

Uro-Tainer 0,02% Polyhexanide



Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 12/5/2012 Revision date: 3/20/2023 Supersedes: 6/25/2020 Version: 2.1
SDS No: 00056-0273

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

1.1. Product identifier

Product form : Mixture
Product name : Uro-Tainer 0,02% Polyhexanide
UFI : MVHQ-406E-200D-CTSA
Type of product : Medical devices

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Irrigation solution / Maintenance solution for urethral and suprapubic catheters

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

B. Braun Medical AG
Seesatz 17
CH-6204 Sempach
Switzerland
T +41 (0) 58 / 258 50 00
info.bbmch@bbraun.com

Supplier

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen – Deutschland
Zentrale Service-Bereich / Logistik und Supply Chain
T +49 (0) 5661 / 71-4422
logistics.service@bbraun.com

E-mail address of competent person responsible for the SDS: sds@gbk-ingelheim.de

1.4. Emergency telephone number

Emergency number : INTERNATIONAL: +49 - (0) 6132 - 84463, GBK GmbH (24h - 7d/w - 365d/a)
In England and Northern Ireland: NHS 111

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Extra phrases : 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

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

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SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Chemical characterization : Aqueous solution

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: 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. Take off immediately all contaminated clothing.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. In the event of symptoms refer for medical treatment.
First-aid measures after skin contact	: Get medical advice if skin irritation persists.
First-aid measures after eye contact	: Wash immediately with plenty water (during 20 minutes), also under eyelids. Consult a medical specialist if eye irritation persists.
First-aid measures after ingestion	: Do not induce vomiting. Drink plenty of water. Call a physician immediately.

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

No additional information available

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Alcohol resistant foam. Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: high volume water jet. Do not use a solid water stream as it may scatter and spread fire.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Product itself does not burn.
Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: Irritant/corrosive, flammable as well as toxic distillation gases (carbonization gases).

5.3. Advice for firefighters

Precautionary measures fire	: Cool endangered containers with water spray jet.
Firefighting instructions	: Fight fire from safe distance and protected location.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information	: 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

6.1.1. For non-emergency personnel

Emergency procedures	: Ventilate spillage area.
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6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Do not discharge into the drains/surface waters/groundwater.

6.3. Methods and material for containment and cleaning up

For containment : Dike and contain spill.
Methods for cleaning up : Take up liquid spill into absorbent material.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

Refer to protective measures listed in sections 7 and 8. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.
Hygiene measures : Wash contaminated clothing before reuse. Always wash hands after handling the product.
Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep only in original container.
Information on mixed storage : Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

See Section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

Monitoring methods	
Monitoring methods	A specific exposure sampling method is not available.
Biological monitoring methods	A specific exposure sampling method is not available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

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8.2.2. Personal protection equipment

Personal protective equipment:

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.

8.2.2.1. Eye and face protection

Eye protection:

Eyewash bottle with clean water (EN 15154)

Eye protection			
Type	Field of application	Characteristics	Standard
Protective goggles (EN 166)	Liquid splashes may occur		EN 166

8.2.2.2. Skin protection

Hand protection:

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

Hand protection					
Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Chemically resistant protective gloves	Butyl rubber, Natural rubber	6 (> 480 minutes)	0,7		EN ISO 374

8.2.2.3. Respiratory protection

Respiratory protection:

No personal breathing protective equipment is normally required

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Other information:

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Colourless.
Appearance	: Liquid.
Odour	: Odourless.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability (solid, gas)	: Non flammable.
Explosive properties	: Product is not explosive.
Oxidising properties	: Not oxidising.
Lower explosive limit (LEL)	: Not available
Upper explosive limit (UEL)	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available

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Decomposition temperature	: Not available
pH	: 4 – 7 at 20 °C
Viscosity, kinematic	: Not available
Solubility	: Water: Miscible
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: ≈ 1 g/cm ³ at 20 °C
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

VOC content	: 0 %
Solvent content	: 0 %
Solvent separation test (%)	: 0

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 dangerous 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 hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 4 – 7 at 20 °C
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 4 – 7 at 20 °C
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)

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STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties	: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %
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11.2.2. Other information

Potential adverse human health effects and symptoms	: High concentration of vapours may induce: headache, nausea, dizziness
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SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Based on available data, the classification criteria are not met)

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties	: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.
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12.7. Other adverse effects

Additional information	: Ecological injuries are not known or expected under normal use. When low concentrations are discharged correctly into adapted biological sewage treatment plants, interference with the degradation activity of activated sludge is not likely. Do not flush into surface water or sewer system
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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
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Product/Packaging disposal recommendations : Empty containers should be taken for recycling, recovery or waste in accordance with local regulation.
European List of Waste (LoW) code : 07 06 99 - wastes not otherwise specified

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
No dangerous goods as defined by the transport regulations				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

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REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

VOC Directive (2004/42)

VOC content : 0 %

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

All chapters have been modified since the previous version.

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
ATE	Acute Toxicity Estimate
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
DOT	Department of Transport
TDG	Transportation of Dangerous Goods
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
IARC	International Agency for Research on Cancer
vPvB	Very Persistent and Very Bioaccumulative
PBT	Persistent Bioaccumulative Toxic

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Abbreviations and acronyms:	
PNEC	Predicted No-Effect Concentration
IBC-Code	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
MARPOL 73/78	MARPOL 73/78: International Convention for the Prevention of Pollution From Ships
ADG	Transport of Australian Dangerous Goods
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
ED	Endocrine disrupting properties

Other information

: Data of sections 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.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should therefore not be construed as guaranteeing any specific property of the product.