

Helimatic Cleaner enzymatic NF



Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Issue date: 8/14/2017 Revision date: 12/16/2022

Supersedes: 5/18/2020

Version: 2.1

SDS No: 00056-0356

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

1.1. Product identifier

Product form : Mixture
Product name : Helimatic Cleaner enzymatic NF
UFI : UXNU-FDDE-WT07-62DF

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture : Instrument cleaner

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

B. Braun Medical AG
Seesatz 17
CH-6204 Sempach
Switzerland
T +41 (0) 58 / 258 50 00
info.bbmch@bbraun.com

Supplier

B. Braun Melsungen AG
Carl-Braun-Straße 1
D-34212 Melsungen
Germany
T +49(0) 5661 / 71-4422
logistics.service@bbraun.com

E-mail address of competent person responsible for the SDS: sds@gbk-ingelheim.de

1.4. Emergency telephone number

Emergency number : INTERNATIONAL: +49 - (0) 6132 - 84463, GBK GmbH (24h - 7d/w - 365d/a)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

EUH-statements : EUH208 - Contains Subtilisin. May produce an allergic reaction.
EUH210 - Safety data sheet available on request.

2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

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SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Comments : Mixture of the substances listed below with nonhazardous additives

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sodiummono (2-ethylhexyl) sulphate	CAS-No.: 126-92-1 EC-No.: 204-812-8 REACH-no: 01-2119971586-23	< 3	Skin Irrit. 2, H315 Eye Dam. 1, H318
Subtilisin	CAS-No.: 9014-01-1 EC-No.: 232-752-2 EC Index-No.: 647-012-00-8 REACH-no: 01-2119480434-38	< 0,3	STOT SE 3, H335 Skin Irrit. 2, H315 Eye Dam. 1, H318 Resp. Sens. 1, H334

Specific concentration limits:

Name	Product identifier	Specific concentration limits
Sodiummono (2-ethylhexyl) sulphate	CAS-No.: 126-92-1 EC-No.: 204-812-8 REACH-no: 01-2119971586-23	(10 ≤C < 20) Eye Irrit. 2, H319 (20 ≤C < 100) Eye Dam. 1, H318

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Data of item 4 do partly not refer to the use and the regular employing of the product (in this sense consult package leaflet and expert information), but to liberation of major amounts in case of accidents and irregularities. Take off immediately all contaminated clothing. If you feel unwell, seek medical advice.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. If you feel unwell, seek medical advice.
First-aid measures after skin contact	: Wash off immediately with soap and plenty of water. Get medical advice if skin irritation persists.
First-aid measures after eye contact	: Wash immediately with plenty water (during 20 minutes), also under eyelids. Call a physician immediately.
First-aid measures after ingestion	: Do not induce vomiting. Drink plenty of water. Do not give an unconscious person anything to drink. Do not induce vomiting without medical advice. Call a physician immediately.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact	: Contact during a long period may cause light irritation.
Symptoms/effects after eye contact	: Direct contact with the eyes is likely to be irritating.
Symptoms/effects after ingestion	: Watch out. Beware, hazard of foam aspiration.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Product itself does not burn. Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media : high volume water jet.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Not flammable.
Explosion hazard : Product is not explosive.
Hazardous decomposition products in case of fire : Irritant/corrosive, flammable as well as toxic distillation gases (carbonization gases).

5.3. Advice for firefighters

Precautionary measures fire : Fight fire from safe distance and protected location. Cool endangered containers with water spray jet.
Firefighting instructions : Move containers from fire area if it can be done without personal risk.
Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information : Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Ventilate spillage area. Evacuate unnecessary personnel.

6.1.1. For non-emergency personnel

Emergency procedures : Avoid contact with skin and eyes. Do not breathe mist.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Do not allow to enter into surface water or drains. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).
Methods for cleaning up : Mechanically recover the product. Notify authorities if product enters sewers or public waters.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

Refer to protective measures listed in sections 7 and 8. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Avoid contact with skin, eyes and clothing.
Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.
Hygiene measures : Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Provide for a tub to collect spills.

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Storage conditions : Keep container tightly closed in a dry, cool and well-ventilated place.
Information on mixed storage : Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

See Section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

Monitoring methods	
Monitoring methods	A specific exposure sampling method is not available.
Biological monitoring methods	A specific exposure sampling method is not available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment:

Data of item 8 do partly not refer to the use and the regular employing of the product (in this sense consult package leaflet and expert information), but to liberation of major amounts in case of accidents and irregularities.

