

**Helimatic Disinfectant**

Revision date: 22.06.2020

Product code: 00056-0190

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**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Helimatic Disinfectant

UFI: 1E7V-U711-0009-TTES

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

Instrument disinfectant

**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****Regulation (EC) No. 1272/2008**

Hazard categories:

Acute toxicity: Acute Tox. 4

Acute toxicity: Acute Tox. 4

Skin corrosion/irritation: Skin Corr. 1B

Serious eye damage/eye irritation: Eye Dam. 1

Respiratory or skin sensitisation: Resp. Sens. 1

Respiratory or skin sensitisation: Skin Sens. 1A

Specific target organ toxicity - single exposure: STOT SE 3

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

Harmful if swallowed.

Harmful if inhaled.

Causes severe skin burns and eye damage.

Causes serious eye damage.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

May cause respiratory irritation.

Harmful to aquatic life with long lasting effects.

**2.2. Label elements****Regulation (EC) No. 1272/2008****Hazard components for labelling**

Glutaraldehyde

**Signal word:** Danger

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**Pictograms:**



**Hazard statements**

- H302+H332 Harmful if swallowed or if inhaled.
- H314 Causes severe skin burns and eye damage.
- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H317 May cause an allergic skin reaction.
- H335 May cause respiratory irritation.
- H412 Harmful to aquatic life with long lasting effects.

**Precautionary statements**

- P260 Do not breathe mist.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
- P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- 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.
- P273 Avoid release to the environment.
- P501 Dispose of contents/container to an approved waste disposal plant. .

**Special labelling of certain mixtures**

- EUH071 Corrosive to the respiratory tract.

**Labelling of packages where the contents do not exceed 125 ml**

**Signal word:** Danger

**Pictograms:**



**Hazard statements**

- H314-H334-H317-H412

**Precautionary statements**

- P260-P280-P303+P361+P353-P304+P340-P305+P351+P338-P310-P501

**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**

Alcoholic concentrate with glutaral and salts of organic acids

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**Hazardous components**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
111-30-8	Glutaraldehyde			< 25 %
	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 (M-Factor = 1), Aquatic Chronic 2; H330 H301 H314 H334 H317 H335 H400 H411 EUH071			
64-17-5	Ethanol			< 10 %
	200-578-6	603-002-00-5	01-2119457610-43	
	Flam. Liq. 2, Eye Irrit. 2; H225 H319			

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

**SECTION 4: First aid measures****4.1. Description of first aid measures****General information**

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.

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 immediately with soap and plenty of water.

Treat subsequently with skin cream.

Consult a physician.

**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**

Drink plenty of water.

Summon a doctor immediately.

Induce vomiting only upon the advice of a physician.

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

Harmful if swallowed or if inhaled.

May cause an allergic skin reaction.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause respiratory irritation.

Causes severe skin burns and eye damage.

**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 is ignitable, but does not keep burning.

Fire-extinguishing activities according to surrounding.

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**Unsuitable extinguishing media**

Full water jet

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

Fire may produce:

carbon monoxide and carbon dioxide

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.

Do not release chemically contaminated water into drains, soil or surface waters. Sufficient measures must be taken to retain water used for extinguishing.

**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

In case of vapour formation use respirator.

Avoid contact with skin, eyes and clothing.

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.

**SECTION 7: Handling and storage****7.1. Precautions for safe handling****Advice on safe handling**

Keep container tightly closed.

Keep a good ventilation and air-exhaust at the place of work.

Avoid contact with skin, eyes and clothing.

**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 dry, well-ventilated place.

**Hints on joint storage**

Incompatible with strong acids and oxidizing agents.

**Further information on storage conditions**

Keep away from food, drink and animal feeding stuffs.

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

Instrument disinfectant

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters**

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#### 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
111-30-8	Glutaraldehyde	0.05	0.2		TWA (8 h)	WEL
		0.05	0.2		STEL (15 min)	WEL

#### DNEL/DMEL values

CAS No	Substance	Exposure route	Effect	Value
64-17-5	Ethanol			
	DNEL, acute	inhalation	local	1900 mg/m <sup>3</sup>
	DNEL, long-term	oral	systemic	343 mg/kg bw/day
	DNEL, long-term	dermal	systemic	343 mg/kg bw/day
	DNEL, long-term	inhalation	systemic	950 mg/m <sup>3</sup>

#### PNEC values

CAS No	Substance	Value
64-17-5	Ethanol	
	Freshwater	0,96 mg/l
	Marine water	0,79 mg/l
	Freshwater sediment	3,6 mg/kg
	Marine sediment	2,9 mg/kg
	Micro-organisms in sewage treatment plants (STP)	580 mg/l
	Soil	0,63 mg/kg

## 8.2. Exposure controls

### Appropriate engineering controls

Ensure adequate ventilation, especially in confined areas.

