

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

1.1. Product identifier

Helimatic Cleaner neutral

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

Use of the substance/mixture

Neutral cleaner for the mechanical reprocessing of medical devices incl. flexible endoscopes

1.3. Details of the supplier of the safety data sheet

Manufacturer

Company name: B. Braun Medical AG
Street: Seesatz 17
Place: CH-6204 Sempach
Responsible Department: Zentrale
Telephone: +41 (0) 58 / 258 50 00
E-Mail: info.bbmch@bbraun.com
Responsible for the safety data sheet: sds@gbk-ingelheim.de

Supplier

Company name: B. Braun Melsungen AG
Street: Carl-Braun-Straße 1
Place: D-34212 Melsungen
Responsible Department: Zentrale Service-Bereiche / Logistik und Supply Chain
Telephone: +49 (0) 5661 / 71-4422
E-Mail: logistics.service@bbraun.com

1.4. Emergency telephone number: INTERNATIONAL: +49 - (0) 6132 - 84463, GBK GmbH (24h - 7d/w - 365d/a)
In England and Wales: NHS 111 In Scotland: NHS 24 - dial 111

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture according to 1272/2008/EC

Hazard categories:

Serious eye damage/eye irritation: Eye Dam. 1

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

Causes serious eye damage.

Harmful to aquatic life with long lasting effects.

2.2. Label elements

Hazard components for labelling

Glycolic acid ethoxylate octyl ether

Signal word:

Danger

Pictograms:



Hazard statements

H318 Causes serious eye damage.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

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

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor.

Special labelling of certain mixtures

EUH208 Contains 1-Dodecyl-2-pyrrolidone, Glutaraldehyde. May produce an allergic reaction.

Helimatic Cleaner neutral

Revision date: 10.10.2018

Revision No: 1,3

Product code: 00056-0178

2.3. Other hazards

According to Regulation (EC) No 1907/2006 (REACH) none of the substances, contained in this product are a PBT / vPvB substance.

High risk of slipping due to leakage/spillage of product.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Neutral concentrate with anionic and non-ionic surfactants

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
53563-70-5	Glycolic acid ethoxylate octyl ether			< 5 %
	Skin Irrit. 2, Eye Dam. 1; H315 H318			
146340-16-1	Fatty alcohol alkyl glyceryl ether			< 5 %
	Skin Irrit. 2, Eye Irrit. 2; H315 H319			
2687-96-9	1-Dodecyl-2-pyrrolidone			< 1 %
	403-730-1	613-099-00-6	01-0000015338-68	
	Skin Corr. 1B, Skin Sens. 1, Aquatic Acute 1 (M-Factor = 1), Aquatic Chronic 1 (M-Factor = 1); H314 H317 H400 H410			
111-30-8	Glutaraldehyde			< 0,1 %
	203-856-5	605-022-00-X	01-2119455549-26	
	Acute Tox. 2, Acute Tox. 3, Skin Corr. 1B, Resp. Sens. 1, Skin Sens. 1A, STOT SE 3, Aquatic Acute 1, Aquatic Chronic 2; H330 H301 H314 H334 H317 H335 H400 H411 EUH071			

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

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Remove contaminated soaked clothing immediately.

If you feel unwell, seek medical advice.

After inhalation

Move to fresh air in case of accidental inhalation of fumes from overheating or combustion.

After contact with skin

Wash off with soap and plenty of water.

Consult a doctor if skin irritation persists.

After contact with eyes

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Seek medical treatment by eye specialist.

After ingestion

Do not provoke vomiting. Consult physician. Attention in case of vomiting - acute danger of suffocating, produced by foaming ingredients. Rinse mouth. Make drink some glasses of water. The decision whether to provoke vomiting is to be taken by a physician.

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

Causes serious eye damage.

Prolonged contact may cause skin irritation.

Watch out. Beware, hazard of foam aspiration.

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

Treat symptoms.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Product does not burn, fire-extinguishing activities according to surrounding.

Unsuitable extinguishing media

Full water jet.

5.2. Special hazards arising from the substance or mixture

Fire may produce:

carbon monoxide (CO), carbon dioxide (CO₂) and nitrogen oxides (NO_x)

5.3. Advice for firefighters

Use breathing apparatus with independent air supply.

Protective suit.

Additional information

Cool containers at risk with water spray jet.

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

Attention. Hazard of skidding.

Avoid contact with skin, eyes and clothing.

Use personal protective clothing.

6.2. Environmental precautions

Do not discharge into the drains/surface waters/ground water.

6.3. Methods and material for containment and cleaning up

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder).

Shovel into suitable container for disposal.

6.4. Reference to other sections

Observe protective instructions (see Sections 7 and 8).

Information for disposal see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Avoid contact with eyes, skin or mucous membrane.

Advice on protection against fire and explosion

No special protective measures against fire required.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep containers tightly closed in a cool, well-ventilated place.

