

Prontosan Wound Gel X

Revision date: 29.06.2020

Product code: 00056-0401

Page 1 of 8

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

1.1. Product identifier

Prontosan Wound Gel X

UFI: PX02-FMKA-6102-HQT2

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

Use of the substance/mixture

For cleansing, decolonization and moisturizing of acute/chronic skin wounds and burns

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 substance.

Prontosan Wound Gel X

Revision date: 29.06.2020

Product code: 00056-0401

Page 2 of 8

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

Viscous gel

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.

Never give anything by mouth to an unconscious person.

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).

Prontosan Wound Gel X

Revision date: 29.06.2020

Product code: 00056-0401

Page 3 of 8

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)

For cleansing, decolonization and moisturizing of acute/chronic skin wounds and burns

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.

Prontosan Wound Gel X

Revision date: 29.06.2020

Product code: 00056-0401

Page 4 of 8

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:	Viscous	
Colour:	Colourless - yellowish	
Odour:	Odourless	
pH-Value (at 20 °C):		4 - 9

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.
Vapour pressure:	n.d.

Density (at 20 °C):	approx. 1,0 g/cm ³
Water solubility: (at 20 °C)	Miscible

Solubility in other solvents

n.d.

Partition coefficient:	n.d.
Viscosity / dynamic: (at 25 °C)	10000 - 25000 mPa·s
Viscosity / kinematic:	n.d.
Flow time:	n.d.
Vapour density:	n.d.
Evaporation rate:	n.d.
Solvent separation test:	0 %
Solvent content:	0 %

9.2. Other information

Prontosan Wound Gel X

Revision date: 29.06.2020

Product code: 00056-0401

Page 5 of 8

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.

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
27083-27-8	Polyhexamethylene biguanide hydrochloride				
	oral	LD50 501 mg/kg	Rat (female)		
	dermal	LD50 > 5000 mg/kg	Rat		
	inhalation vapour	ATE 0,5 mg/l			
	inhalation (4 h) aerosol	LC50 0,37 mg/l	Rat		

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.

Prontosan Wound Gel X

Revision date: 29.06.2020

Product code: 00056-0401

Page 6 of 8

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

Ecological data are not available.

Harmful to aquatic life with long lasting effects.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
27083-27-8	Polyhexamethylene biguanide hydrochloride					
	Acute fish toxicity	LC50 mg/l	0,026	96 h	Oncorhynchus mykiss	
	Acute algae toxicity	ErC50 mg/l	0,0191	72 h	Pseudokirchneriella subcapitata	OECD 201
	Acute crustacea toxicity	EC50 mg/l	0,09	48 h	Daphnia magna	OECD 202
	Crustacea toxicity	NOEC mg/l	0,0084	21 d	Daphnia magna	OECD 211

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 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)

Prontosan Wound Gel X

Revision date: 29.06.2020

Product code: 00056-0401

Page 7 of 8

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
 vPvB = Very Persistent and very Bio-accumulative

Prontosan Wound Gel X

Revision date: 29.06.2020

Product code: 00056-0401

Page 8 of 8

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.
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)

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