

URO-TAINER PHMB (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 PHMB (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 : Maintenance solution for urethral 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)

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 %

URO-TAINER PHMB (0.02% Polyhexanide)

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0273

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. |
|----------------------|----------------------------|

URO-TAINER PHMB (0.02% Polyhexanide)

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0273

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.

URO-TAINER PHMB (0.02% Polyhexanide)

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0273

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. |
| Explosive limits | : Not available |
| Lower explosive limit (LEL) | : Not available |
| Upper explosive limit (UEL) | : Not available |
| Flash point | : Not available |

URO-TAINER PHMB (0.02% Polyhexanide)

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0273

| | |
|---|----------------------------------|
| Auto-ignition temperature | : Not available |
| 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) |

URO-TAINER PHMB (0.02% Polyhexanide)

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0273

| | |
|------------------------|---|
| Reproductive toxicity | : Not classified (Based on available data, the classification criteria are not met) |
| 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 % |
|--|--|

11.2.2. Other information

| | |
|---|---|
| Potential adverse human health effects and symptoms | : High concentration of vapours may induce: headache, nausea, dizziness |
|---|---|

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 %. |
|--|---|

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 |
|------------------------|---|

URO-TAINER PHMB (0.02% Polyhexanide)

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0273

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
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 | | | | |
| 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

URO-TAINER PHMB (0.02% Polyhexanide)

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0273

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)

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 |

URO-TAINER PHMB (0.02% Polyhexanide)

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0273

| Abbreviations and acronyms: | |
|------------------------------------|---|
| 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 |
| 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 |

URO-TAINER PHMB (0.02% Polyhexanide)

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
SDS No: 00056-0273

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.