

**Prontosan Wound Irrigation Solution**

Revision date: 27.05.2020

Product code: 00056-0220

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

Prontosan Wound Irrigation Solution

UFI: VSAV-J7XG-X00M-M459

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

Wound irrigation solution for cleansing, rinsing and moisturizing of acute and chronic skin wounds

**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**

Hazard categories:  
Hazardous to the aquatic environment: Aquatic Chronic 3  
Hazard Statements:  
Harmful to aquatic life with long lasting effects.

**2.2. Label elements****Regulation (EC) No. 1272/2008****Hazard statements**

H412 Harmful to aquatic life with long lasting effects.

**Precautionary statements**

P273 Avoid release to the environment.  
P501 Dispose of contents/container to an approved waste disposal plant. .

**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) d) of Regulation (EC) no. 1272/2008 under the form of a medical product because it is used under body contact.

**Labelling of packages where the contents do not exceed 125 ml****Hazard statements**

H412

**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.

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

Aqueous solution

**Hazardous components**

CAS No	Chemical name	Quantity		
	EC No	Index No	REACH No	
	GHS Classification			
27083-27-8	Polyhexamethylene biguanide hydrochloride			0,1 - < 0,25 %
	-	616-207-00-X		
	Carc. 2, Acute Tox. 2, Acute Tox. 4, Eye Dam. 1, Skin Sens. 1B, STOT RE 1, Aquatic Acute 1 (M-Factor = 10), Aquatic Chronic 1 (M-Factor = 10); H351 H330 H302 H318 H317 H372 H400 H410			

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.

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).

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**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 cleansing, rinsing and moisturizing of acute and chronic skin wounds

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

Avoid contact with the eyes.

Remove and wash contaminated clothing before re-use.

**Eye/face protection**

No special protective equipment required.

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**Hand protection**

No special protective equipment required.

**Skin protection**

No special protective equipment required.

**Respiratory 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):		6 - 8

**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.
Density (at 20 °C):	approx. 1,0 g/cm <sup>3</sup>	
Bulk density:		n.a.
Water solubility: (at 20 °C)		Miscible

**Solubility in other solvents**

n.d.

Partition coefficient:		n.d.
Viscosity / dynamic:	0,5 - 5 mPa·s	
Viscosity / kinematic:		n.d.
Flow time:		n.d.
Vapour density:		n.d.
Evaporation rate:		n.d.
Solvent separation test:		0 %

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Solvent content:

0 %

**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**

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

No toxicological data available.

Polyhexamethylene biguanide hydrochloride 20%

LD50/oral/rat: &gt; 2000 mg/kg

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
27083-27-8	Polyhexamethylene biguanide hydrochloride				
	oral	ATE 500 mg/kg			
	inhalation vapour	ATE 0,5 mg/l			
	inhalation aerosol	ATE 0,05 mg/l			

**Irritation and corrosivity**

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

**Sensitising effects**

Contains Polyhexamethylene biguanide hydrochloride. May produce an allergic reaction.

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

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

Animal tests have shown that polyhexanide constitutes no carcinogenic or teratogenic risk to human being.

**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**

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**Other observations**

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**

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)****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.

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

- 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.

**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 %
- Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

**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

**Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]**

Classification	Classification procedure
Aquatic Chronic 3; H412	Calculation method

**Relevant H and EUH statements (number and full text)**

- H302 Harmful if swallowed.
- H317 May cause an allergic skin reaction.
- H318 Causes serious eye damage.

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H330	Fatal if inhaled.
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)

For the identified uses, see also A.I.S.E. ([www.aise.eu](http://www.aise.eu)). There you will find further information under the keyword SUMI (safe use mixtures information).

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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.)*