

SAFETY DATA SHEET

Product name:	TrypsiNNex	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: TrypsiNNex
TrypsiNNex 0.5 MU
TrypsiNNex 5 MU
TrypsiNNex 50 MU
TrypsiNNex - Trial size 0.17 MU

UFI: D300-W0XG-7009-GSTG

Container size: TrypsiNNex 0.5 MU: 5 ml
TrypsiNNex 5 MU: 30 ml
TrypsiNNex 50 MU: 250 ml
TrypsiNNex - Trial size 0.17 MU: 5 ml

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

Application: Process enzyme in pharmaceutical production and development.

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.

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SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

CLP: Resp. Sens. 1;H334

2.2. Label elements



Danger

Contains:

Trypsin

H334

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

P261

Avoid breathing vapours/spray.

P284

In case of inadequate ventilation wear respiratory protection.

P304 + P340

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P342 + P311

If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

2.3. Other hazards

PBT/vPvB:

This product does not contain any PBT or vPvB substances.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

The product contains: enzymes, inorganic salt and water.

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>
1-<10	9002-07-7	232-650-8	-	Trypsin	Eye Irrit. 2;H319 STOT SE 3;H335 Skin Irrit. 2;H315 Resp. Sens. 1;H334	

References:

The full text for all hazard statements is displayed in section 16.

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SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation: Move injured person into fresh air and keep person calm under observation. If uncomfortable: Seek hospital and bring along these instructions. In case of persistent throat irritation or coughing: Seek medical attention and bring along these instructions.

Skin contact: Remove contaminated clothing immediately and wash skin with soap and water.

Eye contact: Immediately flush with plenty of water for at least 15 minutes. Remove any contact lenses and open eyelids widely. If irritation persists: Seek medical attention and bring along these instructions.

Ingestion: Immediately rinse mouth and drink plenty of water. Keep person under observation. If person becomes uncomfortable seek hospital and bring 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: During fire, gases hazardous to health may be formed.

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.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Avoid inhalation of aerosols and contact with skin and eyes. Follow precautions for safe handling described in this safety data sheet.

6.2. Environmental precautions

Environmental precautions: Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Absorb spillage with suitable absorbing material.

6.4. Reference to other sections

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

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SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

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

Technical measures: Work practice should minimise contact.

Technical precautions: Mechanical ventilation may be required.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures for safe storage: No special precautions.

Storage conditions: Store in tightly closed original container.

7.3. Specific end use(s)

Specific use(s): Not relevant.

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 vapours and aerosols. Provide adequate ventilation. The risk of inhalation of vapours and spray mist must be minimised as much as possible.

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: Risk of inhalation of vapours and aerosols: Use respiratory equipment with combination filter, type A2/P3.

Hand protection: Risk of contact: Wear protective gloves. Nitrile gloves are recommended, but be aware that the liquid may penetrate the gloves. Frequent change is advisable. 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: Risk of splashes: Wear goggles/face shield.

Hygiene measures: Wash hands after contact.

Environmental Exposure Controls: Not available.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Form: Clear liquid.
Colour: Colourless.
Odour: Not available.
pH: 2
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: Miscible with water.
Explosive properties: Not available.

9.2. Other information

Other data: Not relevant.

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: Bases. Strong oxidising agents.

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

<u>Acute Toxicity (Oral):</u>	Based on available data, the classification criteria are not met.
<u>Acute Toxicity (Dermal):</u>	Based on available data, the classification criteria are not met.
<u>Acute Toxicity (Inhalation):</u>	Based on available data, the classification criteria are not met.
<u>Skin Corrosion/Irritation:</u>	Based on available data, the classification criteria are not met.
<u>Serious eye damage/irritation:</u>	Based on available data, the classification criteria are not met.
<u>Respiratory or skin sensitisation:</u>	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
<u>Germ cell mutagenicity:</u>	Based on available data, the classification criteria are not met.
<u>Carcinogenicity:</u>	Based on available data, the classification criteria are not met.
<u>Reproductive Toxicity:</u>	Based on available data, the classification criteria are not met.
<u>STOT - Single exposure:</u>	Based on available data, the classification criteria are not met.
<u>STOT - Repeated exposure:</u>	Based on available data, the classification criteria are not met.
<u>Aspiration hazard:</u>	Based on available data, the classification criteria are not met.
<u>Inhalation:</u>	Inhalation of enzyme dust/aerosols may cause sensitisation and inhalation hypersensitivity (occupational asthma) in sensitive individuals.
<u>Skin contact:</u>	Prolonged contact may cause redness and irritation.
<u>Eye contact:</u>	May irritate and cause redness and pain.
<u>Ingestion:</u>	May irritate and cause nausea, stomach pain and vomiting.

11.2. Information on other hazards

<u>Endocrine disrupting properties:</u>	The product does not contain any substance 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 product does not contain any substance 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 is classified as hazardous waste.

Waste from residues: EWC-code: 16 05 08

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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

Special provisions: As a general rule, persons under 18 years of age are not allowed to work with this product. Users must be carefully instructed in the proper work procedure, the dangerous properties of the product and the necessary safety instructions.

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.

Council Directive 94/33/EC of 22 June 1994 on the protection of young people 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

For restrictions on use see section 15.

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: PBT = Persistent, Bioaccumulative and Toxic.
vPvB = very Persistent and very Bioaccumulative.

Additional information: Classification according to Regulation (EC) No. 1272/2008:
Calculation method.

Wording of H-statements:

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 May cause respiratory irritation.

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, Artensvej 5, DK-2970 Hørsholm, Denmark.
www.dhigroup.com.
