

Uro-Tainer NaCl 0,9% B. Braun / Uro-Tainer M NaCl 0,9% B. Braun



Safety Data Sheet

according to UK REACH Regulation

Issue date: 05/12/2012

Revision date: 20/03/2023

Supersedes: 25/06/2020

Version: 2.1

SDS No: 00056-0276

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

1.1. Product identifier

Product form : Mixture
Product name : Uro-Tainer NaCl 0,9% B. Braun / Uro-Tainer M NaCl 0,9% B. Braun

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

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

Supplier

B. Braun Medical Ltd.
Thornccliffe Park Estate, Brookdale Road
Sheffield S35 2PW, UK - Medical Information Department
T +44 (0)114 225 9000
medinfo.bbmuk@bbraun.com

1.4. Emergency telephone number

Emergency 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

Classification according to GB CLP Regulation

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 GB CLP Regulation

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

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

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3.2. Mixtures

Comments : 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. Remove and wash contaminated clothing before re-use. If you feel unwell, seek medical advice.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact : Wash skin with plenty of water.

First-aid measures after eye contact : Rinse eyes with water as a precaution.

First-aid measures after ingestion : Rinse mouth. Never give anything by mouth to an unconscious person. Call a poison center or a doctor if you feel unwell.

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 : Water spray. Dry powder. Foam. Carbon dioxide.

Unsuitable extinguishing media : 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.

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

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.

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.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.

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Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

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 : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

See Section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

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.

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Colour : colourless to yellowish.
Odour : Odourless.
Odour threshold : No data available
pH : 4 – 7 (20°C)
Relative evaporation rate (butylacetate=1) : No data available
Melting point : No data available
Freezing point : No data available
Boiling point : No data available
Flash point : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Flammability (solid, gas) : Non flammable.

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Vapour pressure	: No data available
Relative vapour density at 20°C	: No data available
Relative density	: No data available
Density	: ≈ 1 g/cm ³ (20°C)
Solubility	: Miscible.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: Product is not explosive.
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

VOC content	: 0 %
Solvent content	: 0%

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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 (20°C)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 4 – 7 (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)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)

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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)

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

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This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Other adverse effects

No additional information available

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 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.
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				
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

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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. Transport in bulk according to Annex II of Marpol and the IBC Code

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

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

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

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

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

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

VOC content : 0 %

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15.1.2. National regulations

United Kingdom

British National Regulations

- Statutory Instrument 2019 No. 758 - The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019
- Statutory Instrument 2019 No. 858 - The REACH etc. (Amendment etc.) (EU Exit) (No. 2) Regulations 2019
- Statutory Instrument 2019 No. 1144 - The REACH etc. (Amendment etc.) (EU Exit) (No. 3) Regulations 2019
- Statutory Instrument 2020 No. 1577 - The REACH etc. (Amendment etc.) (EU Exit) Regulations 2020
- Statutory Instrument 2021 No. 904 - The REACH etc. (Amendment) Regulations 2021

- Statutory Instrument 2019 No. 720 – The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019
- Statutory Instrument 2020 No. 1567 – The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU exit) Regulations 2020
- Statutory Instrument 2022 No. 1037 – The Chemicals (Health and Safety) Trade and Miscellaneous Amendments Regulations 2022.

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
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level

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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
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
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
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties
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
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

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.