

**Uro-Tainer Suby G B. Braun / Uro-Tainer Twin Suby G B. Braun**

Revision date: 25.06.2020

Product code: 00056-0275

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

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UFI: MVHQ-406E-200D-CTSA

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

Maintenance solution for urethral catheters

**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**

This mixture is not classified as hazardous in accordance with Regulation (EC) No. 1272/2008.

**2.2. Label elements****Regulation (EC) No. 1272/2008****Special labelling of certain mixtures**

EUH210 Safety data sheet available on request.

**Additional advice on labelling**

This product is not subject to labeling obligation according to art. 1 (5) d) of Regulation (EC) no. 1272/2008 under the form of a medical product because it is used under body contact.

**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.

**SECTION 3: Composition/information on ingredients****3.2. Mixtures****Chemical characterization**

Aqueous solution

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**Hazardous components**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
5949-29-1	Citric acid, monohydrate			< 5 %
	201-069-1		01-2119457026-42	
	Eye Irrit. 2; 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 and wash contaminated clothing before re-use.

If you feel unwell, seek medical advice.

**After inhalation**

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

In the event of symptoms refer for medical treatment.

**After contact with skin**

Consult a doctor if skin irritation persists.

**After contact with eyes**

Rinse thoroughly with plenty of water, also under the eyelids.

If eye irritation persists, consult a specialist.

**After ingestion**

Rinse out mouth and give plenty of water to drink.

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**

Contact with eyes may cause 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.

**Unsuitable extinguishing media**

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.

**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**

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**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.

**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.  
When using do not eat, drink or smoke.  
Avoid contact with eyes.

**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 only in original container.

**Further information on storage conditions**

Keep away from food, drink and animal feeding stuffs.

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

Maintenance solution for urethral catheters

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

CAS No	Substance	
	Environmental compartment	Value
5949-29-1	Citric acid, monohydrate	
Freshwater		0,44 mg/l
Marine water		0,044 mg/l
Freshwater sediment		7,52 mg/kg
Marine sediment		0,752 mg/kg
Soil		29,2 mg/kg

**Additional advice on limit values**

This product does not contain any substances for which a Workplace Exposure Limit has been set in concentrations above the limits.

**8.2. Exposure controls****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.  
When using do not eat, drink or smoke.

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Avoid contact with the eyes.  
 Remove and wash contaminated clothing before re-use.  
 No special protective equipment required.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state:	Liquid
Colour:	Colourless
Odour:	Odourless
pH-Value (at 20 °C):	3,8 - 4,2

**Changes in the physical state**

Melting point:	n.d.
Initial boiling point and boiling range:	n.d.
Sublimation point:	n.a.
Softening point:	n.d.
Flash point:	n.a.
Sustaining combustion:	Not sustaining combustion

**Flammability**

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

**Explosive properties**

The product is not explosive.

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

**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):	approx. 1,0 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:	0 %
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Solvent content:	0 %
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**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**

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**

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

No toxicological data available.

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
5949-29-1	Citric acid, monohydrate				
	oral	LD50 mg/kg	5400	mouse	
	dermal	LD50 mg/kg	> 2000	Rat	

**Irritation and corrosivity**

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

**Sensitising effects**

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

Not classified.

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

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

**STOT-single exposure**

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

**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**

Contact with eyes may cause irritation.

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

Ecological data are not available.

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CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
5949-29-1	Citric acid, monohydrate					
	Acute fish toxicity	LC50 440 - 706 mg/l	96 h	Fish		
	Acute crustacea toxicity	EC50 1535 mg/l	48 h	Daphnia magna		

**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
5949-29-1	Citric acid, monohydrate	~ -1,72

**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 flush into surface water or sanitary sewer system.

**SECTION 13: Disposal considerations****13.1. Waste treatment methods****Disposal recommendations**

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

**List of Wastes Code - 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)**

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<b>14.1. UN number:</b>	No dangerous good in sense of this transport regulation.
<b>14.2. UN proper shipping name:</b>	No dangerous good in sense of this transport regulation.
<b>14.3. Transport hazard class(es):</b>	No dangerous good in sense of this transport regulation.
<b>14.4. Packing group:</b>	No dangerous good in sense of this transport regulation.

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

<b>14.1. UN number:</b>	No dangerous good in sense of this transport regulation.
<b>14.2. UN proper shipping name:</b>	No dangerous good in sense of this transport regulation.
<b>14.3. Transport hazard class(es):</b>	No dangerous good in sense of this transport regulation.
<b>14.4. Packing group:</b>	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

2004/42/EC (VOC): 0 %

#### National regulatory information

### 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 intérieur  
 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)

H319 Causes serious eye irritation.  
 EUH210 Safety data sheet available on request.

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### 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.)*