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SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006

Version 6.4 Revision Date 05.02.2023 Print Date 09.05.2024 GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1	Product identifiers Product name	:	Human Insulin solution
	Product Number Brand REACH No.	•	I-034 Cerilliant
1.2	Relevant identified us	ses	of the substance or mixture and uses advised against

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

	Company	:	Merck Life Science S.r.l. Via Monte Rosa 93 I-20149 MILANO
1.4	Telephone Fax E-mail address Emergency telephone	:	+39 02 3341 7340 +39 02 3801 0737 serviziotecnico@merckgroup.com
	Emergency Phone #	:	800-789-767 (CHEMTREC Italia) +39-02-4555-7031 (CHEMTREC chiamate internazionali) +39 02-6610-1029 (Centro Antiveleni Niguarda Ca' Granda - Milano)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

2.2 Label elements

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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SECTION 3: Composition/information on ingredients

3.2 Mixtures

No components need to be disclosed according to the applicable regulations.

SECTION 4: First aid measures

4.1 Description of first-aid measures

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration.

In case of skin contact

Wash off with soap and plenty of water.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

- **5.2** Special hazards arising from the substance or mixture Oxides of phosphorus Sodium oxides
- **5.3** Advice for firefighters Wear self-contained breathing apparatus for firefighting if necessary.
- **5.4 Further information** No data available

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Avoid breathing vapors, mist or gas. For personal protection see section 8.
- **6.2 Environmental precautions** No special environmental precautions required.
- **6.3 Methods and materials for containment and cleaning up** Keep in suitable, closed containers for disposal.
- **6.4 Reference to other sections** For disposal see section 13.

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SECTION 7: Handling and storage

7.1 Precautions for safe handling For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Keep container tightly closed in a dry and well-ventilated place. Store in cool place.

Storage stability

Recommended storage temperature -20 °C

Storage class

Storage class (TRGS 510): 10: Combustible liquids

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with workplace control parameters

8.2 Exposure controls

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

Body Protection

Impervious clothing, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Respiratory protection not required. For nuisance exposures use type OV/AG (US) or type ABEK (EU EN 14387) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

No special environmental precautions required.

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

TUI	ormation on basic pr	iysical and chemical properties
a)	Physical state	liquid
b)	Color	No data available
c)	Odor	No data available
d)	Melting point/freezing point	No data available
e)	Initial boiling point and boiling range	No data available
f)	Flammability (solid, gas)	No data available
g)	Upper/lower flammability or explosive limits	No data available
h)	Flash point	No data available
i)	Autoignition temperature	No data available
j)	Decomposition temperature	No data available
k)	рН	No data available
I)	Viscosity	Viscosity, kinematic: No data available Viscosity, dynamic: No data available
m)	Water solubility	No data available
n)	Partition coefficient: n-octanol/water	No data available
o)	Vapor pressure	No data available
p)	Density	No data available
	Relative density	No data available
q)	Relative vapor density	No data available
r)	Particle characteristics	No data available

- s) Explosive properties Not classified as explosive.
- t) Oxidizing properties none
- 9.2 Other safety information No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

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10.2 Chemical stability

Stable under recommended storage conditions.

- 10.3 Possibility of hazardous reactions No data available
- **10.4 Conditions to avoid** No data available
- **10.5 Incompatible materials** Strong oxidizing agents
- **10.6 Hazardous decomposition products** In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Mixture

Acute toxicity

Oral: No data available Inhalation: No data available Dermal: No data available

Skin corrosion/irritation No data available

Serious eye damage/eye irritation No data available

Respiratory or skin sensitization No data available

Germ cell mutagenicity No data available

Carcinogenicity No data available

Reproductive toxicity No data available

Specific target organ toxicity - single exposure No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard No data available

11.2 Additional Information

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

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SECTION 12: Ecological information

12.1 Toxicity

Mixture No data available

- **12.2 Persistence and degradability** No data available
- **12.3 Bioaccumulative potential** No data available
- **12.4 Mobility in soil** No data available

12.5 Results of PBT and vPvB 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 No data available

12.7 Other adverse effects

No data available

Components

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging

Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number ADR/RID: -	IMDG: -	IATA: -							
IMDG: Not dangerous	ADR/RID: Not dangerous goods IMDG: Not dangerous goods								
14.3 Transport hazard class ADR/RID: -	(es) IMDG: -	IATA: -							
14.4 Packaging group ADR/RID: -	IMDG: -	IATA: -							
14.5 Environmental hazards ADR/RID: no	IMDG Marine pollutant: no	IATA: no							
14.6 Special precautions for user No data available									
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Not classified as dangerous in the meaning of transport regulations.

SECTION 15: Regulatory information

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

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM -American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS -Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx -Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; 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; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. -Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIOC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS -Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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Further information

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