# SAFETY DATA SHEET

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|---|---|---|---|
| Product name: | TrypsiNNex | Page: | 1/11 |
| Supersedes date: | 2021-08-27 | Revision date: | 2026-01-19 |
| | | SDS-ID | GB-EN/2.0 |

## 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
150 ml, 15 ml, 1.5 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: NHS: 111

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GB CLP: The product is classified: Resp. Sens. 1;H334

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

### 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.

Other: The product does not contain any substance identified as having endocrine disrupting properties.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.2. Mixtures

The product contains: enzymes, inorganic salt and water.

GB CLP:

| %: | CAS-No.: | EC No.: | REACH Reg. No: | Chemical name: | Hazard classification: | Notes: |
|---|---|---|---|---|---|---|
| 1-<10 | 9002-07-7 | 232-650-8 | - | Trypsin | Eye Irrit. 2;H319<br>STOT SE 3;H335<br>Skin Irrit. 2;H315<br>Resp. Sens. 1;H334 | |

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

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

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|---|---|
| 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 1-2 glasses 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

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| 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

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|---|---|
| Medical attention/treatments: | Treat symptomatically. |

## SECTION 5: FIREFIGHTING MEASURES

### 5.1. Extinguishing media

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

### 5.2. Special hazards arising from the substance or mixture

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

### 5.3. Advice for firefighters

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| 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 absorbent material.

### 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: 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.

### 8.2. Exposure controls

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|---|---|
| Engineering measures: | 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.<br>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. |

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

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|---|---|
| Form: | Clear liquid. |
| Colour: | Colourless. |
| Odour: | Not available. |
| pH: | 2 |
| Melting point / freezing point: | Not available. |
| Boiling point: | Not available. |
| Flash point: | Not available. |
| Explosive limits | Not available. |
| Vapour pressure: | Not available. |
| Relative density: | Not available. |
| Solubility: | Miscible with water. |
| Explosive properties: | Not available. |
| Oxidising properties: | Not available. |

### 9.2. Other information

| | |
|---|---|
| Other data: | Not relevant. |

## SECTION 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

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|---|---|
| Reactivity: | None known. |

### 10.2. Chemical stability

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|---|---|
| Stability: | Stable under the prescribed storage conditions. |

### 10.3. Possibility of hazardous reactions

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|---|---|
| Hazardous Reactions: | None known. |

### 10.4. Conditions to avoid

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|---|---|
| Conditions/materials to avoid: | None specific. |

### 10.5. Incompatible materials

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|---|---|
| Incompatible materials: | Bases. Strong oxidising agents. |

### 10.6. Hazardous decomposition products

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|---|---|
| Hazardous decomposition products: | None in particular. |

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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|---|---|
| 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: | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| 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: | Inhalation of enzyme dust/aerosols may cause sensitisation and inhalation hypersensitivity (occupational asthma) in sensitive individuals. |
| Skin contact: | Prolonged contact may cause redness and irritation. |
| Eye contact: | May irritate and cause redness and pain. |
| Ingestion: | May irritate and cause nausea, stomach pain and vomiting. |

### 11.2. Information on other hazards

| | |
|---|---|
| Endocrine disrupting properties: | The product does not contain any substance identified as having endocrine disrupting properties in humans. |

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

Ecotoxicity: There is no data on the ecotoxicity of this product.
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 in aquatic organisms.

### 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

Contaminated packaging: Dispose of contaminated packings as residue.

## SECTION 14: TRANSPORT INFORMATION

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

### 14.1. UN number or ID 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. Maritime transport in bulk according to IMO instruments

Transport in bulk: Not relevant.

## 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: UK Statutory Instruments, 2023 No. 722, CONSUMER PROTECTION ENVIRONMENTAL PROTECTION HEALTH AND SAFETY.
The REACH etc. (Amendment) Regulations 2023.
The REACH etc. (Amendment) Regulations 2021, known as UK REACH, as amended; including (EU) 2020/878.
Retained CLP Regulation (EU) No. 1272/2008 as amended for Great Britain, known as GB CLP, with amendments.
The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019 No. 720), as amended.
The Control of Substances Hazardous to Health Regulations 2002 (S.I 2002 No. 2677) with amendments.
EH40/2005, Workplace exposure limits 2005, with amendments.
The Management of Health and Safety at Work Regulations 1999 (SI 1999 No. 3242), with amendments.
The List of Wastes (England) (Amendment) Regulations 2005. (SI 2005 No. 895).

### 15.2. Chemical Safety Assessment

CSA status: No chemical safety assessment has been carried out.

## SECTION 16: OTHER INFORMATION

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

For restrictions on use see section 15.

The following sections contain revisions or new statements: 1, 2, 3, 4, 8, 9, 11, 12, 13, 14, 15, 16.

| | |
|---|---|
| Abbreviations and acronyms used in the safety data sheet: | CSA = Chemical Safety Assessment.<br>PBT = Persistent, Bioaccumulative and Toxic.<br>STOT = Specific Target Organ Toxicity.<br>UFI = Unique Formula Identifier.<br>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.