

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

B. Braun Melsungen AG

Revision date: 10.06.2009

Revision no.: 1,50

PRONTOSAN Wound Gel

00047-0219

1. Identification of the substance/preparation and of the company/undertaking

Identification of the substance or preparation

PRONTOSAN Wound Gel

Use of the substance/preparation

Wound gel for cleansing, decontamination and moistening of acute and chronic skin wounds

Company/undertaking identification

B. Braun Melsungen AG

Carl-Braun-Straße 1

D-34212 Melsungen

B. Braun Medical AG

Seesatz

CH-6204 Sempach

Responsible Department

Zentrale Service-Bereiche/Logistik und Supply Chain

Telefonnummer: ++49 (0) 5661 / 71-4422

Emergency telephone :++49 (0) 6132 / 84463 (GBK Gefahrgut Buero GmbH, Ingelheim)

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

2. Hazards identification

Explication of special hazards for human health and environment

Repeated contact may cause allergic reactions with very susceptible persons.

3. Composition/information on ingredients

Chemical characterization (Mixture)

Aqueous gel

Hazardous components

EC-No.	CAS-No.	Chemical name	Quantity	Classification
	27083-27-8	Polyhexanide	< = 0,1 %	Xi, N R38-43-50-53

Full text of each relevant R phrase can be found in heading 16.

4. 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.

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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.

5. Fire-fighting measures

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.

Special exposure hazards arising from substance or preparation itself, combustion products, resulting gases

Fire may produce:
Irritant/corrosive, flammable as well as toxic distillation gases (carbonization gases).

Special protective equipment for fire-fighters

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.

6. Accidental release measures

Personal precautions

In case of vapour formation use respirator.
Avoid contact with skin, eyes and clothing.
Ensure adequate ventilation.

Environmental precautions

Do not discharge into the drains/surface waters/groundwater.

Methods for cleaning up/taking up

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder).
Shovel into suitable container for disposal.

7. Handling and storage

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.

Storage

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.

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8. Exposure controls/personal protection**Exposure limit values****Exposure limits (EH40)**

CAS-No.	Chemical name	ml/m ³	mg/m ³	F/ml	Category	Origin
56-81-5	Glycerol, mist	-	10		TWA (8 h)	WEL
	Glycerol, mist	-	-		STEL (15 min)	WEL

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.

No special protective equipment required.

9. Physical and chemical properties**General information**

Physical state Viscous
 Colour Colourless - yellowish
 Odour Odourless

Important health, safety and environmental information

pH-Value (at 20 °C) :	approx. 6 - 8	Test method
Changes in the physical state		
Flash point	n.a.	
Flammability		
Lower explosion limits	n.a.	
Upper explosion limits		
Ignition temperature	n.a.	
Density (at 20 °C) :	approx. 1,0 g/cm ³	
Water solubility :	Miscible	
at (20 °C)		
Viscosity / dynamic :	approx. 2000 mPa·s	
at (20 °C)		

10. Stability and reactivity**Conditions to avoid**

To avoid thermal decomposition, do not overheat.

Hazardous decomposition products

No hazardous decomposition products known.

Additional information

No decomposition if stored and applied as directed.

11. Toxicological information

Acute toxicity

LD50/oral/rat: > 2000 mg/kg (Polyhexanide 20%)

Carcinogenic/mutagenic/toxic effects for reproduction

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

Empirical data on effects on humans

Contact with eyes may cause irritation.

Further information

No toxicological data available.

12. Ecological information

Further information

Do not flush into surface water or sanitary sewer system.

Low hazard to waters.

13. Disposal considerations

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.

14. Transport information

Land transport (ADR/RID)

Inland waterways transport

Marine transport

Air transport

Other applicable information

No hazardous material as defined by the transport regulations.

15. Regulatory information

Labelling

Hazardous components which must be listed on the label

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

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Special labelling for certain preparations

Contains Polyhexanide. May produce an allergic reaction.

National regulatory information

Water contaminating class (D)	1 - slightly water contaminating
1999/13/EC (VOC)	0 %

16. Other information

Full text of R-phrases referred to under sections 2 and 3

- 38 Irritating to skin.
- 43 May cause sensitization by skin contact.
- 50 Very toxic to aquatic organisms.
- 53 May cause long-term adverse effects in the aquatic environment.

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.)