

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 24.03.2021

Revision: 24.03.2021

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

#### 1.1 Product identifier

**Trade name: Prontomed SoleaDerm Creme 100ml**

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

No further relevant information available.

**Application of the substance / the preparation:** wound care, medical device

#### 1.3 Details of the supplier of the safety data sheet

**Manufacturer/Supplier:**

Prontomed GmbH

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32120 Hiddenhausen

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E-Mail: [info@prontomed.de](mailto:info@prontomed.de)[www.prontomed.de](http://www.prontomed.de)**Further information obtainable from:** Prontomed GmbH**1.4 Emergency telephone number:** (+49) 5221 2750250 (during business hours)

### SECTION 2: Hazards identification

#### 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 Label elements:

**Labelling according to Regulation (EC) No 1272/2008:** Void**Hazard pictograms:** Void**Signal word:** Void**Hazard statements:** Void

#### 2.3 Other hazards:

**Results of PBT and vPvB assessment:****PBT:** Not applicable.**vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

#### 3.2 Chemical characterization: Mixtures

**Description:** Mixture of substances listed below with nonhazardous additions.**Dangerous components:** Void**Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures:

**General information:** No special measures required.**After inhalation:** Supply fresh air; consult doctor in case of complaints.**After skin contact:** Generally, the product does not irritate the skin.**After eye contact:** Rinse opened eye for several minutes under running water.**After swallowing:** Call a doctor immediately.

#### 4.2 Most important symptoms and effects, both acute and delayed:

No further relevant information available.

#### 4.3 Indication of any immediate medical attention and special treatment needed:

No further relevant information available.

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media:

#### Suitable extinguishing agents:

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

**For safety reasons unsuitable extinguishing agents:** Water with full jet

**5.2 Special hazards arising from the substance or mixture:** No further relevant information available.

### 5.3 Advice for firefighters:

**Protective equipment:** Do not inhale explosion gases or combustion gases.

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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures:

Wear protective equipment. Keep unprotected persons away.

Ensure adequate ventilation.

**6.2 Environmental precautions:** Do not allow to enter sewers/ surface or groundwater.

### 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

### 6.4 Reference to other sections:

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

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## 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 to be met by storerooms and receptacles:** No special requirements.

**Information about storage in one common storage facility:** Not required.

**Further information about storage conditions:** None.

**7.3 Specific end use(s):** No further relevant information available.

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## SECTION 8: Exposure controls/personal protection

**Additional information about design of technical facilities:** No further data; see item 7.

### 8.1 Control parameters:

#### Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

### 8.2 Exposure controls:

#### Personal protective equipment:

#### General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Do not inhale gases / fumes / aerosols.

**Protection of hands:** Protective gloves

**Material of gloves:**

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The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

**Penetration time of glove material:**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

**Eye protection:** Goggles recommended during refilling

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties:

**General Information:****Appearance:**

<b>Form:</b>	Creme
<b>Colour:</b>	White
<b>Odour:</b>	scented

**Odour threshold:** Not determined.

**pH-value at 20 °C:** 6.0 - 6.8

**Change in condition:**

<b>Melting point/Melting range:</b>	-3°C
<b>Boiling point/Boiling range:</b>	100 °C

**Flash point:** Not applicable.

**Flammability (solid, gaseous):** Not applicable.

**Ignition temperature:**

**Decomposition temperature:** Not determined.

**Self-igniting:** Product is not selfigniting.

**Danger of explosion:** Product does not present an explosion hazard.

**Explosion limits:**

<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.

**Vapour pressure:** Not determined.

**Density at 20 °C:** 0.98 – 1.10 g/cm<sup>3</sup>

**Relative density:** Not determined.

**Vapour density:** Not determined.

**Evaporation rate:** Not determined.

**Solubility in / Miscibility with water:**

Fully miscible.

**Partition coefficient (n-octanol/water):** Not determined.

**Viscosity:**

<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.

**9.2 Other information:** No further relevant information available.

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### SECTION 10: Stability and reactivity

**10.1 Reactivity:** No further relevant information available.

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**10.2 Chemical stability:****Thermal decomposition / conditions to be avoided:**

No decomposition if used according to specifications.

**10.3 Possibility of hazardous reactions:** No dangerous 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:** Chlor

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**SECTION 11: Toxicological information****11.1 Information on toxicological effects:****Acute toxicity** Based on available data, the classification criteria are not met.**Primary irritant effect:****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.**Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.**CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction):****Germ cell mutagenicity** Based on available data, the classification criteria are not met.**Carcinogenicity** Based on available data, the classification criteria are not met.**Reproductive toxicity** Based on available data, the classification criteria are not met.**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.

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**SECTION 12: Ecological 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.**Additional ecological information:****General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

**12.5 Results of PBT and vPvB assessment:****PBT:** Not applicable.**vPvB:** Not applicable.**12.6 Other adverse effects:** No further relevant information available.

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**SECTION 13: Disposal considerations****13.1 Waste treatment methods:****European waste catalogue:**

Dispose of contents/container in accordance with local/regional/national/international regulations.

**Uncleaned packaging:****Recommendation:** Disposal must be made according to official regulations.

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**SECTION 14: Transport information****14.1 UN-Number:****ADR, ADN, IMDG, IATA** Void**14.2 UN proper shipping name:****ADR, ADN, IMDG, IATA** Void

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**14.3 Transport hazard class(es):****ADR, ADN, IMDG, IATA****Class:** Void**14.4 Packing group:****ADR, IMDG, IATA** Void**14.5 Environmental hazards:** Not applicable.**14.6 Special precautions for user:** Not applicable.**14.7 Transport in bulk according to Annex II of****Marpol and the IBC Code** Not applicable.**UN "Model Regulation":** Void**SECTION 15: Regulatory information****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 is listed.**15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.**SECTION 16: Other information**

The information is based on the current state of our knowledge, but does not constitute a guarantee of product properties and does not establish a contractual legal agreement.

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[www.prontomed.de](http://www.prontomed.de)**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