

Safety Data Sheet according to Regulation (EC) No 1907/2006

B. Braun Melsungen AG

Revision date: 27.02.2015

Revision No: 1,1

Prontosan Wound Irrigation Solution

00056-0220

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

1.1. Product identifier

Prontosan Wound Irrigation Solution

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

Use of the substance/mixture

Wound irrigation solution for cleaning, rinsing and moistening of acute and chronic skin wounds

1.3. Details of the supplier of the safety data sheet

B. Braun Melsungen AG

Carl-Braun-Straße 1

D-34212 Melsungen

B. Braun Medical AG

Seesatz 17

CH-6204 Sempach

Responsible Department

Zentrale Service-Bereiche/Logistik und Supply Chain

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Responsible for the safety data sheet: sds@gbk-ingelheim.de

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

R phrases:

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

Hazard categories:

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

Harmful to aquatic life with long lasting effects.

2.2. Label elements

R phrases

52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

S phrases

61 Avoid release to the environment. Refer to special instructions / Safety data sheets.

Special labelling of certain mixtures

Contains Polyhexamethylene biguanide hydrochloride. May produce an allergic reaction.

Hazard statements

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P273 Avoid release to the environment.

Special labelling of certain mixtures

EUH208 Contains Polyhexamethylene biguanide hydrochloride. May produce an allergic reaction.

Additional advice on labelling

This product is not subject to labeling obligation according to art. 1 (5) g) of directive 1999/45/EG under the form of a medical product because it is used under body contact.

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

Not known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Aqueous solution

Hazardous components

EC No	Chemical name	Quantity
CAS No	Classification according to Directive 67/548/EEC	
Index No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
REACH No		
	Polyhexamethylene biguanide hydrochloride	0,1 - < 0,25 %
27083-27-8	T - Toxic, Xn - Harmful, Xi - Irritant, N - Dangerous for the environment R40-22-48/23-41-43-50-53	
616-207-00-X	Carc. 2, Acute Tox. 4, STOT RE 1, Eye Dam. 1, Skin Sens. 1B, Aquatic Acute 1 (M-Factor = 10), Aquatic Chronic 1 (M-Factor = 10); H351 H302 H372 H318 H317 H400 H410	

Full text of R-, H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

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.

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.

Extinguishing media which must not be used for safety reasons

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

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)

Wound irrigation solution for cleaning, rinsing and moistening of acute and chronic skin wounds

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Protective and hygiene measures

When using do not eat, drink or smoke.

Avoid contact with the eyes.

Remove and wash contaminated clothing before re-use.

Respiratory protection

No special protective equipment required.

Hand protection

No special protective equipment required.

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Eye protection

No special protective equipment required.

Skin protection

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):

approx. 6 - 8

Test method

Changes in the physical state

Flash point: n.a.

Lower explosion limits: n.a.

Upper explosion limits:

Ignition temperature: n.a.

Density (at 20 °C): approx. 1,0 g/cm³

Water solubility:
(at 20 °C) Miscible

9.2. Other information

No data available.

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

No toxicological data available.

Polyhexamethylene biguanide hydrochloride 20%

LD50/oral/rat: > 2000 mg/kg

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CAS No	Chemical name				
	Exposure routes	Method	Dose	Species	h
27083-27-8	Polyhexamethylene biguanide hydrochloride				
	Acute oral toxicity	ATE 500 mg/kg			

Irritation and corrosivity

Skin irritation: Not classified.

Eye irritation: Not classified.

Sensitising effects

Not classified.

Severe effects after repeated or prolonged exposure

STOT - Single exposure: Not classified.

STOT - Repeated exposure: Not classified.

Aspiration hazard: Not classified.

Carcinogenic/mutagenic/toxic effects for reproduction

Carcinogenicity: Not classified. [Animal tests have shown that polyhexanide constitutes no carcinogenic or teratogenic risk to human being.]

Mutagenicity: Not classified.

Reproductive toxicity: Not classified.

Additional information on tests

Classification in compliance with the assessment procedure specified in the Regulation (EC) no 1272/2008.

Empirical data on effects on humans

Contact with eyes may cause irritation.

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

Ecological data are not available.

Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

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****Advice on disposal**

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

Where possible recycling is preferred to disposal.

Waste disposal number of waste from 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

Other applicable information

No hazardous material as defined by the transport regulations.

SECTION 15: Regulatory information

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

EU regulatory information

1999/13/EC (VOC): 0 %

National regulatory information

Water contaminating class (D): 1 - slightly water contaminating

15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other information

Relevant R-phrases (Number and full text)

22	Harmful if swallowed.
40	Limited evidence of a carcinogenic effect.
41	Risk of serious damage to eyes.
43	May cause sensitisation by skin contact.
48/23	Toxic: danger of serious damage to health by prolonged exposure through inhalation.
50	Very toxic to aquatic organisms.
53	May cause long-term adverse effects in the aquatic environment.

Relevant H- and EUH-phrases (Number and full text)

H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H351	Suspected of causing cancer.
H372	Causes damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
EUH208	Contains Polyhexamethylene biguanide hydrochloride. May produce an allergic reaction.

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)

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