1 Identification

- **Product identifier**
  - **Trade name:** Neutral Protease NB GMP Grade
    from Clostridium histolyticum
  - **Article number:** N0002936
  - **CAS Number:** 9001-92-7
  - **EC number:** 232-642-4
  - **Index number:** 647-014-00-9

- **Application of the substance / the mixture** Laboratory chemicals

- **Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:** Nordmark Arzneimittel GmbH & Co. KG
    Pinnauallee 4
    D-25436 Uetersen
    Tel.: +49 4122 712-0
    FAX.: +49 4122 712-220
    sicherheitsdatenblatt@nordmark-pharma.de
  - **Information department:** Product Safety department
    Tel.: +49 4122 712 242
  - **Emergency telephone number:**
    Medical Emergency Information in case of poisoning:
    Poison Information Center Göttingen - Phone: +49 (0) 551 19240
    (advisory service in German or English language)

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2 Hazard(s) identification

- **Classification of the substance or mixture**
  
  ![GHS08](image)
  Resp. Sens. 1  H334  May cause allergy or asthma symptoms or breathing difficulties if inhaled.

  ![GHS07](image)
  Skin Irrit. 2  H315  Causes skin irritation.
  Eye Irrit. 2A  H319  Causes serious eye irritation.
  STOT SE 3  H335  May cause respiratory irritation.

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- **Label elements**
  - **GHS label elements**
    The substance is classified and labeled according to the Globally Harmonized System (GHS).
  - **Hazard pictograms** GHS07, GHS08
  - **Signal word** Danger
  - **Hazard statements**
    Causes skin irritation.
    Causes serious eye irritation.
    May cause allergy or asthma symptoms or breathing difficulties if inhaled.
    May cause respiratory irritation.
  - **Precautionary statements**
    Avoid breathing dust/particle/gas/mist/vapors/spray

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Wash thoroughly after handling.
Use only outdoors or in a well-ventilated area.
Wear protective gloves / eye protection / face protection.
[In case of inadequate ventilation] wear respiratory protection.
IF ON SKIN: Wash with plenty of water.
IF INHALED: Remove person to fresh air and keep comfortable for breathing.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Call a POISON CENTER/doctor if you feel unwell.
Specific treatment (see on this label).
If skin irritation occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
Take off contaminated clothing and wash it before reuse.
Store in a well-ventilated place. Keep container tightly closed.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

Classification system:

NFPA ratings (scale 0 - 4)

- Health = 1
- Fire = 0
- Reactivity = 0

HMIS-ratings (scale 0 - 4)

- Health = *1
- Fire = 0
- Reactivity = 0

Other hazards
- Results of PBT and vPvB assessment
  - PBT: PBT - assessment not available.
  - vPvB: vPvB - assessment not available.

3 Composition/information on ingredients

- Chemical characterization: Substances
- CAS No. Description
  9001-92-7 Proteinase
- Identification number(s)
- EC number: 232-642-4
- Index number: 647-014-00-9
- Description:
- MW: ca. 34000

4 First-aid measures

- Description of first aid measures
- After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact:
  Immediately wash with water and soap and rinse thoroughly.
  Remove contaminated clothing immediately.
- After eye contact:
  Rinse opened eye for several minutes under running water. Remove present contact lenses, if easy to do, and continue rinsing. Consult ophthalmologist In case of complaints.

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Trade name: Neutral Protease NB GMP Grade from Clostridium histolyticum

- After swallowing:
  Wash out mouth. Drink plenty of water and supply fresh air. Consult doctor if you feel unwell.
- Information for doctor:
  - Most important symptoms and effects, both acute and delayed No further relevant information available.
  - Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire-fighting measures

- Extinguishing media
  - Suitable extinguishing agents:
    CO₂ extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- Special hazards arising from the substance or mixture
  Formation of dangerous gases or vapours is possible in case of fire.
  - In case of fire, the following can be released:
    Carbon monoxide and carbon dioxide
- Advice for firefighters
  - Protective equipment: Wear self-contained respiratory protective device.

