

SAFETY DATA SHEET

Product name:	TrypsiNNex	Page:	1/10
Revision Date:		Print date:	2021-08-27
		SDS-ID:	CA-EN/1.0

1. IDENTIFICATION

Product identifier

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

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
 150 ml, 15 ml, 1.5 ml

Recommended use and restrictions on use

Application: Process enzyme in pharmaceutical production and development.

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

Emergency telephone number

Emergency telephone: Alberta & NWT:
 Poison & Drug Information Service (PADIS): 1-800-332-1414
 British Columbia:
 Drug and Poison Information Centre (DPIC): 604-682-5050 / 1-800-567-8911
 Ontario:
 Poison Centre: 1-800-268-9017
 Québec:
 Poison Control Centre: 1-800-463-5060

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2. HAZARDS IDENTIFICATION

Classification of the hazardous product

WHMIS 2015: Respiratory Sensitizer — Category 1

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.

P501 Dispose of contents/container in accordance with local regulations.

Other hazards

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixtures

The product contains: enzymes, inorganic salt and water.

WHMIS 2015:

<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 Irritation Category 2 STOT Single Exposure Category 3 Skin Irritation Category 2 Respiratory Sensitizer — Category 1	

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4. FIRST-AID MEASURES

Description of first-aid measures

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

Most important symptoms and effects, both acute and delayed

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

Indication of any immediate medical attention and special treatment needed

Medical attention/treatments: Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Extinguishing media

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

Specific hazards arising from the hazardous product

Specific hazards: During fire, health hazardous gases may be formed.

Advice for fire-fighters

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

6. ACCIDENTAL RELEASE MEASURES

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.

Environmental precautions

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

Methods and material for containment and cleaning up

Spill Cleanup Methods: Absorb spillage with suitable absorbent material.

Reference to other items

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

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7. HANDLING AND STORAGE

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 minimize contact.

Technical precautions: Mechanical ventilation may be required.

Conditions for safe storage, including any incompatibilities

Technical measures for safe storage: No special precautions.

Storage conditions: Store in tightly closed original container.

Specific end-use(s)

Specific use(s): Not relevant

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

No occupational exposure limit assigned.

Exposure controls

Engineering measures: Provide adequate ventilation. The risk of inhalation of vapours and spray mist must be minimized as much as possible.

Personal protection: Personal protection equipment should be chosen according to relevant 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 consultation with the gloves supplier, 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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9. PHYSICAL AND CHEMICAL PROPERTIES

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.

Other information

Other data: Not relevant.

10. STABILITY AND REACTIVITY

Reactivity

Reactivity: None known.

Chemical stability

Stability: Stable under the prescribed storage conditions.

Possibility of hazardous reactions

Hazardous Reactions: None known.

Conditions to avoid

Conditions/materials to avoid: None specific

Incompatible materials

Incompatible materials: Bases. Strong oxidising agents.

Hazardous decomposition products

Hazardous decomposition products: None in particular.

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11. TOXICOLOGICAL INFORMATION

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 sensitization:</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.
<u>Specific effects:</u>	This product contains no ingredient listed on the IARC, NTP and OSHA as carcinogenic.

Other provincial regulations may apply.

Information on other hazards

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12. ECOLOGICAL INFORMATION

Ecotoxicity

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

Persistence and degradability

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

Bioaccumulative potential

Bioaccumulative potential: No data available on bioaccumulation.

Mobility in soil

Mobility: No data available.

Results of PBT and vPvB assessment

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

Other adverse effects

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Dispose of waste material according to Local, State, Federal, and Provincial Environmental Regulations.

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14. TRANSPORT INFORMATION

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

UN number

UN-No: -

UN proper shipping name

Proper Shipping Name: -

Transport hazard class(es)

Class: -

Packing group

PG: -

Environmental hazards

Marine pollutant: -

Environmentally Hazardous substance: -

Special precautions for user

Special precautions: None known.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Transport in bulk: Not relevant

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15. REGULATORY INFORMATION

Safety, health and environmental regulations specific to the product

Special provisions:

This product has been classified in accordance with the hazard criteria of the Hazardous Products Regulations (HPR) and the SDS contains all the information required by the HPR.

TSCA: All chemicals included in the product are TSCA listed.

Domestic Substance List (DSL): Not listed.

NFPA Rating: Health: 2 Fire: 0 Reactivity: 0 Other: -

National regulation:

Hazardous Products Regulations, with amendments.

Alberta: Occupational Health and Safety Code 2009.

British Columbia: OHS Guidelines Part 5: Chemical Agents and Biological Agents. Occupational Health and Safety Regulation 296/97, with amendments.

Manitoba: Manitoba Workplace Safety and Health Act and Regulation 2016.

New Brunswick: New Brunswick Regulation 91-191 under the Occupational Health and Safety Act (o.c. 91-1035).

Newfoundland and Labrador: Occupational Health and Safety Regulations, 2012.

Northwest Territories & Nunavut: Safety Act - Occupational Health and Safety Regulations (2015), with amendments.

Ontario: Control of Exposure to Biological or Chemical Agents R.R.O. 1990, Reg. 833, with amendments (2019).

Quebec: Regulation respecting the quality of the work environment, with amendments (2021).

Saskatchewan: The Occupational Health and Safety Regulations, 2020, with amendments.

Yukon: Occupational Health and Safety Regulations, with amendments (2020).

Canadian Environmental Protection Act, Reporting for the Domestic Substances List (DSL), with amendments.

Department of Justice. Canadian Environmental Protection Act 1999 (CEPA), 1999, c. 33, with amendments.

U.S. Department of health and human services: 2011 - Report on Carcinogens - 12th Edition.

International Agency for Research on Cancer (IARC): IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Lyon: IARC, World Health Organization.

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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 WHMIS 2015:
Calculation method.

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, Artens Allé 5, DK-2970 Hørsholm, Denmark.
www.dhigroup.com.
