

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

### 1.1. Product identifier

Helimatic Rinse neutral

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

#### Use of the substance/mixture

Rinsing agent for the mechanical reprocessing of medical devices

### 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)  
England and Wales: NHS Direct - 0845 4647; Scotland: NHS 24 - 08454 24 24 24

## SECTION 2: Hazards identification

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

Hazard categories:

Flammable liquid: Flam. Liq. 3

Serious eye damage/eye irritation: Eye Dam. 1

Hazard Statements:

Flammable liquid and vapour.

Causes serious eye damage.

### 2.2. Label elements

#### Hazard components for labelling

Propan-1-ol

D-Glucopyranose, oligomeric, C8-10 glycosides

Signal word:

Danger

Pictograms:



#### Hazard statements

H226 Flammable liquid and vapour.

H318 Causes serious eye damage.

#### Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233 Keep container tightly closed.

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.

**Helimatic Rinse neutral**

P312 Call a POISON CENTER/doctor if you feel unwell.

**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.

Vapours may form explosive mixture with air.

**SECTION 3: Composition/information on ingredients**

**3.2. Mixtures**

**Chemical characterization**

Neutral, alcoholic concentrate with 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]			
64-17-5	Ethanol			< 20 %
	200-578-6	603-002-00-5	01-2119457610-43	
	Flam. Liq. 2, Eye Irrit. 2; H225 H319			
71-23-8	Propan-1-ol			< 15 %
	200-746-9	603-003-00-0	01-2119486761-29	
	Flam. Liq. 2, Eye Dam. 1, STOT SE 3; H225 H318 H336			
501019-90-5	Fatty alcohol polyglycol ether, modified			< 5 %
	Eye Irrit. 2, Aquatic Chronic 3; H319 H412			
68515-73-1	D-Glucopyranose, oligomeric, C8-10 glycosides			< 5 %
	500-220-1		01-2119488530-36	
	Eye Dam. 1; H318			
67-63-0	Propan-2-ol			< 5 %
	200-661-7	603-117-00-0	01-2119457558-25	
	Flam. Liq. 2, Eye Irrit. 2, STOT SE 3; H225 H319 H336			

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 vapours or decomposition products.

In the event of symptoms refer for medical treatment.

**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**

Rinse out mouth and give plenty of water to drink.

Do not induce vomiting.

Never give anything by mouth to an unconscious person.

Seek medical treatment immediately.

Induce vomiting only upon the advice of a physician.

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

Causes serious eye damage.

Inhalation of vapours in high concentration can cause narcotic effects.

Repeated or prolonged exposure may cause skin irritation and dermatitis, due to degreasing properties of the product.

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

Treat symptoms.

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### **SECTION 5: Firefighting measures**

#### **5.1. Extinguishing media**

##### **Suitable extinguishing media**

Alcohol-resistant foam, dry chemical, carbon dioxide (CO<sub>2</sub>), water-spray.

##### **Unsuitable extinguishing media**

Full water jet.

#### **5.2. Special hazards arising from the substance or mixture**

Fire may produce:

carbon monoxide and carbon dioxide

#### **5.3. Advice for firefighters**

Use breathing apparatus with independent air supply.

Protective suit.

##### **Additional information**

Cool containers at risk with water spray jet.

Vapours are heavier than air and spread along ground.

The vapour/air mixture is explosive, even in empty, uncleaned receptacles.

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**

Remove all sources of ignition.

In case of vapour formation use respirator.

Ensure adequate ventilation.

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**

Keep container tightly closed.

Use only in thoroughly ventilated areas.

Avoid contact with skin, eyes and clothing.

When using do not eat, drink or smoke.

##### **Advice on protection against fire and explosion**

Don't smoke.

Keep product and empty container away from heat and sources of ignition.

#### **7.2. Conditions for safe storage, including any incompatibilities**

##### **Requirements for storage rooms and vessels**

Keep container tightly closed in a dry, cool and well-ventilated place.

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**Advice on storage compatibility**

Incompatible with:

Oxidizing agents

Alkaline metals and earth alkaline metals.

**Further information on storage conditions**

Keep away from food, drink and animal feeding stuffs.

**7.3. Specific end use(s)**

Rinsing agent for the mechanical reprocessing of medical devices

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

**8.1. Control parameters**

**Exposure limits (EH40)**

CAS No	Substance	ppm	mg/m <sup>3</sup>	fibres/ml	Category	Origin
64-17-5	Ethanol	1000	1920		TWA (8 h)	WEL
		-	-		STEL (15 min)	WEL
71-23-8	Propan-1-ol	200	500		TWA (8 h)	WEL
		250	625		STEL (15 min)	WEL
67-63-0	Propan-2-ol	400	999		TWA (8 h)	WEL
		500	1250		STEL (15 min)	WEL

**8.2. Exposure controls**

**Appropriate engineering controls**

Ensure adequate ventilation, especially in confined areas.

**Protective and hygiene measures**

Do not inhale vapours.

Wash hands before breaks and at the end of workday.

When using do not eat, drink or smoke.

Remove and wash contaminated clothing before re-use.

Avoid contact with eyes and skin.

**Eye/face protection**

Safety goggles with side protection (EN 166).

Eye wash bottle with pure water (EN 15154).