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures
  - Wear protective clothing.
  - Ensure adequate ventilation
  - Avoid contact with the eyes and skin.
- Environmental precautions: Do not allow to enter sewers/surface or ground water.
- Methods and material for containment and cleaning up:
  - Pick up mechanically.
  - Dispose contaminated material as waste according to item 13.
- Reference to other sections
  - See Section 7 for information on safe handling.
  - See Section 8 for information on personal protection equipment.
  - See Section 13 for disposal information.

7 Handling and storage

- Handling:
  - Precautions for safe handling
    Ensure good ventilation/exhaustion at the workplace.
    Prevent formation of dust.
  - Information about protection against explosions and fires: No special measures required.
- Conditions for safe storage, including any incompatibilities
- Storage:
  - Requirements to be met by storerooms and receptacles: Store at +2 to +8 °C
  - Information about storage in one common storage facility: Not required.
  - Further information about storage conditions: Keep receptacle tightly sealed and store in dry conditions.
  - Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- Additional information about design of technical systems: No further data; see item 7.
- Control parameters
- Components with limit values that require monitoring at the workplace: Not required.
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from Clostridium histolyticum

- **Additional information:** The lists that were valid during the creation were used as basis.

- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
  - Keep away from foodstuffs, beverages and feed.
  - Store protective clothing separately.
  - Immediately remove all soiled and contaminated clothing.
  - Avoid contact with the eyes and skin.
  - Wash hands before breaks and at the end of work.

- **Breathing equipment:**
  - Short term filter device:
  - Filter P2

- **Protection of hands:**
  - Protective gloves
  - The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
  - Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
  - Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**
  - The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

- **Penetration time of glove material**
  - The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**
  - Natural rubber, NR
  - Nitrile rubber, NBR

- **Eye protection:** Safety glasses

- **Body protection:** Protective work clothing

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### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
  - Form: lyophilisate
  - Color: beige to brown
  - Odor: Odorless

- **pH-value:** no information available

- **Change in condition**
  - Melting point/Melting range: no information available
  - Boiling point/Boiling range: no information available

- **Flash point:** Not applicable.

- **Flammability (solid, gaseous):** Product is not flammable.

- **Danger of explosion:** Product is not explosive. However, formation of explosive dust-air mixtures are possible.

- **Density:** no information available

- **Solubility in / Miscibility with**
  - Water: Soluble.
Trade name: Neutral Protease NB GMP Grade  
from Clostridium histolyticum

- Other information  
No further relevant information available.

10 Stability and reactivity

- Reactivity  
No further relevant informations available

- Chemical stability

- Thermal decomposition / conditions to be avoided:  
No decomposition if used according to specifications.  
Denaturation of proteins by strong heating.

- Possibility of hazardous reactions  
As the product is supplied it is not capable of dust explosion; however enrichment with fine dust causes risk of dust explosion.

- Conditions to avoid thermal decomposition: protein denaturation

- Incompatible materials: No further relevant information available.

- Hazardous decomposition products: In case of fire: See Section 5

11 Toxicological information

- Information on toxicological effects

- Acute toxicity:

- Primary irritant effect:

- on the skin: Irritant to skin and mucous membranes.

- on the eye: Irritating effect.

- Sensitization:  
Sensitization possible through inhalation.  
Sensitization possible through skin contact.

- Additional toxicological information:

- Carcinogenic categories  
IARC (International Agency for Research on Cancer) Substance is not listed.  
NTP (National Toxicology Program) Substance is not listed.  
OSHA-Ca (Occupational Safety & Health Administration) Substance is not listed.

12 Ecological information

- Toxicity

- Aquatic toxicity: No further relevant information available.

- Persistence and degradability: No further relevant information available.

- Behavior in environmental systems:

- Bioaccumulative potential: No further relevant information available.

- Mobility in soil: No further relevant information available.

- Additional ecological information:

- General notes:  
Water hazard class 1 (Self-assessment): slightly hazardous for water  
Do not allow product to reach ground water, water course or sewage system.

- Results of PBT and vPvB assessment

- PBT: Not applicable.

- vPvB: Not applicable.

- Other adverse effects: No further relevant information available.
13 Disposal considerations

- Waste treatment methods
  - Recommendation:
    Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Disposal must be made according to official regulations.

