

1348 - Insulin Human recombinant $\geq 95\%$

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 **Product identifier:** 1348 - Insulin Human recombinant $\geq 95\%$
Insulin (human)
CAS: 11061-68-0
Other means of identification:
Non-applicable
- 1.2 **Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses: For use in laboratory and production. Not for human or animal use. . For professional users only.
Uses advised against (Professional users): Not for human or animal use
- 1.3 **Details of the supplier of the safety data sheet:**
GERBU Biotechnik GmbH
69123 Heidelberg - Germany
Phone: +49 6221 7264167
safety@gerbu.de
www.gerbu.de
- 1.4 **Emergency telephone number:** Toxicological Information Freiburg
+49 (0) 761 19240

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 **Classification of the substance or mixture:**
GB CLP Regulation:
The product is not classified as hazardous according to GB CLP Regulation.
- 2.2 **Label elements:**
GB CLP Regulation:
None
- 2.3 **Other hazards:**
Product fails to meet PBT/vPvB criteria

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 **Substance:**
Chemical description: Chemical substance
Components:
In accordance with Annex II of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2020, the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 11061-68-0	Insulin (human)	75 - <100 %

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

- 3.2 **Mixture:**
Non-applicable

SECTION 4: FIRST AID MEASURES

- 4.1 **Description of first aid measures:**
Consult a doctor in case of discomfort showing the SDS for the product.
By inhalation:
In case of symptoms, move the person affected into fresh air.
By skin contact:

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SECTION 4: FIRST AID MEASURES (continued)

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of changes to the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety Data Sheet

By eye contact:

Rinse with water until the product has been eliminated. In case of problems, consult a doctor showing the SDS for the product.

By ingestion/aspiration:

In case of consumption in large quantities, it is recommended to seek medical assistance.

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

Acute and delayed effects are indicated in sections 2 and 11.

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

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

Product is non-flammable, with a low risk of fire due to the flammability characteristics of the product in normal conditions of storage, handling and use. In the case of the existence of sustained combustion as a result of improper handling, storage or use any type of extinguishing agent can be used (ABC Powder, water,...)

Unsuitable extinguishing media:

Non-applicable

5.2 Special hazards arising from the substance or mixture:

Due to its non-inflammable nature, the product does not present a fire risk under normal conditions of storage, handling and use.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...).

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel:

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

For emergency responders:

Wear protective equipment. Keep unprotected persons away. See section 8.

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

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SECTION 7: HANDLING AND STORAGE (continued)

A.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks with regards manually handling weights. Maintain order, cleanliness and dispose of using safe methods (section 6).

B.- Technical recommendations for the prevention of fires and explosions

Due to its non-inflammable nature, the product does not present a fire risk under normal conditions of storage, handling and use.

C.- Technical recommendations on general occupational hygiene

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is not necessary to take special measures to prevent environmental risks. For more information see subsection 6.2

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Minimum Temp.: 8 °C

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace:

Nuisance dust: Inhalable dust 10 mg/m³ // Respirable dust 4 mg/m³

DNEL (Workers):

Non-applicable

DNEL (General population):

Non-applicable

PNEC:

Non-applicable

8.2 Exposure controls:

A.- Individual protection measures, such as personal protective equipment

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<UKCA marking>>. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection, ..) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

The use of protection equipment will be necessary if a mist forms or if the occupational exposure limits are exceeded.

C.- Specific protection for the hands

Non-applicable

D.- Eye and face protection

Non-applicable

E.- Body protection

Non-applicable

F.- Additional emergency measures

It is not necessary to take additional emergency measures.

Environmental exposure controls:

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C:	Solid
Appearance:	Not available
Colour:	Not available
Odour:	Not available
Odour threshold:	Non-applicable *

Volatility:

Boiling point at atmospheric pressure:	Non-applicable *
Vapour pressure at 20 °C:	Non-applicable *
Vapour pressure at 50 °C:	Non-applicable *
Evaporation rate at 20 °C:	Non-applicable *

Product description:

Density at 20 °C:	Non-applicable *
Relative density at 20 °C:	Non-applicable *
Dynamic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 40 °C:	Non-applicable *
Concentration:	Non-applicable *
pH:	Non-applicable *
Vapour density at 20 °C:	Non-applicable *
Partition coefficient n-octanol/water 20 °C:	Non-applicable *
Solubility in water at 20 °C:	Non-applicable *
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *

Flammability:

Flash Point:	Non-applicable
Flammability (solid, gas):	Non-applicable *
Autoignition temperature:	Non-applicable *
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *
Explosive (Solid):	
Lower explosive limit:	Non-applicable *
Upper explosive limit:	Non-applicable *

Particle characteristics:

Median equivalent diameter:	Non-applicable *
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9.2 Other information:

Information with regard to physical hazard classes:

*Not relevant due to the nature of the product, not providing information property of its hazards.

