

Kit SDS Cover Sheet

STD PROCHO5 POWDER KIT W/O PR 50 L

Version 4.0

Revision Date 01.05.2024

Print Date 17.01.2025

Product Information

Product name : STD PROCHO5 POWDER KIT W/O PR 50 L

Material number : BE15-766F

Components

(STD) ProCHO5 Powder	SDS attached
(STD) CHO 7 LIPIDS 2X CONCENTRATE	SDS attached
Recombinant human insulin 0.5%	SDS attached

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

(STD) ProCHO5 Powder

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

Product name : (STD) ProCHO5 Powder
Unique Formula Identifier (UFI) : GY7Y-N8U5-E000-V2SY

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)**

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.

Precautionary statements

: **Prevention:**

P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.

Response:

P333 + P313 If skin irritation or rash occurs: 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.

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

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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 - < 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.
In the case of inhalation of aerosol/mist consult a physician if necessary.
- 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
Foam

5.2 Special hazards arising from the substance or mixture

- Hazardous combustion products : Nitrogen oxides (NOx)
Sodium oxides
Potassium oxides
Carbon oxides (COx)

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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.

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.

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

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practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : No special storage conditions required. Store in cool place.

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.

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Calcium chloride	Workers	Inhalation	Acute local effects	10 mg/m ³
	Workers	Inhalation	Long-term local effects	5 mg/m ³
	Consumer use	Inhalation	Acute local effects	5 mg/m ³
	Consumer use	Inhalation	Long-term local effects	2,5 mg/m ³

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.

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Respiratory protection : Dust safety masks are recommended when the dust concentration is more than 10 mg/m³.

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

Physical state : solid

Appearance : powder

Colour : colourless

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

Solubility(ies)
Water solubility : No data available

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

Vapour pressure : No data available

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

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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.

The following toxicological data refer to:**2-Oxopropionic acid sodium salt (CAS-No.: 113-24-6)****Acute toxicity**

Acute oral toxicity : LD50 (Rat): > 5 600 mg/kg

Respiratory or skin sensitisationMethod: OECD Test Guideline 429
Result: May cause sensitisation by skin contact.

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GLP: yes

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.

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-trimethylethanaminium 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:**

Skin Sens. 1 H317

Classification procedure:

Calculation method

Full text of H-StatementsH317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.**Full text of other abbreviations**Eye Irrit. : Eye irritation
Skin Sens. : Skin sensitisation

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL -

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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 numberEmergency 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.

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

- Suitable extinguishing media : Water spray
Dry powder
Alcohol-resistant foam
Carbon dioxide (CO₂)
- 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 firefightersSpecial 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 precautionsEnvironmental 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.

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 ³	CH SUVA
		STEL	1 000 ppm 1 920 mg/m ³	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

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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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.

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.

99 / EN

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

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Recombinant human insulin 0.5%

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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 numberEmergency 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.

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.

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 firefightersSpecial 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 precautionsEnvironmental 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.

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

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/irritationResult: 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.

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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XIV)

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 –

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

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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

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

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