Safety data sheet
according to 1907/2006/EC, Article 31

Print date: 30.01.2024 revised on: 30.01.2024

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

1.1 Product identifier

Trade name: Prontoman Wound Gel 20ml

1.2 Relevant identified uses of the substance or mixture and uses advised against:
No further relevant information available.
Application of the substance / the mixture:
Wound care, infection protection, medical device

1.3 Details of the supplier providing the safety data sheet
Manufacturer/Supplier:
PRONTOMED GmbH
Am Bahndamm 70
32120 Hiddenhausen / Germany

Phone: (+49) 0 52 21/ 275025-0
Fax: (+49) 0 52 21/ 6 11 98
E-mail: info@prontomed.de
www.prontomed.de

Providing information: PRONTOMED GmbH
1.4 Emergency number: (+49) 0 52 21/ 275025-0 (während der Geschäftszeiten / during business hours)

SECTION 2: Potential hazards

2.1 Classification of the substance or mixture
Classification according to Regulation (EC) No 1272/2008:
The product is not classified according to the CLP Regulation.

2.2 Labelling elements
Labelling according to Regulation (EC) No 1272/2008 not applicable
Hazard pictograms not applicable
Signal word not applicable
Hazard warnings not applicable
2.3 Other hazards
Results of the PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterization: Mixtures
Description: Mixture of the following substances with non-hazardous additions.
Hazardous ingredients:

CAS: 32289-58-0	polyhexamethylene biguanide hydrochloride PHMB	≥0,08-≤0,09%
EINECS: 608-723-9	Eye Dam. 1, H318; Skin Sens. 1B, H317; STOT RE 1, H372; Carc. 2, H351 Acute Tox 4, H302; Acute Tox. 2, H330; Aquatic Acute 1m H400 (M=10); Aquatic Chronic 1, H410 (M=1)	
CAS: 98510-75-9	(carboxymethyl)dimethyl[3-[(1-oxoundecenyl)amino]propyl]ammonium hydroxide	≥0,09-≤0,1%
EINECS: 308-783-3	Eye Dam. 1, H318;	
CAS: 9004-62-0	Cellulose, 2-hydroxyethyl ether	≥2,0-≤2,2%
EINECS: 618-387-5	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	

Additional information:
The wording of the listed hazard statements can be found in section 16.

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SECTION 4: First aid measures:

4.1 Description of first aid measures
General information: No special measures required.
After inhalation: Supply fresh air, consult a doctor if symptoms occur.
After skin contact: In general, the product is not irritating to the skin.
After eye contact: Rinse opened eye for several minutes under running water. Consult a doctor immediately.
After swallowing: Rinse out mouth and drink plenty of water. Consult a doctor immediately.
4.2 Most important symptoms and effects, both acute and delayed:
No further relevant information available.
4.3 Information on immediate medical assistance or specialized treatment:
No further relevant information available.

SECTION 5: Fire-fighting measures

5.1 Extinguishing agents:
Suitable extinguishing agents:
CO2, extinguishing powder or water spray jet. Fight larger fires with a water spray jet or alcohol-resistant foam.
Unsuitable extinguishing agents for safety reasons: Water in a full jet
5.2 Special hazards arising from the substance or mixture:
No further relevant information available.
5.3 Instructions for fire fighting:
Special protective equipment: Wear breathing apparatus. Do not inhale explosion and combustion gases.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Procedure:
Wear protective equipment. Keep unprotected persons away. Ensure adequate ventilation.
6.2 Environmental protection measures:
Do not allow to enter drains/surface water/groundwater.
6.3 Methods and material for containment and cleaning:
Absorb with liquid-binding material (sand, diatomaceous earth, acid binder, universal binder, sawdust).
6.4 Reference to other sections:
See section 7 for information on safe handling.
For information on personal protective equipment, see section 8.
For information on disposal, see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling: No special measures required.
Information about fire and explosion protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities:
Storage:
Requirements for storage rooms and containers: No special requirements.
Storage instructions: Not required.
Further information on storage conditions: None.
Storage class: 10-13
7.3 Specific end uses: No further relevant information available.

