

SAFETY DATA SHEET

Product name:	Insulin Human AF	Page:	1/10
Revision:		Print date:	2022-12-06
		SDS-ID:	EU-EN/1.0

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

1.1. Product identifier

Product name: Insulin Human AF
CAS-No.: 11061-68-0
EC No.: 234-279-7
Container size: HDPE plastic bottles.
1 g, 10 g, 50 g, 100 g, 1 kg.

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

Application: For Cell Culture Medium Use. For Further Manufacturing Use Only. Not for Therapeutic Use.

1.3. Details of the supplier of the safety data sheet

Supplier: Novo Nordisk Pharmatech A/S
Københavnsvej 216
DK-4600 Køge
Tel:+45 56 67 10 00
www.novonordiskpharmatech.com

Responsible for safety data sheet authoring: nnprinfo@novonordiskpharmatech.com

1.4. Emergency telephone number

Emergency telephone: National Poison Control Centres are available in Member Countries.

+ 45 56 67 10 00
(Only during office hours)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

CLP: The product is not classified.

2.2. Label elements

The substance/mixture does not meet the criteria for classification and labelling.

2.3. Other hazards

PBT/vPvB: This product does not contain any PBT or vPvB substances.

Other: Dust may form explosive mixture with air. May cause irritation to skin, eyes and respiratory system.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

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CLP:

<u>%:</u>	<u>CAS-No.:</u>	<u>EC No.:</u>	<u>REACH Reg. No:</u>	<u>Chemical name:</u>	<u>Hazard classification:</u>	<u>Notes:</u>
100	11061-68-0	234-279-7	-	Insulin (human)	-	

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation: Move into fresh air and keep at rest.

Skin contact: Rinse with water. If skin irritation occurs: Get medical advice/attention.

Eye contact: Rinse the eye with water immediately. Contact physician if irritation persists.

Ingestion: Immediately rinse mouth and drink 1-2 glasses of water. Keep person under observation. If uncomfortable: Transportation to hospital. Bring along these instructions.

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

Symptoms/effects: See section 11 for more detailed information on health effects and symptoms.

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

Medical attention/treatments: Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Extinguishing media: Use fire-extinguishing media appropriate for surrounding materials.

5.2. Special hazards arising from the substance or mixture

Specific hazards: Dust may form an explosive mixture in the atmosphere.

5.3. Advice for firefighters

Protective equipment for fire-fighters: Selection of respiratory protection for fire fighting: follow the general fire precautions indicated in the workplace.

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SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Follow precautions for safe handling described in this safety data sheet.

6.2. Environmental precautions

Environmental precautions: Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Collect spillage with shovel, broom or the like and reuse, if possible. Dispose of large amounts of spillage/waste according to agreement with local authorities. Flush contaminated area with plenty of water. Use spark-proof tools and explosion-proof equipment.

6.4. Reference to other sections

References: For personal protection, see section 8.
For waste disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Safe handling advice: Observe good chemical hygiene practices. Avoid inhalation of dust and contact with skin and eyes.

Technical measures: Do not smoke or use open fire or other sources of ignition. Use spark-proof tools and explosion-proof equipment.

Technical precautions: Provide adequate ventilation. Provide easy access to water supply and eye wash facilities.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures for safe storage: No special precautions.

Storage conditions: Insulin Human must be kept in a deep freezer at $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$ in tightly closed original packing.

7.3. Specific end use(s)

Specific use(s): Not relevant.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No occupational exposure limit assigned.

Please note that there may be national occupational exposure limits.

8.2. Exposure controls

Engineering measures: Provide adequate ventilation. Observe occupational exposure limits and minimise the risk of inhalation of dust.

Personal protection: Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Respiratory equipment: In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter (type P2).

Hand protection: Risk of contact: Wear protective gloves. PVC gloves are recommended. The most suitable glove must be chosen in collaboration with the supplier of gloves, who can inform about the breakthrough time of the glove material.

Eye protection: During dust-raising work: Wear goggles/face shield.

Hygiene measures: Wash hands after contact.

Environmental Exposure Controls: Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Form: Powder.

