

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 12.04.2023

Version number 4

Revision: 12.04.2023

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

- **1.1 Product identifier**
- **Trade name:** Collagenase AF-1 GMP Grade
from Clostridium histolyticum
- **Article number:** N0003554, N0003855
- **CAS Number:**
9001-12-1
- **EC number:**
232-582-9
- **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.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317 May cause an allergic skin reaction.

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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 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.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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

· **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.

H317 May cause an allergic skin reaction.

· **Precautionary statements**

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

P302+P352 IF ON SKIN: Wash with plenty of 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:**

9001-12-1 Collagenase

· **Identification number(s):**

· **EC number:** 232-582-9

· **Description:**

· **MW:** ca. 95000

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 immediately.

· **After swallowing:**

Wash out mouth. Drink plenty of water and supply fresh air. Seek medical advice if discomfort occurs.

· **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:**
CO₂, 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_x)
Carbon monoxide and carbon dioxide
Sulphur oxides (SO_x)
- **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:**
Keep receptacles tightly sealed.
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.*

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- **Individual protection measures, such as 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.
- **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.

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SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information:**
- **Physical state:** Solid.
- **Colour:** white to almost white
- **Odour:** Weak, characteristic
- **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:** 6-7
- **Viscosity:**
- **Kinematic viscosity:** Not applicable.
- **Dynamic viscosity:** Not applicable.
- **Solubility:**
- **Water at 20 °C:** 300 g/l
- **Partition coefficient n-octanol/water (log value):** Not determined.
- **Vapour pressure:** Not applicable.

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- | | |
|---|--------------------------|
| · Density and/or relative density: | |
| · Density: | no information available |
| · Relative density: | Not determined. |
| · Particle characteristics | No information available |
-
- | | |
|--|--|
| · 9.2 Other information | |
| · Appearance: | |
| · Form: | lyophilisate |
| · Important information on protection of health and environment, and on safety: | |
| · Explosive properties: | Product is not explosive. However, formation of explosive dust-/air mixtures are possible. |
| · Molecular weight | ~95,000 g/mol |

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SECTION 10: Stability and reactivity

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

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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.
- **11.2 Information on other hazards:**
- **Endocrine disrupting properties:** no relevant information available

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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

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

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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
- **Abbreviations and acronyms:**
 ICAO: International Civil Aviation Organisation
 RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
 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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