**Hand protection**

Protective gloves resistant to chemicals made off butyl, minimum coat thickness 0.7 mm, permeation resistance approx. 480 minutes, i.e. protective glove <Butoject 898> made by www.kcl.de.

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 (EN 368).

**Respiratory protection**

In case of insufficient ventilation wear suitable respiratory equipment (gas filter type A) (EN 14387).

**SECTION 9: Physical and chemical properties**

**9.1. Information on basic physical and chemical properties**

Physical state:

Liquid

Colour:

Colourless

Odour:

Alcoholic

pH-Value (at 20 °C):

approx. 6,5

Concentrate

**Changes in the physical state**

Initial boiling point and boiling range:	approx. 78 °C	
Flash point:	34 °C	DIN 51755
Lower explosion limits:	2,0 g/m <sup>3</sup>	
Upper explosion limits:	n.d.	
Ignition temperature:	> 400 °C	
Density (at 20 °C):	approx. 0,96 g/cm <sup>3</sup>	
Water solubility: (at 20 °C)	Completely miscible	
Solvent content:	< 35 %	

**9.2. Other information**

No data available.

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**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**

Reactions with oxidizing agents.  
Reactions with alkali metals.  
Reactions with earth alkali metals.

**10.4. Conditions to avoid**

Vapour/air mixtures are explosive at intensive warming.  
Heating can release vapours which can be ignited.

**10.5. Incompatible materials**

Oxidizing agents  
Alkaline metals and earth alkaline metals.

**10.6. Hazardous decomposition products**

Carbon monoxide and carbon dioxide

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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.  
Skin irritation: Not classified.

**Sensitising effects**

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

**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.

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## **Practical experience**

### **Other observations**

Inhalation of high vapour concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.

Inhalation of vapours in high concentration can cause narcotic effects.

Repeated or prolonged exposure may cause skin irritation and dermatitis, due to degreasing properties of the product.

May cause irritation of the mucous membranes.

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## **SECTION 12: Ecological information**

### **12.1. Toxicity**

Ecological data are not available.

### **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**

Low hazard to waters.

### **Further information**

Do not discharge into surface waters/groundwater.

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## **SECTION 13: Disposal considerations**

### **13.1. Waste treatment methods**

#### **Advice on disposal**

Can be incinerated, when in compliance with local regulations.

Where possible recycling is preferred to disposal.

#### **Waste disposal number of waste from residues/unused products**

070604 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics; other organic solvents, washing liquids and mother liquors; hazardous waste

#### **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:**

UN 1987

#### **14.2. UN proper shipping name:**

ALCOHOLS, N.O.S. (Ethanol, Propan-1-ol)

#### **14.3. Transport hazard class(es):**

3

#### **14.4. Packing group:**

III

Hazard label:

3

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**Helimatic Rinse neutral**

Revision date: 02.10.2017

Revision No: 1,2

Product code: 00056-0265



Classification code: F1  
Limited quantity: 5 L / 30 kg  
Excepted quantity: E1  
Transport category: 3  
Hazard No: 30  
Tunnel restriction code: D/E

**Inland waterways transport (ADN)**

**14.1. UN number:** UN 1987  
**14.2. UN proper shipping name:** ALCOHOLS, N.O.S. (Ethanol, Propan-1-ol)  
**14.3. Transport hazard class(es):** 3  
**14.4. Packing group:** III  
Hazard label: 3



Classification code: F1  
Limited quantity: 5 L / 30 kg  
Excepted quantity: E1

**Marine transport (IMDG)**

**14.1. UN number:** UN 1987  
**14.2. UN proper shipping name:** ALCOHOLS, N.O.S. (Ethanol, Propan-1-ol)  
**14.3. Transport hazard class(es):** 3  
**14.4. Packing group:** III  
Hazard label: 3



Marine pollutant: No  
Limited quantity: 5 L / 30 kg  
Excepted quantity: E1  
EmS: F-E, S-D

**Air transport (ICAO-TI/IATA-DGR)**

**14.1. UN number:** UN 1987  
**14.2. UN proper shipping name:** ALCOHOLS, N.O.S. (Ethanol, Propan-1-ol, Solution)  
**14.3. Transport hazard class(es):** 3  
**14.4. Packing group:** III  
Hazard label: 3



Limited quantity Passenger: 10 L  
Passenger LQ: Y344  
Excepted quantity: E1  
IATA-packing instructions - Passenger: 355  
IATA-max. quantity - Passenger: 60 L  
IATA-packing instructions - Cargo: 366  
IATA-max. quantity - Cargo: 220 L

**14.5. Environmental hazards**

ENVIRONMENTALLY HAZARDOUS: no

**14.6. Special precautions for user**

Handle in accordance with good industrial hygiene and safety practice.

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

The transport takes place only in approved and appropriate packaging.

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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**

2004/42/EC (VOC): < 35 %

**Additional information**

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

Non-ionic surfactants < 5%

Ingredients subject to the labelling obligation according to SCCP: -

**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)**

H225 Highly flammable liquid and vapour.

H226 Flammable liquid and vapour.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

H412 Harmful to aquatic life with long lasting effects.

**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

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

B. Braun Medical AG

**Helimatic Rinse neutral**

Revision date: 02.10.2017

Revision No: 1,2

Product code: 00056-0265

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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.)*