

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Recombinant human insulin 0.5%

Version 4.0

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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%
Material number : BE02-033E

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

Use of the Substance/Mixture : Suitable for GMP manufacturing.
Recommended restrictions on use : Not for human or animal in vivo or diagnostic use.

1.3 Details of the supplier of the safety data sheet

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

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

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

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

1.4 Emergency telephone number

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

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

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

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

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

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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

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

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.

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

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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).

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 : Keep container tightly closed. Keep in a well-ventilated place.

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containers	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.
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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

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. 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

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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
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.

10.4 Conditions to avoid

Conditions to avoid : Heat

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

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

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levels of 0.1% or higher.

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

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.

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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

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

15.2 Chemical safety assessment

not required

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SECTION 16: Other information

Full text of other abbreviations

ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; ATE - Acute Toxicity Estimate; AwSV - Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / Ordinance on facilities for handling substances that are hazardous to water; BPR – Biocidal Product Regulation; bw - Body weight; CAS - Chemical Abstract Service; CLP - Classification Labelling Packaging Regulation, Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DNEL-Derived No Effect Level; DOT - Department of Transportation; EC – European Community; ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; EmS (Emergency Response Procedures for Ships Carrying Dangerous Goods); EN – European Standard; ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; EU OEL - European Occupational Exposure Limit; GHS -Globally Harmonized System of Classification and Labelling of Chemicals; GLP - Good Laboratory Practice; GV – Danish Exposure Limits for Substances and Materials; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IMDG - International Maritime Dangerous Goods; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); LOFT - Danish Threshold Limit Value; MAK - German Threshold Limit Value; MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NIOSH/Guide – National Institute of Safety and Health Guidebook; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; PBT - Persistent, Bioaccumulative and Toxic substance; PEL - Permissible Exposure Limit; PNEC - Predicted no Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; REL - Recommended Exposure Limit; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; STEL - Short-Term Exposure Limit; TDG - Transportation of Dangerous Goods; TGG – Dutch Threshold Limit Value; TGV – Swedish OEL; TLV Threshold Limit Value; TLV-C - Threshold Limit Value Ceiling; TWA -Time Weighted Average; UDS - Unscheduled DNA Synthesis; UN - United Nations; VLE - Valeurs limites d'exposition professionnelle aux agents chimiques en France; VME - Valeur (Limite) Moyenne d'Exposition; VOC - Volatile Organic Compound[s]; WEEL - Workplace Environmental Exposure Level; % w/w Percent weight by weight; %(V) Percent Volume

Further information

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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