

SAFETY DATA SHEET

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

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

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

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

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 material safety data sheet authoring: nnprinfo@novonordiskpharmatech.com

Emergency telephone number

Emergency telephone: National Capital Poison Center: 1-800-222-1222

SAFETY DATA SHEET

Product name: TrypsiNNex

Page: 2/10

Revision Date:

Print date: 2021-08-27

SDS-ID: US-EN/1.0

SECTION 2: HAZARDS IDENTIFICATION

Classification of the substance or mixture

OSHA 2012: Respiratory Sensitizer Category 1

Label elements



Danger

Contains:

Trypsin

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

P261 Avoid breathing vapors/spray.

P284 In case of inadequate ventilation wear respiratory protection.

P304 + P341 If inhaled: If breathing is difficult, 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.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Mixtures

The product contains: enzymes, inorganic salt and water.

OSHA 2012:

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

SAFETY DATA SHEET

Product name: TrypsiNNex

Page: 3/10

Revision Date:

Print date: 2021-08-27

SDS-ID: US-EN/1.0

SECTION 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 bring these instructions. In case of persistent throat irritation or coughing: Seek medical attention and bring 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.

SECTION 5: FIREFIGHTING MEASURES

Extinguishing media

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

Special hazards arising from the substance or mixture

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

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

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 sections

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

SAFETY DATA SHEET

Product name: TrypsiNNex

Page: 4/10

Revision Date:

Print date: 2021-08-27

SDS-ID: US-EN/1.0

SECTION 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.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

No occupational exposure limit assigned.

Exposure controls

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

Personal protection: Personal protection equipment should be chosen according to the ANSI 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.

SAFETY DATA SHEET

Product name: TrypsiNNex

Page: 5/10

Revision Date:

Print date: 2021-08-27

SDS-ID: US-EN/1.0

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Form: Clear liquid.
Color: Colorless.
Odor: Not available.
pH: 2
Melting point / freezing point: Not available.
Boiling point: Not available.
Flash point: Not available.
Explosion limits: Not available.
Vapor pressure: Not available.
Relative density: Not available.
Solubility: Miscible with water.
Explosive properties: Not available.

Other information

Other data: Not relevant.

SECTION 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 oxidizing agents.

Hazardous decomposition products

Hazardous decomposition products: None in particular.

SAFETY DATA SHEET

Product name: TrypsiNNex

Page: 6/10

Revision Date:

Print date: 2021-08-27

SDS-ID: US-EN/1.0

SECTION 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 sensitization 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 NTP, OSHA, IARC or California Proposition 65 carcinogen lists.

Information on other hazards

SAFETY DATA SHEET

Product name: TrypsiNNex

Page: 7/10

Revision Date:

Print date: 2021-08-27

SDS-ID: US-EN/1.0

SECTION 12: ECOLOGICAL INFORMATION

Toxicity

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.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods

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

SAFETY DATA SHEET

Product name: TrypsiNNex

Page: 8/10

Revision Date:

Print date: 2021-08-27

SDS-ID: US-EN/1.0

SECTION 14: TRANSPORT INFORMATION

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

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.

SAFETY DATA SHEET

Product name: TrypsiNNex

Page: 9/10

Revision Date:

Print date: 2021-08-27

SDS-ID: US-EN/1.0

SECTION 15: REGULATORY INFORMATION

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

Special provisions:

All chemicals included in the product are TSCA listed.

SARA Section 302: No.

SARA Section 304: No.

SARA Section 313: No.

SARA (311/312) Hazard categories: Yes.

NFPA Rating:

Health:2

Fire:0

Reactivity:0

Other:-

State and local regulation may apply.

National regulation:

The following lists have been checked:

The Code of Federal Regulation, Title 29, part 1910. Occupational Safety and Health Standards, Hazard Communication, with amendments.

Threshold Limit Values (2020), ACGIH, by the American Conference on Governmental Industrial Hygienists.

The Code of Federal Regulation, Title 29, part 1910. Occupational Safety and Health Standards, Air contaminants (OSHA), with amendments.

NIOSH Pocket Guide to Chemical Hazards.

The Code of Federal Regulation, Title 40, part 261.33. Identification and listing of hazardous waste.

The Code of Federal Regulation. Title 40, part 372.65. Toxic Chemical Release Reporting: Community Right to Know.

The Code of Federal Regulation. Title 40, part 355.50. Emergency Planning and Notification.

The Code of Federal Regulation. Title 40, part 302.4. Designation, Reportable Quantities, and Notification.

The Code of Federal Regulation. Title 40, part 68.130. Chemical Accident Prevention Provisions.

U.S. Department of health and human services: 2016 - Report on Carcinogens - 14th Edition.

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

State of California. Environmental Protection Agency. California Proposition 65, with amendments.

SAFETY DATA SHEET

Product name: TrypsiNNex

Page: 10/10

Revision Date:

Print date: 2021-08-27

SDS-ID: US-EN/1.0

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 HCS 2012:
Calculation method.

Date of compilation: 2021-05-07

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.