### Protective and hygiene measures

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.

Do not inhale vapours.

Wash hands before breaks and immediately after handling the product.

When using do not eat or drink.

Take off immediately all contaminated clothing.

Avoid contact with eyes, skin or mucous membrane.

### 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 (DIN EN ISO 6530)

Apron (EN 467).

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### 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:	Aldehyde-like

#### Test method

pH-Value (at 20 °C):	3,8 - 4,2
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#### Changes in the physical state

Melting point:	n.d.
Initial boiling point and boiling range:	approx. 100 °C
Sublimation point:	n.a.
Softening point:	n.d.
Flash point:	39 °C DIN 51755 *)
Sustaining combustion:	Not sustaining combustion

#### Flammability

Solid:	n.a.
Gas:	n.a.

#### Explosive properties

The product is not explosive.

Lower explosion limits:	n.d.
Upper explosion limits:	n.d.
Ignition temperature:	n.d.

#### Auto-ignition temperature

Solid:	n.a.
Gas:	n.a.

Decomposition temperature:	n.d.
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#### Oxidizing properties

Not oxidising.

Vapour pressure:	n.d.
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Density (at 20 °C):	1,04 - 1,07 g/cm <sup>3</sup>
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Bulk density:	n.a.
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Water solubility: (at 20 °C)	Miscible
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#### Solubility in other solvents

n.d.

Partition coefficient:	n.d.
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Viscosity / dynamic:	n.d.
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Viscosity / kinematic:	n.d.
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Flow time:	n.d.
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Vapour density:	n.d.
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Evaporation rate:	n.d.
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Solvent separation test:	n.d.
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Solvent content:	< 10 %
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### 9.2. Other information

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\*) Product is ignitable, but does not keep burning.

**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 acids and strong oxidizing agents.

**10.4. Conditions to avoid**

To avoid thermal decomposition, do not overheat.

**10.5. Incompatible materials**

Strong acids and oxidizing agents

**10.6. Hazardous decomposition products**

No hazardous decomposition products known.

Fire may produce:

Irritant/corrosive, flammable as well as toxic distillation gases (carbonization gases).

Carbon monoxide and carbon dioxide

**SECTION 11: Toxicological information****11.1. Information on toxicological effects****Acute toxicity**

Harmful if swallowed.

Harmful if inhaled.

No toxicological data available.

ATEmix/oral: ~ 750 mg/kg

ATEmix/inhalation: ~ 2,4 mg/l/4 h [mist]

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
111-30-8	Glutaraldehyde				
	oral	LD50 mg/kg 151	Rat		OECD 401
	dermal	LD50 mg/kg > 1000	Rabbit		US-EPA
	inhalation vapour	ATE 0,5 mg/l			
	inhalation (4 h) aerosol	LC50 0,48 mg/l	Rat		OECD 403
64-17-5	Ethanol				
	oral	LD50 mg/kg 10470	Rat		
	dermal	LD50 mg/kg 15800	Rabbit		
	inhalation (4 h) vapour	LC50 30 mg/l	Rat		

**Irritation and corrosivity**

Causes severe skin burns and eye damage.

Causes serious eye damage.

**Sensitising effects**

May cause allergy or asthma symptoms or breathing difficulties if inhaled. (Glutaraldehyde)

May cause an allergic skin reaction. (Glutaraldehyde)

**Carcinogenic/mutagenic/toxic effects for reproduction**

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

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**STOT-single exposure**

May cause respiratory irritation. (Glutaraldehyde )

**STOT-repeated exposure**

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**

Inhalation of vapours is irritating to the respiratory system, may cause throat pain and cough.

**SECTION 12: Ecological information****12.1. Toxicity**

Ecological data are not available.

