutralizing agents.  
Neutralize with chalk, alkali solution or ammonia.  
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).

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**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 : No special precautions required.  
For personal protection see section 8.

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

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.  
To maintain product quality, do not store in heat or direct sunlight.

Advice on common storage : No special restrictions on storage with other products.

Further information on storage stability : 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.

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

Use only in area provided with appropriate exhaust ventilation.

**Personal protective equipment**

Eye protection : Safety glasses



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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	:	No personal respiratory protective equipment normally required. In the case of vapour formation use a respirator with an approved filter.

---

**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties**

Physical state	:	liquid
Appearance	:	Aqueous solution
Colour	:	colourless
Odour	:	odourless
Melting point/freezing point	:	No data available
Boiling point/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	:	Water
Auto-ignition temperature	:	No data available
Decomposition temperature Decomposition temperature	:	No data available
pH	:	2 - 4
Viscosity Viscosity, kinematic	:	No data available

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Solubility(ies)	
Water solubility	: completely soluble
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	: 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**

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.
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**10.4 Conditions to avoid**

Conditions to avoid	: Heat
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**10.5 Incompatible materials**

Materials to avoid	: Oxidizing agents Strong acids and strong bases
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**10.6 Hazardous decomposition products**

No decomposition if used as directed.

---

**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
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Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

#### Skin corrosion/irritation

Result: No skin irritation  
Assessment: No skin irritation

#### Serious eye damage/eye irritation

Result: No eye irritation  
Assessment: No eye irritation

#### 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.

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#### Further information

Remarks: Insulin: may cause hypoglycaemia.  
Insulin is inactivated in the gastro-intestinal tract when ingested.  
May cause central nervous system depression.  
May induce sweating, pallor or visual disturbances.

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

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.

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Additional ecological information : No data available

**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

Product : Solutions with low pH-value must be neutralized before discharge.  
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.

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

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

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

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Regulation (EU) 2019/1021 on persistent organic pollutants : Not applicable  
(recast)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) : nwg not water endangering

**15.2 Chemical safety assessment**

not required

**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 –

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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.

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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Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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

Product name : Polyethylene Glycol

**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.

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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 combustible dust concentrations in air.

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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 : Remove to fresh air.  
If breathing is irregular or stopped, administer artificial respiration.  
If symptoms persist, call a physician.
- In case of skin contact : After contact with skin, wash immediately with plenty of soap and water.  
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 : If swallowed, do not induce vomiting - seek medical advice.  
Immediately give large quantities of water to drink.  
Never give anything by mouth to an unconscious person.

**4.2 Most important symptoms and effects, both acute and delayed**

Symptoms : No information available.

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**4.3 Indication of any immediate medical attention and special treatment needed**

Treatment : No information available.

**SECTION 5: Firefighting measures****5.1 Extinguishing media**Suitable extinguishing media : Dry powder  
Water spray  
Foam**5.2 Special hazards arising from the substance or mixture**Hazardous combustion products : Carbon oxides (COx)  
Hydrogen chloride (HCl)**5.3 Advice for firefighters**

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

Further information : Use water spray to cool unopened 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 : Prevent product from entering drains.

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

Methods for cleaning up : 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). Non-sparking tools should be used.

**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 : 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.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Advice on protection against fire and explosion : Avoid dust formation. During processing, dust may form explosive mixture in air.
- 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.
- Further information on storage conditions : Dark and Dry

**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.

**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.

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).

Use only appropriately classified electrical equipment and powered industrial trucks.

**Personal protective equipment**

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Eye protection	:	Safety glasses with side-shields
Hand protection	:	
Material	:	Nitrile rubber
Rate of permeability	:	> 480 min
Skin and body protection	:	No special protective equipment required.
Respiratory protection	:	Dust safety masks are recommended when the dust concentration is more than 10 mg/m <sup>3</sup> .

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**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties**

Physical state	:	solid
Appearance	:	flakes
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	:	Not applicable
Lower explosion limit / Lower flammability limit	:	Not applicable
Flash point	:	No data available Not applicable
Auto-ignition temperature	:	Not applicable
Decomposition temperature Decomposition temperature	:	No data available
pH	:	Not applicable
Viscosity Viscosity, kinematic	:	Not applicable

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Solubility(ies)	
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

**9.2 Other information**

Molecular weight : 382,88 g/mol

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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

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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

**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 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**

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.

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.



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Contact waste disposal services.

**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

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<b>TDG</b>	:	Not dangerous goods
<b>14.1 UN number</b>	:	Not applicable
<b>14.2 Proper shipping name</b>	:	Not applicable
<b>14.3 Transport hazard class(es)</b>	:	Not applicable
<b>14.4 Packing group</b>	:	Not applicable
<b>14.5 Environmental hazards</b>	:	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

Water hazard class (Germany) : WGK 1 slightly hazardous to water  
Code Number: 6 780  
Remarks: 11 2017

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**15.2 Chemical safety assessment**

not required

**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

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Print Date 09.09.2024

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

Product name : Fe Citrate concentrated solution (100x)

**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.

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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.

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**SECTION 3: Composition/information on ingredients****3.2 Mixtures****Components**

Remarks : No hazardous ingredients

---

**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.

Further information : Use water spray to cool unopened containers.

**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.

**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 : No special precautions required.

Hygiene measures : Handle in accordance with good industrial hygiene and safety

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practice.

#### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Store in cool place.

#### 7.3 Specific end use(s)

Specific use(s) : No information available.

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

Countries not listed may have their own country specific values.

##### Occupational Exposure Limits

##### Switzerland

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Iron(3+) citrate	3522-50-7	TWA (inhalable dust)	1 mg/m <sup>3</sup> (Iron)	CH SUVA

#### 8.2 Exposure controls

##### Engineering measures

Avoid splashes.

##### Personal protective equipment

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.

### SECTION 9: Physical and chemical properties

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

Physical state : liquid



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Appearance	:	Aqueous solution
Colour	:	light brown
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	:	ca. 2,1
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
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	No data available
Particle characteristics	:	No data available

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**9.2 Other information**

No data available

**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.

**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

**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

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**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**

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.

Additional ecological information : No data available

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**SECTION 13: Disposal considerations****13.1 Waste treatment methods**

Product : Solutions with low pH-value must be neutralized before discharge.

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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

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<b>TDG</b>	:	Not dangerous goods
<b>14.1 UN number</b>	:	Not applicable
<b>14.2 Proper shipping name</b>	:	Not applicable
<b>14.3 Transport hazard class(es)</b>	:	Not applicable
<b>14.4 Packing group</b>	:	Not applicable
<b>14.5 Environmental hazards</b>	:	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

Water hazard class (Germany) : WGK 2 obviously hazardous to water

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**15.2 Chemical safety assessment**

not required

**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

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Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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