Further information on storage conditions

Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

Neutral cleaner for the mechanical reprocessing of medical devices incl. flexible endoscopes

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Helimatic Cleaner neutral

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
111-30-8	Glutaraldehyde	0.05	0.2		TWA (8 h)	WEL
		0.05	0.2		STEL (15 min)	WEL

Additional advice on limit values

No data available.

8.2. Exposure controls

Protective and hygiene measures

Wash hands before breaks and at the end of workday.

When using do not eat or drink.

Avoid contact with skin, eyes and clothing.

Remove and wash contaminated clothing before re-use.

Eye/face protection

Tightly fitting goggles (EN 166).

Eye wash bottle with pure water (EN 15154).

Hand protection

Also suitable are gloves made of:

Polychloropren - CR (0,5 mm): Breakthrough time > 8 h

Nitrile rubber/nitrile latex - NBR (0,35 mm): Breakthrough time > 8 h

Butyl rubber - Butyl (0,5 mm): Breakthrough time > 8 h

Fluoro-rubber - FKM (0.4 mm): Breakthrough time > 8 h

Polyvinyl chloride - PVC (0.5 mm): Breakthrough time > 8 h

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.

Skin protection

Long sleeved clothing (DIN EN ISO 6530)

Respiratory protection

No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	Colourless to slightly yellowish
Odour:	Perfumed, like surfactant

pH-Value (at 20 °C): approx. 6,0 Concentrate

Changes in the physical state

Initial boiling point and boiling range: approx. 100 °C

Flash point: n.a.

Lower explosion limits: n.a.

Upper explosion limits: n.a.

Ignition temperature: n.a.

Density (at 20 °C): approx. 1,09 g/cm³

Water solubility: Miscible
(at 20 °C)

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

No decomposition if stored and applied as directed.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

To avoid thermal decomposition, do not overheat.

10.5. Incompatible materials

No materials to be especially mentioned.

10.6. Hazardous decomposition products

Carbon monoxide (CO), carbon dioxide (CO₂) and nitrogen oxides (NO_x)

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.

No toxicological data available.

Irritation and corrosivity

Causes serious eye damage.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Sensitising effects

Contains 1-Dodecyl-2-pyrrolidone, Glutaraldehyde. May produce an allergic reaction.

STOT-single exposure

Based on available data, the classification criteria are not met.

Severe effects after repeated or prolonged exposure

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Additional information on tests

Classification in compliance with the assessment procedure specified in the Regulation (EC) no 1272/2008.

Practical experience

Other observations

Prolonged contact may cause skin irritation.

Watch out. Beware, hazard of foam aspiration.

SECTION 12: Ecological information

12.1. Toxicity

Ecological data are not available.

Harmful to aquatic life with long lasting effects.

12.2. 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 data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

According to Regulation (EC) No 1907/2006 (REACH) none of the substances, contained in this product are a PBT / vPvB substance.

12.6. Other adverse effects

Hazardous water pollutant.

Further information

Product is not allowed to be discharged into aquatic environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Where possible recycling is preferred to disposal.

Can be incinerated, when in compliance with local regulations.

Waste disposal number of waste from residues/unused products

070699 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics; wastes not otherwise specified

Contaminated packaging

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.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

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

EU regulatory information

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

2004/42/EC (VOC): 0 %

Additional information

Regulation (EC) No 648/2004 (Regulation on detergents):

Phosphonates < 5%, Anionic surfactants < 5%, Non-ionic surfactants < 5%, Polycarboxylates < 5%, Parfum

Ingredients subject to the labelling obligation according to SCCP:

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National regulatory information

Employment restrictions: Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other information

Abbreviations and acronyms

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route

RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses

ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure

IMDG = International Maritime Code for Dangerous Goods

IATA/ICAO = International Air Transport Association / International Civil Aviation Organization

MARPOL = International Convention for the Prevention of Pollution from Ships

IBC-Code = International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

REACH = Registration, Evaluation, Authorization and Restriction of Chemicals

CAS = Chemical Abstract Service

EN = European norm

ISO = International Organization for Standardization

DIN = Deutsche Industrie Norm

PBT = Persistent Bioaccumulative and Toxic

vPvB = Very Persistent and very Bio-accumulative

LD = Lethal dose

LC = Lethal concentration

EC = Effect concentration

IC = Median immobilisation concentration or median inhibitory concentration

Relevant H and EUH statements (number and full text)

H301	Toxic if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Safety Data Sheet according to Regulation (EC) No 1907/2006

B. Braun Medical AG

Helimatic Cleaner neutral

Revision date: 10.10.2018

Revision No: 1,3

Product code: 00056-0178

EUH071 Corrosive to the respiratory tract.

EUH208 Contains 1-Dodecyl-2-pyrrolidone, Glutaraldehyde. May produce an allergic reaction.

Further Information

Data of items 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.

(n.a. = not applicable; n.d. = not determined)

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)