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 NB 1 GMP Grade from Clostridium histolyticum

· Article number: N0002937

· 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 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.

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 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:

9001-12-1 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.

GB

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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 (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
- 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.
- \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.

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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 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: 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 applicable

Plash point:
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

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

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 eve damage/irritation: Causes serious eye irritation.
- · Respiratory or skin sensitisation:

 ${\it May \ cause \ allergy \ or \ as thma \ symptoms \ or \ breathing \ difficulties \ if \ inhaled.}$

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

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.

· 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	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.
- \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.

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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
- · 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

GB