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SECTION 8: Exposure controls/personal protective equipment

8.1 Parameters to be monitored:
Components with limit values that require monitoring at the workplace:
The product does not contain any relevant quantities of substances with limit values to be monitored at the workplace.
8.2 Limitation and supervision of exposure:
Suitable technical control equipment: No further details, see section 7.
Individual protective measures, for example personal protective equipment:
General protective and hygiene measures:
The usual precautionary measures for handling chemicals must be observed.
Keep away from food, drink and animal feed.
Remove soiled, soaked clothing immediately.
Wash hands before breaks and at the end of work.
Do not inhale gases/vapours/aerosols.
Hand protection: Protective gloves
Glove material: Nitrile rubber
Recommended material thickness: ≥0.35 mm
The selection of a suitable glove depends not only on the material, but also on other quality features and varies from manufacturer to manufacturer.
Penetration time of the glove material:
The exact breakthrough time must be obtained from the protective glove manufacturer and adhered to.
Eye protection: Tightly sealed safety goggles

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties General information:

Aggregate state:	Hydrogel
Colour:	Clear
Odour:	Characteristic
Odour threshold:	Not determined.
Melting point/freezing point:	Not determined.
Boiling point/boiling range:	101 °C
Flammability:	Not applicable.
Lower and upper explosion limit:	
Bottom:	Not determined.
Upper:	Not determined.
Flash point:	Not applicable.
Decomposition temperature:	Not determined.
pH value at 20 °C:	5,0 -9,5
Viscosity:	
Kinematic viscosity:	Not determined.
Dynamic:	Not determined.
Solubility:	
Water:	Fully miscible.
Partition coefficient n-octanol/water (log value):	
Vapour pressure:	Not determined.
Density and/or relative density:	
Density at 20 °C:	0.99 - 1.03 g/cm³
Relative density:	Not determined.
Vapour density:	Not determined.

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9.2 Other information: No further relevant information available.
Appearance:
Mould: Hydrogel
Important information on health, environmental protection and safety:
Ignition temperature: The product is not self-igniting
Explosive properties: The product is not explosive
Change of state:
Evaporation rate: Not determined.

Information on physical hazard classes:
Explosive substances/mixtures and articles containing explosives:

Explosive:	Not applicable
Flammable gases:	Not applicable
Aerosols:	Not applicable
Gases under pressure:	Not applicable
Flammable liquids:	Not applicable
Self-replacing substances and mixtures:	Not applicable
Pyrophoric liquids:	Not applicable
Pyrophoric solids:	Not applicable
Self-heating substances and mixtures:	Not applicable
Substances and mixtures which, in contact with water, emit flammable gases	Not applicable
Oxidising liquids:	Not applicable
Oxidising solids:	Not applicable
Organic peroxides:	Not applicable
Substances and mixtures corrosive to metals:	Not applicable
Desensitised substances/mixtures and articles containing explosives:	Not applicable

SECTION 10: Stability and reactivity:

10.1 Reactivity: No further relevant information available.
10.2 Chemical stability:
Thermal decomposition / conditions to be avoided:
No decomposition when used as intended.
10.3 Possibility of hazardous reactions: No hazardous reactions known.
10.4 Conditions to avoid: No further relevant information available.
10.5 Incompatible materials: No further relevant information available.
10.6 Hazardous decomposition products: No hazardous decomposition products known.

SECTION 11: Toxicological information

11.1 Information on hazard classes according to Regulation (EC) No 1272/2008:
Acute toxicity Based on available data, the classification criteria are not met.
Skin corrosion/irritation Based on available data, the classification criteria are not met.
Serious eye damage/irritation
Based on available data, the classification criteria are not met.
Sensitization of the respiratory tract/skin
Based on available data, the classification criteria are not met.
Germ cell mutagenicity Based on available data, the classification criteria are not met.

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Carcinogenicity Based on available data, the classification criteria are not met. **Reproductive toxicity Based on available data, the classification criteria** are not met.
Specific target organ toxicity (single exposure)
Based on available data, the classification criteria are not met.
Specific target organ toxicity with repeated exposure
Based on available data, the classification criteria are not met.
Aspiration hazard Based on available data, the classification criteria are not met.
11.2 Information on other hazards:
Endocrine disrupting properties:
None of the ingredients are contained.

