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.
SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization
Aqueous solution

Hazardous components

<table>
<thead>
<tr>
<th>CAS No</th>
<th>Chemical name</th>
<th>Quantity</th>
<th>EC No</th>
<th>Index No</th>
<th>REACH No</th>
<th>GHS Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>27083-27-8</td>
<td>Polyhexamethylene biguanide hydrochloride</td>
<td>0,1 - &lt; 0,25 %</td>
<td>-</td>
<td>616-207-00-X</td>
<td>-</td>
<td>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</td>
</tr>
</tbody>
</table>

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).
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.
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

<table>
<thead>
<tr>
<th>Physical state:</th>
<th>Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour:</td>
<td>Colourless</td>
</tr>
<tr>
<td>Odour:</td>
<td>Odourless</td>
</tr>
<tr>
<td>pH-Value (at 20 °C):</td>
<td>6 - 8</td>
</tr>
</tbody>
</table>

**Changes in the physical state**

<table>
<thead>
<tr>
<th>Melting point:</th>
<th>n.d.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial boiling point and boiling range:</td>
<td>n.d.</td>
</tr>
<tr>
<td>Sublimation point:</td>
<td>n.a.</td>
</tr>
<tr>
<td>Softening point:</td>
<td>n.d.</td>
</tr>
<tr>
<td>Flash point:</td>
<td>n.a.</td>
</tr>
<tr>
<td>Sustaining combustion:</td>
<td>Not sustaining combustion</td>
</tr>
</tbody>
</table>

**Flammability**

<table>
<thead>
<tr>
<th>Solid:</th>
<th>n.a.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gas:</td>
<td>n.a.</td>
</tr>
</tbody>
</table>

**Explosive properties**

The product is not explosive.

<table>
<thead>
<tr>
<th>Lower explosion limits:</th>
<th>n.a.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper explosion limits:</td>
<td>n.a.</td>
</tr>
<tr>
<td>Ignition temperature:</td>
<td>n.a.</td>
</tr>
</tbody>
</table>

**Auto-ignition temperature**

<table>
<thead>
<tr>
<th>Solid:</th>
<th>n.a.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gas:</td>
<td>n.a.</td>
</tr>
</tbody>
</table>

**Decomposition temperature:**

| n.d. |

**Oxidizing properties**

Not oxidising.

<table>
<thead>
<tr>
<th>Vapour pressure:</th>
<th>n.d.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Density (at 20 °C):</td>
<td>approx. 1,0 g/cm³</td>
</tr>
<tr>
<td>Bulk density:</td>
<td>n.a.</td>
</tr>
<tr>
<td>Water solubility:</td>
<td>Miscible</td>
</tr>
<tr>
<td>Water solubility (at 20 °C):</td>
<td>Miscible</td>
</tr>
</tbody>
</table>

**Solubility in other solvents**

| n.d. |

<table>
<thead>
<tr>
<th>Partition coefficient:</th>
<th>n.d.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viscosity / dynamic:</td>
<td>0,5 - 5 mPa·s</td>
</tr>
<tr>
<td>Viscosity / kinematic:</td>
<td>n.d.</td>
</tr>
<tr>
<td>Flow time:</td>
<td>n.d.</td>
</tr>
<tr>
<td>Vapour density:</td>
<td>n.d.</td>
</tr>
<tr>
<td>Evaporation rate:</td>
<td>n.d.</td>
</tr>
<tr>
<td>Solvent separation test:</td>
<td>0 %</td>
</tr>
</tbody>
</table>
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: > 2000 mg/kg

<table>
<thead>
<tr>
<th>CAS No</th>
<th>Chemical name</th>
<th>Exposure route</th>
<th>Dose</th>
<th>Species</th>
<th>Source</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>27083-27-8</td>
<td>Polyhexamethylene biguanide hydrochloride</td>
<td>oral</td>
<td>ATE 500 mg/kg</td>
<td>500 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>inhalation vapour</td>
<td>ATE 0,5 mg/l</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>inhalation aerosol</td>
<td>ATE 0,05 mg/l</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
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.
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
tvPvB = 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]

<table>
<thead>
<tr>
<th>Classification</th>
<th>Classification procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Chronic 3; H412</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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.
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). There you will find further information under the keyword SUMI (safe use mixtures information).

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