Printing date 01/16/2018

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Reviewed on 01/16/2018

Identificatio	on				
Product iden	tifier			C	
Trade name:		B5 Sterile Grade um histolyticum			Biochemical
Article numb	oer: N0002778				
CAS Number	r:				
<i>9001-12-1 EC number:</i>					
232-582-9					
	of the substance	/ the mixture			
Laboratory c Pharma Activ	hemicals ve ingredients				
		aafotu data ahoo	4		
Manufacture		safety data shee	L.		
Nordmark Ar	zneimittel Gmbl	H & Co. KG			
Pinnauallee					
D-25436 Uet Tel.: +49 412					
FAX.: +49 4.					
sicherheitsda	tenblatt@nordn	ıark-pharma.de			
			rtment Tel.: +49 412	22 712 242	
	elephone numb		·		
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Hazard(s) id	lentification				
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Printing date 01/16/2018

Reviewed on 01/16/2018

Trade name: Collagenase NB5 Sterile Grade from Clostridium histolyticum

(Contd. of page 1)
· Precautionary statements
Avoid breathing dust.
Wash thoroughly after handling.
Use only outdoors or in a well-ventilated area.
Contaminated work clothing must not be allowed out of the workplace.
<i>Wear protective gloves / eye protection / face protection.</i>
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 or rash 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.
Wash contaminated clothing 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)
$\begin{array}{c} \textbf{Health} = 1\\ \textbf{Fire} = 0\\ \textbf{Reactivity} = 0 \end{array}$
· HMIS-ratings (scale 0 - 4)
HEALTH*1FIRE0Fire0
REACTIVITY 0 <i>Reactivity</i> = 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
9001-12-1 Collagenase
· Identification number(s)
• EC number: 232-582-9

4 First-aid measures

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- · 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.

(Contd. on page 3)

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(Contd. of page 2)

Safety Data Sheet acc. to OSHA HCS

Printing date 01/16/2018

Reviewed on 01/16/2018

Trade name: Collagenase NB5 Sterile Grade from Clostridium histolyticum

· 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.
- Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- \cdot 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 In case of fire, the following can be released: Nitrogen oxides (NOx) Carbon monoxide and carbon dioxide

Sulphur oxides (SOx)

· 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 formation of dust.
 Do not inhale dusts.

· Environmental precautions: Do not allow to enter sewers/ surface or ground water.

- \cdot 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. Keep receptacles tightly sealed.
- Information about protection against explosions and fires: Protect against electrostatic charges. Keep ignition sources away - Do not smoke.
- · 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.

(Contd. on page 4)

US

Trade name: Collagenase NB5 Sterile Grade from Clostridium histolyticum (Contd. of page 3) • 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. • 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. 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 • 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

9 Physical and chemical properties

 Information on basic General Information 	physical and chemical properties	
Appearance:		
Form:	Powder	
Color:	Light brown	
Odor:	Weak, characteristic	
pH-value:	6-7	
Change in condition		
Melting point/Melt	ing range: Undetermined.	
Boiling point/Boili	ng range: Undetermined.	
		(Contd. on page

Reviewed on 01/16/2018

Printing date 01/16/2018

Reviewed on 01/16/2018

Trade name: Collagenase NB5 Sterile Grade from Clostridium histolyticum

	(Contd. of page 4
· 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:	Not determined.
· Bulk density at 20 °C (68 °F):	ca. 500 kg/m ³
 Solubility in / Miscibility with Water at 20 °C (68 °F): Other information 	300 g/l No further relevant information available.

10 Stability and reactivity

· Reactivity No further relevant informations available

- · Chemical stability
- Thermal decomposition / conditions to be avoided: Protein denaturation
- · Possibility of hazardous reactions No further relevant informations available.
- Conditions to avoid No further relevant information available.
- *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.
- \cdot 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.
- Do not allow product to reach ground water, water course or sewage syste
- Results of PBT and vPvB assessment
- **PBT:** Not applicable.

(Contd. on page 6)

(Contd. of page 5)

Safety Data Sheet acc. to OSHA HCS

Printing date 01/16/2018

Reviewed on 01/16/2018

Trade name: Collagenase NB5 Sterile Grade from Clostridium histolyticum

• **vPvB:** Not applicable.

• Other adverse effects No further relevant information available.

13 Disposal considerations

• 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.

UN-Number DOT, ADR, ADN, IMDG, IATA	Void
UN proper shipping name DOT, ADR, ADN, IMDG, IATA	Void
Transport hazard class(es)	
DOT, ADR, IMDG, IATA	
Class	Void
Label	-
ADN/R Class:	Void
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.

(Contd. on page 7)

US

Reviewed on 01/16/2018

Trade name: Collagenase NB5 Sterile Grade from Clostridium histolyticum

Printing date 01/16/2018

	(Contd. of page
Cancerogenity categories	
EPA (Environmental Protection Agency) Substance is not listed.	
TLV (Threshold Limit Value established by ACGIH) Substance is not listed.	
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 an allergic skin reaction.	
May cause respiratory irritation.	
Precautionary statements	
Avoid breathing dust.	
Wash thoroughly after handling.	
Use only outdoors or in a well-ventilated area.	
Contaminated work clothing must not be allowed out of the workplace.	
Wear protective gloves / eye protection / face protection.	
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 d
Continue rinsing.	
Call a POISON CENTER/doctor if you feel unwell.	
Specific treatment (see on this label).	
If skin irritation or rash 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.	
Wash contaminated clothing 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 regula	ations.
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 01/16/2018 / -
- · 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

(Contd. on page 8)

US

Printing date 01/16/2018

Reviewed on 01/16/2018

Trade name: Collagenase NB5 Sterile Grade from Clostridium histolyticum

EINECS: European Inventory of Existing	Commercial Chemical Substances
CAS: Chemical Abstracts Service (division	
NFPA: National Fire Protection Associati	on (USA)
HMIS: Hazardous Materials Identification	n System (USA)
PBT: Persistent, Bioaccumulative and To:	sic
vPvB: very Persistent and very Bioaccum	ılative
NIOSH: National Institute for Occupation	al Safety
OSHA: Occupational Safety & Health	
TLV: Threshold Limit Value	
PEL: Permissible Exposure Limit	
REL: Recommended Exposure Limit	
Skin Irrit. 2: Skin corrosion/irritation – C	ategory 2
Eye Irrit. 2A: Serious eye damage/eye irri	tation – Category 2A
Resp. Sens. 1: Respiratory sensitisation –	Category 1
Skin Sens. 1: Skin sensitisation – Categor	y 1
STOT SE 3: Specific target organ toxicity	(single exposure) – Category 3
• * Data compared to the previous	version altered.

(Contd. of page 7)

US