

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 12.04.2023

Version number 4 (replaces version 3)

Revision: 12.04.2023

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

**1.1 Product identifier**

· **Trade name:** Neutral Protease AF GMP Grade  
from Clostridium histolyticum



· **Article number:** N0003553

· **CAS Number:**  
9001-92-7

· **EC number:**  
232-642-4

· **Index number:**  
647-014-00-9

· **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.

· **Application of the substance / the mixture:** Laboratory chemicals

**1.3 Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Nordmark Pharma GmbH

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 712-7120

· **1.4 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)

**SECTION 2: Hazards identification**

**2.1 Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008:**



GHS08

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

STOT SE 3 H335 May cause respiratory irritation.

**2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008:**

The substance is classified and labelled according to the GB CLP regulation.

· **Hazard pictograms:** GHS07, GHS08

· **Signal word:** Danger

· **Hazard statements:**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

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

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

· **Precautionary statements**

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

P362+P364 Take off contaminated clothing and wash it before reuse.

· **Labelling of packages where the contents do not exceed 125 ml**

· **Hazard pictograms** GHS07, GHS08

· **Signal word** Danger

· **Hazard statements**

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

· **Precautionary statements**

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment:**

· **PBT:** PBT - assessment not available.

· **vPvB:** vPvB - assessment not available.

· **Determination of endocrine-disrupting properties** No further relevant information available.

**SECTION 3: Composition/information on ingredients**

· **3.1 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

**SECTION 4: First aid measures**

· **4.1 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.

· **After swallowing:**

Wash out mouth. Drink plenty of water and supply fresh air. Consult doctor if you feel unwell.

· **4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

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**SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 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 formed, but not limited to:  
Nitrogen oxides (NO<sub>x</sub>)  
Carbon monoxide and carbon dioxide  
Sulphur oxides (SO<sub>x</sub>)
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

**SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective clothing.  
Ensure adequate ventilation  
Avoid formation of dust.  
Do not inhale dusts.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up**  
Dispose contaminated material as waste according to item 13.  
Pick up mechanically.
- **6.4 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.

**SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling:**  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of dust.
- **Information about protection against explosions and fires:** Protect against electrostatic charges.
- **7.2 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.
- **7.3 Specific end use(s):** No further relevant information available.

**SECTION 8: Exposure controls/personal protection**

- **8.1 Control parameters**
- **Components with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls:** No further data; see item 7.
- **Individual protection measures, such as personal protective equipment:**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.

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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.

· **Hand protection:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Protective gloves.

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 through 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/face protection:** Safety glasses

· **Body protection:** Protective work clothing.

**SECTION 9: Physical and chemical properties**

· **9.1 Information on basic physical and chemical properties**

· **General Information:**

· **Physical state:**

Solid.

· **Colour:**

beige to brown

· **Odour:**

Odourless

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

no information available

· **Boiling point or initial boiling point and boiling range:**

no information available

· **Flammability:**

Product is not flammable.

· **Lower and upper explosion limit:**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

Not applicable

· **Decomposition temperature:**

Not determined.

· **pH:**

no information available

· **Viscosity:**

· **Kinematic viscosity:**

Not applicable.

· **Dynamic viscosity:**

Not applicable.

· **Solubility:**

· **Water:**

Soluble

· **Partition coefficient n-octanol/water (log value):**

Not determined.

· **Vapour pressure:**

Not applicable.

· **Density and/or relative density:**

· **Density:**

no information available

· **Relative density:**

Not determined.