8.2.2.1. Eye and face protection

Eye protection:

Eyewash bottle with clean water (EN 15154)

Eye protection			
Type	Field of application	Characteristics	Standard
Protective goggles (EN 166)	Liquid splashes may occur		EN 166

8.2.2.2. Skin protection

Skin and body protection	
Type	Standard
Long sleeved protective clothing	EN ISO 6530

Hand protection:

This recommendation refers exclusively to the chemical compatibility and the lab test conforming to EN 374 carried out under lab conditions. Requirements can vary as a function of the use. Therefore it is necessary to adhere additionally to the recommendations given by the manufacturer of protective gloves

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Hand protection					
Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Chemically resistant protective gloves	Natural rubber	6 (> 480 minutes)	0,6		EN ISO 374

8.2.2.3. Respiratory protection

Respiratory protection:

No personal breathing protective equipment is normally required

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not breathe vapours. Wash hands immediately after handling the product. Wash hands before breaks and at the end of workday. Do not eat, drink or smoke in areas where product is used. Avoid contact with eyes.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Yellowish to brownish.
Appearance	: Liquid.
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: ≈ 100 °C
Flammability (solid, gas)	: Not applicable
Explosive properties	: Product is not explosive.
Oxidising properties	: Not oxidising.
Explosive limits	: Not available
Lower explosive limit (LEL)	: Not available
Upper explosive limit (UEL)	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 7 – 8 Concentrate
Viscosity, kinematic	: Not available
Solubility	: Water: Miscible
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: 1 – 1.1 g/cm ³
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

VOC content	: 0 %
Solvent content	: 0 %

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SECTION 10: Stability and reactivity

10.1. Reactivity

No decomposition if stored normally.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known.

10.4. Conditions to avoid

To avoid thermal decomposition, do not overheat.

10.5. Incompatible materials

Strong acids.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced. Fire may produce: Carbon monoxide. Carbon dioxide. Nitrous fumes.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

Subtilisin (9014-01-1)

ATE CLP (oral)	500 mg/kg bodyweight
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Skin corrosion/irritation : Not classified (Based on available data, the classification criteria are not met)
pH: 7 – 8 Concentrate
Serious eye damage/irritation : Not classified (Based on available data, the classification criteria are not met)
pH: 7 – 8 Concentrate
Respiratory or skin sensitisation : Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity : Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure : Not classified (Based on available data, the classification criteria are not met)

Subtilisin (9014-01-1)

STOT-single exposure	May cause respiratory irritation.
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STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

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11.2.2. Other information

Potential adverse human health effects and symptoms : Prolonged or repeated skin contact can cause irritation, A longer or repeated contact may lead to irritation of eyes and mucous membranes, Repeated or prolonged contact may cause allergic reactions in very susceptible persons

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : No ecotoxicological data about this product are known.
Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic) : Not classified (Based on available data, the classification criteria are not met)

12.2. Persistence and degradability

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Persistence and degradability	The surfactant(s) contained in this preparation complies (comply) with the biodegradability criteria as laid down in Regulation (EC) No. 648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

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This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

12.7. Other adverse effects

Additional information : Prevent entry to sewers and public waters

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Can be incinerated according to local regulations. Recycling is preferred to disposal or incineration. Dispose of contents/container in accordance with licensed collector's sorting instructions.

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Product/Packaging disposal recommendations : Empty containers should be taken for local recycling, recovery or waste disposal. Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse. Packaging that cannot be cleaned should be disposed of like the product.

European List of Waste (LoW) code : 07 06 99 - wastes not otherwise specified

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

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REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

VOC Directive (2004/42)

VOC content : 0 %

Detergent Regulation (648/2004)

Detergent Regulation (648/2004/EC): Labelling of contents:

Component

< 5 % anionic surfactants
< 5 % non-ionic surfactants
< 5 % polycarboxylates
enzymes
Methylparabene
Ingredients subject to the labelling obligation according to SCCP: -

Explosives Precursors Regulation (2019/1148)

Contains substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)
Please see https://ec.europa.eu/home-affairs/system/files/2021-11/list_of_competent_authorities_and_national_contact_points_en.pdf

Drug Precursors Regulation (273/2004)

Contains substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

All chapters have been modified since the previous version.

Abbreviations and acronyms:

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
DOT	Department of Transport
TDG	Transportation of Dangerous Goods
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals

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Abbreviations and acronyms:	
IARC	International Agency for Research on Cancer
vPvB	Very Persistent and Very Bioaccumulative
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
CAS	CAS (Chemical Abstracts Service) number
IBC-Code	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
ATE	Acute Toxicity Estimate
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
BCF	Bioconcentration factor
MARPOL 73/78	MARPOL 73/78: International Convention for the Prevention of Pollution From Ships
ADG	Transport of Australian Dangerous Goods

Other information : Data of sections 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities. The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge. The delivery specifications are contained in the corresponding product sheet. This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

Full text of H- and EUH-statements:	
EUH208	Contains Subtilisin. May produce an allergic reaction.
EUH210	Safety data sheet available on request.
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
Resp. Sens. 1	Respiratory sensitisation, Category 1
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should therefore not be construed as guaranteeing any specific property of the product.