



PRONTOSAN Wound Gel

1. Identification of the substance/preparation and company

1.1 Commercial product name

PRONTOSAN Wound Gel

Use of the substance/preparation

Ready-to-use wound gel for cleaning, moistening and debridement of encrusted, infected and chronic skin wounds.

1.2.1.1 Information manufacturer/supplier

B. Braun Australia Pty Ltd
Contact: Customer Service and Out Patient Market (OPM) Division
Telephone : 1800-251-705 (Australian B. Braun Head Office)

2. Composition/information on ingredients

Chemical characterization : (preparation)

Aqueous gel

Hazardous components

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

EC No. CAS No. Components Quantity Symbols R-phrases

27083-27-8 polyhexanide < = 0,1 % Xi, N R38-43-50-53

200-289-5 56-81-5 glycerol 5 - 10 %

3. Hazards identification

Explication of special hazards for human health and environment

Repeated contact may cause allergic reactions with very susceptible persons.

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.

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 that must not be used for safety reasons

Full water jet

Special exposure hazards arising from the 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 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.

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

7.1 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.

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7.2 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.

Storageclass (VCI): 12

8. Exposure controls/personal protection

8.1 Exposure limit values

Exposure limits (EH40)

Components Exposure limit

CAS No. ml/m³ mg/m³ F/ml Category Origin

Glycerol, mist

56-81-5 - 10 TWA (8 h) OES

- - STEL (15 min) OES

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

No special protective equipment required.

9. Physical and chemical properties

9.1 Appearance

Form: viscous Colour: colourless - yellowish Odour: odourless

9.2 Important health, safety and environmental information

Test method

pH Value 7,0 - 8,5
(at 20 °C)

Changes in the physical state

Flash point: n.a. °C

Ignition temperature: n.a. °C

Lower Explosion limit: n.a. vol. %

Density: 1,0 g/ml approx.
(at 20 °C)

Water solubility: miscible g/l
(at 20 °C)

Further information

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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%)

Carcinogenity, mutagenicity and reproductive toxicity

Animal tests have shown that polyhexanide constitutes no carcinogenic or teratogenic risk to human being. Contact with eyes may cause irritation. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons.

Additional information

No toxicological data available.

12. Ecological information

Additional information

Do not flush into surface water or sanitary sewer system. Slightly water hazardous.

13. Advice on disposal

Dispose

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 product : 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

14.1 Land transport (ADR/RID)

14.2 Inland waterways transport

14.3 Marine transport

14.4 Air transport

14.5 Further Information

Other data

No hazardous material as defined by the transport regulations.

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15. Regulatory information

15.1 Labelling

Hazardous component(s) to be indicated on label

The product is classified as a Medical Device in accordance to the Council Directive 93/42/EEC. National regulations for hazardous substances should be considered.

Special labelling for certain preparations

Contains polyhexanide. May produce an allergic reaction.

15.2 National regulations

Water contaminating class: 1 – slightly water contaminating
1999/13/EC (VOC): 0 %

16. Other information

List of relevant R phrases

- 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.

Other data

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)"