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· <b>Particle characteristics</b>	No information available
· <b>9.2 Other information</b>	
· <b>Appearance:</b>	
· <b>Form:</b>	lyophilisate
· <b>Important information on protection of health and environment, and on safety:</b>	
· <b>Explosive properties:</b>	Product is not explosive. However, formation of explosive dust-/air mixtures are possible.
· <b>Molecular weight</b>	~34,000 g/mol

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity:** No further relevant informations available
- **10.2 Chemical stability:**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 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
- **10.4 Conditions to avoid:** thermal decomposition: protein denaturation
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** In case of fire: See Section 5

**SECTION 11: Toxicological information**

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008:**
- **Acute toxicity:** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation:** Causes skin irritation.
- **Serious eye damage/irritation:** Causes serious eye irritation.
- **Respiratory or skin sensitisation:**  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
May cause an allergic skin reaction.
- **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:** May cause respiratory irritation.
- **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.
- **Additional toxicological information:**
- **Acute effects (acute toxicity, irritation and corrosivity)** Respiratory irritation is possible.
- **11.2 Information on other hazards:**
- **Endocrine disrupting properties:** no relevant information available

**SECTION 12: Ecological information**

- **12.1 Toxicity:**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability:** No further relevant information available.
- **12.3 Bioaccumulative potential:** No further relevant information available.
- **12.4 Mobility in soil:** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment:**
- **PBT:** PBT - assessment not available.
- **vPvB:** vPvB - assessment not available.
- **12.6 Endocrine disrupting properties:** For information on endocrine disrupting properties see section 11.

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- **12.7 Other adverse effects:**
- **Additional ecological information:**
- **General notes:**  
Do not allow product to reach ground water, water course or sewage system.  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.

### SECTION 13: Disposal considerations

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

### SECTION 14: Transport information

- |  |  |
|--|--|
| · <b>14.1 UN number or ID number</b><br>· ADR, ADN, IMDG, IATA                 | Void   |
| · <b>14.2 UN proper shipping name</b><br>· ADR, ADN, IMDG, IATA                | Void   |
| · <b>14.3 Transport hazard class(es)</b><br>· ADR, ADN, IMDG, IATA<br>· Class: | Void   |
| · <b>14.4 Packing group</b><br>· ADR, IMDG, IATA                               | Void   |
| · <b>14.5 Environmental hazards</b><br>· Marine pollutant:                     | No   |
| · <b>14.6 Special precautions for user</b>                                     | Not applicable.                                      |
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b>          | Not applicable.                                      |
| · <b>Transport/Additional information:</b>                                     | Not dangerous according to the above specifications. |
| · <b>UN "Model Regulation":</b>  | Void   |

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** Substance is not listed.
- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**  
Substance is not listed.

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- **REGULATION (EU) 2019/1148**
  - **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**  
Substance is not listed.
  - **Annex II - REPORTABLE EXPLOSIVES PRECURSORS** Substance is not listed.
  - **Regulation (EC) No 273/2004 on drug precursors** Substance is not listed.
  - **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**  
Substance is not listed.
  - **National regulations:**
  - **Technical instructions (air):**
- | Class | Share in % |
|-------|------------|
| I     | 80-100     |
- **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
  - **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**SECTION 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 712-7120
- **Date of previous version:** 28.01.2021
- **Version number of previous version:** 3
- **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 (UK REACH)  
 vPvB: very persistent, very bioaccumulative substance (UK REACH)  
 UK REACH: Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals  
 GB CLP: Regulation on classification, labelling and packaging of substances and mixtures  
 bw: body weight  
 ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)  
 IMDG: International Maritime Code for Dangerous Goods  
 IATA: International Air Transport Association  
 GHS: Globally Harmonised System of Classification and Labelling of Chemicals  
 EINECS: European Inventory of Existing Commercial Chemical Substances  
 CAS: Chemical Abstracts Service (division of the American Chemical Society)  
 PBT: Persistent, Bioaccumulative and Toxic  
 vPvB: very Persistent and very Bioaccumulative  
 Skin Irrit. 2: Skin corrosion/irritation – Category 2  
 Eye Irrit. 2: Serious eye damage/eye irritation – Category 2  
 Resp. Sens. 1: Respiratory sensitisation – Category 1  
 Skin Sens. 1: Skin sensitisation – Category 1  
 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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