Revision: 18.10.2022

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

Printing date 18.10.2022

Version number 4 (replaces version 3)

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

· 1.1 Product identifier

· Trade name: Collagenase NB 4 Standard Grade from Clostridium histolyticum

· Article number: S1745401, S1745402, S1745403

• 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

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P264 Wash thoroughly after handling.
P302+P352 IF ON SKIN: Wash with plenty of water.
P321 Specific treatment (see on this label).

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

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.

H317 May cause an allergic skin reaction.

· Precautionary statements

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.

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:

 CO_2 , 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:

In case of fire, the following can be formed, but not limited to:

Nitrogen oxides (NOx)

Carbon monoxide and carbon dioxide

Sulphur oxides (SOx)

- · 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
- \cdot 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: Store in dry conditions.
- \cdot 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

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· 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 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/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: Light brown

Odour: Weak, characteristic
 Odour threshold: Not determined.
 Melting point/freezing point: undetermined

· Boiling point or initial boiling point and boiling

range: undetermined

· 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:

· 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.

· Density and/or relative density:

Density: Not determinedRelative density: Not determined.

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· 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.

~95,000 g/mol · Molecular weight

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.

 \cdot 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.
- · 11.2 Information on other hazards:
- · Endocrine disrupting properties: Substance is not listed.

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.
- · 12.7 Other adverse effects:
- · Additional ecological information:
- · General notes:

Do not allow product to reach ground water, water course or sewage system.

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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 contaminated 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 · ADR, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA · Class:	Void
· 14.4 Packing group · ADR, IMDG, IATA	Void
· 14.5 Environmental hazards · Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Maritime transport in bulk according instruments	to IMO 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.
- \cdot 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.

- · 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.

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· 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 %
Ι	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: 25.02.2021
- · 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

 $STOT\,SE\,3\colon Specific\ target\ organ\ toxicity\ (single\ exposure)-Category\ 3$

GB