Colour: White.

pH: Not relevant.

Melting point / freezing point: Not available.

Boiling point: Not available.

Flash point: Not available.

Explosion limits: Not available.

Vapour pressure: Not available.

Relative density: Not available.

Solubility: Not available.

Decomposition temperature (°C): Not available.

9.2. Other information

Other data: Not relevant.

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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity: None known.

10.2. Chemical stability

Stability: Stable under the prescribed storage conditions.

10.3. Possibility of hazardous reactions

Hazardous Reactions: None known.

10.4. Conditions to avoid

Conditions/materials to avoid: None specific.

10.5. Incompatible materials

Incompatible materials: Not known.

10.6. Hazardous decomposition products

Hazardous decomposition products: None in particular.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute Toxicity (Oral): Based on available data, the classification criteria are not met.

Acute Toxicity (Dermal): Based on available data, the classification criteria are not met.

Acute Toxicity (Inhalation): Based on available data, the classification criteria are not met.

Skin Corrosion/Irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation: Based on available data, the classification criteria are not met.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive Toxicity: Based on available data, the classification criteria are not met.

STOT - Single exposure: Based on available data, the classification criteria are not met.

STOT - Repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

Inhalation: Dust may irritate throat and respiratory system and cause coughing. Inhalation of dust of insulin crystals may result in a mild temporary decrease of the blood sugar level (hypoglycemia).

Skin contact: Powder may irritate skin.

Eye contact: Direct contact is irritating.

Ingestion: No harmful effects expected in amounts likely to be ingested by accident.

11.2. Information on other hazards

Endocrine disrupting properties: The substance is not identified as having endocrine disrupting properties.

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SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity: The product is not expected to be hazardous to the environment.

12.2. Persistence and degradability

Degradability: The degradability of the product has not been stated.

12.3. Bioaccumulative potential

Bioaccumulative potential: No data available on bioaccumulation.

12.4. Mobility in soil

Mobility: No data available.

12.5. Results of PBT and vPvB assessment

PBT/vPvB: This product does not contain any PBT or vPvB substances.

12.6. Endocrine disrupting properties

Endocrine disrupting properties: The substance is not identified as having endocrine disrupting properties.

12.7. Other adverse effects

Other adverse effects: None known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste and residues in accordance with local authority requirements.

Waste from residues: EWC-code: 16 05 09

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SECTION 14: TRANSPORT INFORMATION

The product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/AND/RID).

14.1. UN number

UN-No: -

14.2. UN proper shipping name

Proper Shipping Name: -

14.3. Transport hazard class(es)

Class: -

14.4. Packing group

PG: -

14.5. Environmental hazards

Marine pollutant: -

Environmentally Hazardous substance: -

14.6. Special precautions for user

Special precautions: None known.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Transport in bulk: Not relevant.

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SECTION 15: REGULATORY INFORMATION

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

National regulation:

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, with amendments.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 with amendments.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work, with amendments.

Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, with amendments.

Commission Directive 91/322/EEC of 29 May 1991 on establishing indicative limit values by implementing Council Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work, with amendments.

Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, with amendments.

Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work, with amendments.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, with amendments.

2014/955/EC: Commission Decision of 18 December 2014 amending Decision 2000/532/EC as regards the list of wastes.

15.2. Chemical Safety Assessment

CSA status:

No chemical safety assessment has been carried out.

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SECTION 16: OTHER INFORMATION

The user must be instructed in the proper work procedure and be familiar with the contents of these instructions.

Abbreviations and acronyms used in the safety data sheet: CSA = Chemical Safety Assessment.
PBT = Persistent, Bioaccumulative and Toxic.
STOT = Specific Target Organ Toxicity.
vPvB = very Persistent and very Bioaccumulative.

The information on this data sheet represents our current data and is reliable provided that the product is used under the prescribed conditions and in accordance with the application specified on the packaging and/or in the technical guidance literature. Any other use of the product which involves using the product in combination with any other product or any other process is the responsibility of the user.

Made by DHI - Environment and Toxicology, Agern Allé 5, DK-2970 Hørsholm, Denmark.
www.dhigroup.com.