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1348 - Insulin Human recombinant ≥95%

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Explosive properties:	Non-applicable *
Oxidising properties:	Non-applicable *
Corrosive to metals:	Non-applicable *
Heat of combustion:	Non-applicable *
Aerosols-total percentage (by mass) of flammable components:	Non-applicable *
Other safety characteristics:	
Surface tension at 20 °C:	Non-applicable *
Refraction index:	Non-applicable *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7.

10.2 Chemical stability:

Chemically stable under the indicated conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Notapplicable	Notapplicable	Notapplicable	Notapplicable	Notapplicable

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Notapplicable	Notapplicable	Notapplicable	Avoid alkalis orstrong bases

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

LD50 oral > 2000 mg/kg (rat)

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

A- Ingestion (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Based on available data, the classification criteria are not met
- Contact with the eyes: Based on available data, the classification criteria are not met

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

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SECTION 11: TOXICOLOGICAL INFORMATION (continued)

- Carcinogenicity: Based on available data, the classification criteria are not met
IARC: Non-applicable
 - Mutagenicity: Based on available data, the classification criteria are not met
 - Reproductive toxicity: Based on available data, the classification criteria are not met
- E- Sensitizing effects:
- Respiratory: Based on available data, the classification criteria are not met
 - Skin: Based on available data, the classification criteria are not met
- F- Specific target organ toxicity (STOT) - single exposure:
- Based on available data, the classification criteria are not met
- G- Specific target organ toxicity (STOT)-repeated exposure:
- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met
 - Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- H- Aspiration hazard:
- Based on available data, the classification criteria are not met
- Other information:**
- Non-applicable
- Specific toxicology information on the substances:**
- Not available

SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

- 12.1 **Toxicity:**
Not available
- 12.2 **Persistence and degradability:**
Not available
- 12.3 **Bioaccumulative potential:**
Not available
- 12.4 **Mobility in soil:**
Not available
- 12.5 **Results of PBT and vPvB assessment:**
Product fails to meet PBT/vPvB criteria
- 12.6 **Other adverse effects:**
Not described

SECTION 13: DISPOSAL CONSIDERATIONS

- 13.1 **Waste treatment methods:**
- Type of waste:**
Non-applicable
- Waste management (disposal and evaluation):**
Consult the authorized waste service manager on the assessment and disposal operations in accordance The Waste Regulations 2011, 2011 No. 988. As under 15 01 of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. Waste should not be disposed of to drains. See paragraph 6.2.
- Regulations related to waste management:**
In accordance with Annex II of UK REACH the provisions related to waste management are stated:

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SECTION 13: DISPOSAL CONSIDERATIONS (continued)

UK legislation: The Waste Regulations 2011.

SECTION 14: TRANSPORT INFORMATION

This product is not regulated for transport (ADR/RID,IMDG,IATA)

SECTION 15: REGULATORY INFORMATION

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

- Substances listed in UK candidate list of substances of very high concern (SVHCs): Non-applicable
- Substances listed in UK REACH Authorisation List (Annex 14): Non-applicable

The Control of Major Accident Hazards Regulations 2015:

Non-applicable

Restrictions to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII UK REACH, etc.):

Non-applicable

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

The REACH etc. (Amendment etc.) (EU Exit) Regulations 2020.

The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020.

Control of Substances Hazardous to Health Regulations 2002 (as amended)

EH40/2005 Workplace exposure limits.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with ANNEX II-The REACH etc. (Amendment etc.) (EU Exit) Regulations 2020.

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

GB CLP Regulation:

Non-applicable

Advice related to training:

Training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50

EC50: Effective concentration 50

LogPOW: Octanolwater partition coefficient

Koc: Partition coefficient of organic carbon

UFI: unique formula identifier

IARC: International Agency for Research on Cancer

- CONTINUED ON NEXT PAGE -

1348 - Insulin Human recombinant $\geq 95\%$

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at UK, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -