

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

B. Braun Melsungen AG

Revision date: 14.06.2012

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Helizyme

00056-0196

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

1.1. Product identifier

Helizyme

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

Use of the substance/mixture

Enzymatic cleaner for manual cleaning of delicate surgical instruments, rigid and flexible endoscopes

1.3. Details of the supplier of the safety data sheet

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Responsible Department

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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Indications of danger: Irritant

R phrases:

Irritating to eyes.

GHS classification

Hazard categories:

Serious eye damage/eye irritation: Eye Dam. 1

Hazard Statements:

Causes serious eye damage.

2.2. Label elements

Danger symbols:

Xi - Irritant



Xi - Irritant

Hazardous components which must be listed on the label

Non-ionic surfactants

Anionic surfactants

R phrases

36 Irritating to eyes.

S phrases

26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

35 This material and its container must be disposed of in a safe way.

2.2. Label elements (GHS classification)

Signal word: Danger

Pictograms: GHS05



Hazardous components which must be listed on the label

Non-ionic surfactants

Anionic surfactants

Hazard statements

H318 Causes serious eye damage.

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 or doctor/physician.

2.3. Other hazards

Not known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Aqueous solution of anionic and non-ionic surfactants

Hazardous components

EC No	Chemical name	Quantity
CAS No	Classification	
Index No	GHS classification	
REACH No		
203-961-6	2-(2-Butoxyethoxy)ethanol	1 - 5 %
112-34-5	Xi - Irritant R36	
603-096-00-8	Eye Irrit. 2; H319	
	Non-ionic surfactants	< 5 %
	Xn - Harmful, Xi - Irritant R22-41	
	Acute Tox. 4, Eye Dam. 1; H302 H318	
	Anionic surfactants	< 5 %
	Xi - Irritant R38-41	
	Skin Irrit. 2, Eye Dam. 1; H315 H318	

Full text of R and H phrases: 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.

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.

Extinguishing media which must not be used for safety reasons

Full water jet.

5.2. Special hazards arising from the substance or mixture

Fire may produce:
Irritant/corrosive, flammable as well as toxic distillation gases (carbonization gases).

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

Avoid contact with skin, eyes and clothing.
Use personal protective clothing.

6.2. Environmental precautions

Do not discharge into the drains/surface waters/groundwater.

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 look up chapter 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)

Enzymatic cleaner for manual cleaning of delicate surgical instruments, rigid and flexible endoscopes

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
112-34-5	2-(2-Butoxyethoxy)ethanol	15	101.2		TWA (8 h)	WEL
		10	67.5		STEL (15 min)	WEL

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.

Respiratory protection

No personal respiratory protective equipment normally required.

Hand protection

Protective gloves resistant to chemicals made off natural-rubber latex, minimum coat thickness 0.6 mm, permeation resistance (wear duration) approx. 480 minutes, i.e. protective glove <Lapren 706> 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.

Eye protection

Tightly fitting goggles.

Eye wash bottle with pure water.

Skin protection

Long sleeved clothing.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Liquid
 Colour: Blue
 Odour: Aromatic

pH-Value (at 20 °C): 6 **Test method**

Changes in the physical state

Boiling point: Approx. 100 °C
 Flash point: n.a.
 Lower explosion limits: n.a.

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Upper explosion limits:

Ignition temperature:

n.a.

Density (at 20 °C):

1,07 g/cm³

Water solubility:
(at 20 °C)

Miscible

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

No hazardous decomposition products known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

No toxicological data available.

CAS No	Chemical name				
	Exposure routes	Method	Dose	Species	h
112-34-5	2-(2-Butoxyethoxy)ethanol				
	Acute oral toxicity	LD50	5660 mg/kg	Rat	
	Acute dermal toxicity	LD50	4120 mg/kg	Rabbit	
	Non-ionic surfactants				
	Acute oral toxicity	ATE	500 mg/kg		

Irritation and corrosivity

Skin irritation: Not classified.

Eye irritation: Causes serious eye damage.

Sensitising effects

Not classified.

Severe effects after repeated or prolonged exposure

STOT/Single exposure: Not classified.

STOT/Repeated exposure: Not classified.

Aspiration hazard: Not classified.

Carcinogenic/mutagenic/toxic effects for reproduction

Carcinogenicity: Not classified.

Mutagenicity: Not classified.

Teratogenicity: Not classified.

Additional information on tests

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

Empirical data on effects on humans

Repeated or prolonged exposure may cause irritation of eyes, skin and respiratory system.
 May cause sensitization of susceptible persons by inhalation of aerosol or dust.

SECTION 12: Ecological information

12.1. Toxicity

Ecological data are not available.

CAS No	Chemical name			
	Aquatic toxicity	Method	Dose	Species
112-34-5	2-(2-Butoxyethoxy)ethanol			h
	Acute algae toxicity	ErC50	> 100 mg/l	Scenedesmus sp.
	Acute crustacea toxicity	EC50	> 100 mg/l	Daphnia magna
				48

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
112-34-5	2-(2-Butoxyethoxy)ethanol	0,56 (25°C)

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 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

Other applicable information

No hazardous material as defined by the transport regulations.

SECTION 15: Regulatory information

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

EU regulatory information

1999/13/EC (VOC): 0 %

Additional information

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

Anionic surfactants < 5%, Non-ionic surfactants < 5%, Polycarboxylates < 5%, Enzymes,

Methylparabene

Ingredients subject to the labelling obligation according to SCCP: -

National regulatory information

Employment restrictions: Observe employment restrictions for young people. Observe employment restrictions for child bearing mothers and nursing.

Water contaminating class (D): 2 - water contaminating

SECTION 16: Other information

Full text of R phrases referred to under Sections 2 and 3

22 Harmful if swallowed.
36 Irritating to eyes.
38 Irritating to skin.
41 Risk of serious damage to eyes.

Full text of H statements referred to under Sections 2 and 3

H302 Harmful if swallowed.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.

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.)