SECTION 12: Environmental information

12.1 Toxicity
Aquatic toxicity: No further relevant information available.
12.2 Persistence and degradability: No further relevant information available.
12.3 Bioaccumulative potential: No further relevant information available.
12.4 Mobility in soil: No further relevant information available.
12.5 Results of PBT and vPvB assessment:
PBT: Not applicable.
vPvB: Not applicable.
12.6 Endocrine disrupting properties:
The product does not contain any substances with endocrine disrupting properties.
12.7 Other adverse effects:
Further ecological information:
General information:
Water hazard class 1 (self-classification): slightly hazardous to water
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or the sewage system.

SECTION 13: Disposal instructions

13.1 Waste treatment processes:
European Waste Catalogue:
Dispose of the contents / container in accordance with local / regional / national / international regulations.
Uncleaned packaging:
Recommendation: Dispose of in accordance with official regulations.

SECTION 14: Transport information

14.1 UN number	
ADR, ADN, IMDG, IATA	Not applicable
14.2 UN proper shipping name	
ADR, ADN, IMDG, IATA	Not applicable
14.3Transport hazard classes	
ADR, ADN, IMDG, IATA	Not applicable
Class	
14.4 Packaging group	
ADR, IMDG, IATA	Not applicable
14.5 Environmental hazards:	Not applicable.
14.6 Special precautions for the User	Not applicable.
14.7 Transport in bulk by sea in accordance with IMO instruments:	Not applicable.
UN "Model Regulation":	Not applicable

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SECTION 15: Legislation

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

Directive 2012/18/EU:
Named dangerous substances - Annex I:
None of the ingredients are included.
Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment - Annex II:
None of the ingredients are included.
REGULATION (EU) 2019/1148:
Annex I - RESTRICTED OUTPUTS FOR EXPLOSIVE SUBSTANCES (Upper concentration limit for authorization under Article 5(3)):
None of the ingredients are present.
Annex II - DECLARABLE EXPLOSIVE MATERIALS:
None of the ingredients is included.
Regulation (EC) No 273/2004 on drug precursors:
None of the ingredients are included.
Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug substitutes:
None of the ingredients are included.

National regulations:

Water hazard class: WGK 1 (self-classification): slightly hazardous to water.
15.2 Chemical safety assessment: A chemical safety assessment has not been carried out.

SECTION 16: Other information

The information is based on our current state of knowledge but does not constitute a guarantee of product properties and does not establish a contractual legal relationship.
Relevant phrases:
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H351 Suspected of causing cancer.
H372 Causes damage to organs.
H302 Harmful if swallowed.
H330 Danger to life if inhaled.
H335 May cause respiratory irritation.
H400Very toxic to aquatic life.
H410Very toxic to aquatic life with long lasting effects.
Training instructions:
Instruction on hazards and protective measures based on operating instructions (TRGS 555). The instructions must be given before the start of employment and at least once a year thereafter.

Data sheet issuing area:
Prontomed GmbH
Am Bahndamm 70
D-32120 Hiddenhausen
Phone +49 (0) 5221 2750250
Fax. +49 (0) 5221 61198
Email: kontakt@prontomed.de
www.prontomed.de

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Contact person: Julia Gettmann

Abbreviations and acronyms:
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 4: Harmful if swallowed - Category 4
Acute Tox. 2: Danger to life if inhaled - Category 2
Skin Sens. 1B: May cause an allergic skin reaction - Category 1B
Skin Irrit. 2: Causes skin irritation - Category 2
Eye Dam. 1: Causes serious eye damage - Category 1
Eye Irrit. 2: Causes serious eye irritation - Category 2
Carc. 2: Suspected of causing cancer - Category 2
STOT RE 1: Causes damage to organs through prolonged or repeated exposure - Category 1
STOT SE 3: May cause respiratory irritation - Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - Acute aquatic hazard - Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - Long-term aquatic hazard - Category 1