Harmful to aquatic life with long lasting effects.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
111-30-8	Glutaraldehyde					
	Acute fish toxicity	LC50	3,5 mg/l	96 h	Oncorhynchus mykiss	ECOTOX
	Acute algae toxicity	ErC50	0,6 mg/l	72 h	Desmodesmus subspicatus	OECD 201
	Acute crustacea toxicity	EC50 mg/l	14,87	48 h	Daphnia magna	OECD 202
	Fish toxicity	NOEC	1,6 mg/l	97 d	Oncorhynchus mykiss	OECD 210
	Crustacea toxicity	NOEC	5 mg/l	21 d	Daphnia magna	OECD 211
64-17-5	Ethanol					
	Acute fish toxicity	LC50 mg/l	11200	96 h	Fish	
	Acute algae toxicity	ErC50	275 mg/l		Algae	
	Acute crustacea toxicity	EC50 mg/l	5012	48 h	Daphnia magna	

**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.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
111-30-8	Glutaraldehyde			
	OECD 301A	90 - 100%	28	
	Readily biodegradable (to OECD criteria).			

**12.3. Bioaccumulative potential**

No data available

**Partition coefficient n-octanol/water**

CAS No	Chemical name	Log Pow
64-17-5	Ethanol	- 0,3



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**BCF**

CAS No	Chemical name	BCF	Species	Source
64-17-5	Ethanol	0,66		

**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****Disposal recommendations**

Can be incinerated, when in compliance with local regulations.

**List of Wastes Code - 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.

**SECTION 14: Transport information****Land transport (ADR/RID)**

<b>14.1. UN number:</b>	UN 1903
<b>14.2. UN proper shipping name:</b>	DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaraldehyde)
<b>14.3. Transport hazard class(es):</b>	8
<b>14.4. Packing group:</b>	II
Hazard label:	8



Classification code:	C9
Limited quantity:	1 L / 30 kg
Excepted quantity:	E2
Transport category:	2
Hazard No:	80
Tunnel restriction code:	E

**Inland waterways transport (ADN)**

<b>14.1. UN number:</b>	UN 1903
<b>14.2. UN proper shipping name:</b>	DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaraldehyde)
<b>14.3. Transport hazard class(es):</b>	8
<b>14.4. Packing group:</b>	II
Hazard label:	8

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Classification code: C9  
 Limited quantity: 1 L / 30 kg  
 Excepted quantity: E2

**Marine transport (IMDG)**

**14.1. UN number:** UN 1903  
**14.2. UN proper shipping name:** DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaraldehyde)  
**14.3. Transport hazard class(es):** 8  
**14.4. Packing group:** II  
 Hazard label: 8



Limited quantity: 1 L / 30 kg  
 Excepted quantity: E2  
 EmS: F-A, S-B

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

**14.1. UN number:** UN 1903  
**14.2. UN proper shipping name:** DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaraldehyde)  
**14.3. Transport hazard class(es):** 8  
**14.4. Packing group:** II  
 Hazard label: 8



Limited quantity Passenger: 0.5 L  
 Passenger LQ: Y840  
 Excepted quantity: E2  
 IATA-packing instructions - Passenger: 851  
 IATA-max. quantity - Passenger: 1 L  
 IATA-packing instructions - Cargo: 855  
 IATA-max. quantity - Cargo: 30 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.

**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): < 10 %  
 Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

**Additional information**

Regulation (EC) No 648/2004 (Regulation on detergents):  
 Phosphonates < 5%

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Ingredients subject to the labelling obligation according to SCCP: -

### National regulatory information

Employment restrictions:

Observe restrictions to employment for juveniles 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

### Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]

Classification	Classification procedure
Acute Tox. 4; H302	Calculation method
Acute Tox. 4; H332	Calculation method
Skin Corr. 1B; H314	Calculation method
Eye Dam. 1; H318	Calculation method
Resp. Sens. 1; H334	Calculation method
Skin Sens. 1A; H317	Calculation method
STOT SE 3; H335	Calculation method
Aquatic Chronic 3; H412	Calculation method

### Relevant H and EUH statements (number and full text)

H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H302+H332	Harmful if swallowed or if inhaled.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H332	Harmful if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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- H335 May cause respiratory irritation.
- H400 Very toxic to aquatic life.
- H411 Toxic to aquatic life with long lasting effects.
- H412 Harmful to aquatic life with long lasting effects.
- EUH071 Corrosive to the respiratory tract.

**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)

For the identified uses, see also A.I.S.E. ([www.aise.eu](http://www.aise.eu)). There you will find further information under the keyword SUMI (safe use mixtures information).

**Identified uses**

No	Short title	LCS	SU	PC	PROC	ERC	AC	TF	Specification
1	Instrument disinfectant	-	-	-	8a, 8b, 9, 19	-	-	-	SUMI VIII

LCS: Life cycle stages

PC: Product categories

ERC: Environmental release categories

TF: Technical functions

SU: Sectors of use

PROC: Process categories

AC: Article categories

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