

## 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

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## 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.

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**Helimatic Cleaner neutral**

**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 (CO<sub>2</sub>) and nitrogen oxides (NO<sub>x</sub>)

### **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.

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## **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.

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## **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

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## **SECTION 8: Exposure controls/personal protection**

### **8.1. Control parameters**

**Helimatic Cleaner neutral**

**Exposure limits (EH40)**

CAS No	Substance	ppm	mg/m <sup>3</sup>	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/cm<sup>3</sup>

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 (CO<sub>2</sub>) and nitrogen oxides (NO<sub>x</sub>)

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**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.

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**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

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### **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.

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## **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.

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## **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.

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## 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.

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## 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

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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)

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