- Uncleaned packagings:
  - Recommendation:
    Disposal of uncleaned packagings must be made according to official regulations in the same manner as the product.

- Recommended cleansing agent: Water, if necessary with cleansing agents.

14 Transport information

- UN-Number
  - DOT, ADR, ADN, IMDG, IATA Void

- UN proper shipping name
  - DOT, ADR, ADN, IMDG, IATA Void

- Transport hazard class(es)
  - DOT, ADN Void
  - Class Void

  - ADR, IMDG, IATA Void
  - Class Void
  - Label -

- Packing group
  - DOT, ADR, IMDG, IATA Void

- Environmental hazards:
  - Marine pollutant: No

- Special precautions for user
  - Not applicable.

- Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code Not applicable.

- Transport/Additional information: Not dangerous according to the above specifications.

- UN “Model Regulation”: Void

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Section 355 (extremely hazardous substances); Substance is not listed.
  - Section 313 (Specific toxic chemical listings); Substance is not listed.
  - TSCA (Toxic Substances Control Act); Substance is listed.
  - Proposition 65 Substance is not listed.
  - Chemicals known to cause cancer; Substance is not listed.
  - Chemicals known to cause reproductive toxicity for females; Substance is not listed.
  - Chemicals known to cause reproductive toxicity for males; Substance is not listed.
  - Chemicals known to cause developmental toxicity; Substance is not listed.

- Cancerogenity categories
  - EPA (Environmental Protection Agency) Substance is not listed.

- TLV (Threshold Limit Value established by ACGIH) Substance is not listed.
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- NIOSH-Ca (National Institute for Occupational Safety and Health) Substance is not listed.
- GHS label elements
  The substance is classified and labeled according to the Globally Harmonized System (GHS).
- Hazard pictograms GHS07, GHS08
- Signal word Danger
- Hazard statements
  Causes skin irritation.
  Causes serious eye irritation.
  May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  May cause respiratory irritation.
- Precautionary statements
  Avoid breathing dust/fume/gas/mist/vapors/spray
  Wash thoroughly after handling.
  Use only outdoors or in a well-ventilated area.
  Wear protective gloves / eye protection / face protection.
  [In case of inadequate ventilation] wear respiratory protection.
  IF ON SKIN: Wash with plenty of water.
  IF INHALED: Remove person to fresh air and keep comfortable for breathing.
  If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.
  Continue rinsing.
  Call a POISON CENTER/doctor if you feel unwell.
  Specific treatment (see on this label).
  If skin irritation occurs: Get medical advice/attention.
  If eye irritation persists: Get medical advice/attention.
  If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
  Take off contaminated clothing and wash it before reuse.
  Store in a well-ventilated place. Keep container tightly closed.
  Store locked up.
  Dispose of contents/container in accordance with local/regional/national/international regulations.
- Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

* 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- Department issuing SDS: Product safety department
- Contact: Tel.: +49 4122 712-242
- Date of preparation / last revision 01/18/2018 / -
- Abbreviations and acronyms:
  RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
  ICAO: International Civil Aviation Organisation
  PBT: persistent, bioaccumulative, toxic substance (REACH)
  vPvB: very persistent, very bioaccumulative substance (REACH)
  REACH: Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
  CLP: Regulation on classification, labelling and packaging of substances and mixtures
  ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
  IMDG: International Maritime Code for Dangerous Goods
  DOT: US Department of Transportation
  IATA: International Air Transport Association
  ACGIH: American Conference of Governmental Industrial Hygienists
  EINECS: European Inventory of Existing Commercial Chemical Substances
  CAS: Chemical Abstracts Service (division of the American Chemical Society)
  NFPA: National Fire Protection Association (USA)
  HMIS: Hazardous Materials Identification System (USA)
  PBT: Persistent, Bioaccumulative and Toxic
  vPvB: very Persistent and very Bioaccumulative
  NIOSH: National Institute for Occupational Safety
  OSHA: Occupational Safety & Health

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TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
Resp. Sens. 1: Respiratory sensitisation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

* Data compared to the previous version altered.