

# Prontosan Wound Gel X

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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Supersedes: 6/29/2020

Version: 1.1

SDS No: 00056-0401

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

#### 1.1. Product identifier

Product name : Prontosan Wound Gel X  
UFI : PX02-FMKA-6102-HQT2

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

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : For cleansing, decolonization and moisturizing of acute/chronic skin wounds and burns

##### 1.2.2. Uses advised against

No additional information available

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

##### Manufacturer

B. Braun Medical AG  
Seesatz 17  
6204 Sempach  
Switzerland  
T +41 (0) 58 / 258 50 00  
[info.bbmch@bbraun.com](mailto:info.bbmch@bbraun.com)

##### Supplier

B. Braun Melsungen AG  
Carl-Braun-Straße 1  
34212 Melsungen – Deutschland  
Zentrale Service-Bereich / Logistik und Supply Chain  
T +49 (0) 5661 / 71-4422  
[logistics.service@bbraun.com](mailto:logistics.service@bbraun.com)

E-mail address of competent person responsible for the SDS: [sds@gbk-ingelheim.de](mailto:sds@gbk-ingelheim.de)

#### 1.4. Emergency telephone number

Emergency number : INTERNATIONAL: +49 - (0) 6132 - 84463, GBK GmbH (24h - 7d/w - 365d/a)

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazardous to the aquatic environment – Chronic Hazard, Category 3 H412

Full text of H- and EUH-statements: see section 16

##### Adverse physicochemical, human health and environmental effects

Harmful to aquatic life with long lasting effects.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Signal word (CLP) : -  
Hazard statements (CLP) : H412 - Harmful to aquatic life with long lasting effects.  
Precautionary statements (CLP) : P273 - Avoid release to the environment.  
P501 - Dispose of contents and container to approved disposal company or local collection.  
EUH-statements : EUH208 - Contains polyhexamethylene biguanide hydrochloride; PHMB. May produce an allergic reaction.  
Extra phrases : 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.

#### 2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

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The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

Comments : Mixture of the substances listed below with nonhazardous additives

| Name  | Product identifier                                | %   | Classification according to Regulation (EC) No. 1272/2008 [CLP]   |
|---|---|-----|---|
| polyhexamethylene biguanide hydrochloride; PHMB | CAS-No.: 27083-27-8<br>EC Index-No.: 616-207-00-X | 0,1 | Carc. 2, H351<br>Acute Tox. 2 (Inhalation), H330<br>Acute Tox. 4 (Oral), H302<br>STOT RE 1, H372<br>Eye Dam. 1, H318<br>Skin Sens. 1B, H317<br>Aquatic Acute 1, H400 (M=10)<br>Aquatic Chronic 1, H410 (M=10) |

Full text of H- and EUH-statements: see section 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general : 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. Take off immediately all contaminated clothing. Wash contaminated clothing before reuse.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. In the event of symptoms refer for medical treatment.

First-aid measures after skin contact : Get medical advice if skin irritation persists.

First-aid measures after eye contact : Rinse thoroughly and plentifully with water, also under the eyelids. If eye irritation persists, consult a specialist.

First-aid measures after ingestion : Rinse mouth. Drink plenty of water. Do not give an unconscious person anything to drink. Call a physician immediately. Do not induce vomiting without medical advice.

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

Symptoms/effects after skin contact : May cause sensitisation of susceptible persons by skin contact.

Symptoms/effects after eye contact : May cause eye-irritation of susceptible persons.

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

Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media : Product does not burn, fire-extinguishing activities according to surrounding.

Unsuitable extinguishing media : Do not use a solid water stream as it may scatter and spread fire.

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### 5.2. Special hazards arising from the substance or mixture

Fire hazard : Non flammable.  
Explosion hazard : Product is not explosive.  
Hazardous decomposition products in case of fire : Toxic fumes may be released.

### 5.3. Advice for firefighters

Precautionary measures fire : Cool endangered containers with water spray jet.  
Firefighting instructions : Move containers from fire area if it can be done without personal risk. Use water spray or fog for cooling exposed containers.  
Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.  
Other information : 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

General measures : Ensure adequate ventilation. Evacuate unnecessary personnel.

#### 6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid contact with skin, eyes and clothing.

#### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

Emergency procedures : Ventilate area. Stop leak if safe to do so.

### 6.2. Environmental precautions

Avoid release to the environment. Prevent liquid from entering sewers, watercourses, underground or low areas.

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

For containment : Does not require any specific or particular technical measures.

Methods for cleaning up : Take up liquid spill into absorbent material.

Other information : Dispose of materials or solid residues at an authorized site.

### 6.4. Reference to other sections

For further information refer to section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Keep container tightly closed. Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with eyes.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

### 7.3. Specific end use(s)

See Section 1.

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### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### 8.1.1 National occupational exposure and biological limit values

No additional information available

##### 8.1.2. Recommended monitoring procedures

| Monitoring methods            |   |
|-------------------------------|---|
| Monitoring methods            | A specific exposure sampling method is not available. |
| Biological monitoring methods | A specific exposure sampling method is not available  |

##### 8.1.3. Air contaminants formed

No additional information available

##### 8.1.4. DNEL and PNEC

No additional information available

##### 8.1.5. Control banding

No additional information available

#### 8.2. Exposure controls

##### 8.2.1. Appropriate engineering controls

###### Appropriate engineering controls:

Ensure good ventilation of the work station.

##### 8.2.2. Personal protection equipment

###### Personal protective equipment:

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.

###### 8.2.2.1. Eye and face protection

###### Eye protection:

No specific measures are necessary

###### 8.2.2.2. Skin protection

###### Skin and body protection:

No specific measures are necessary

###### Hand protection:

None under normal use

###### Other skin protection

###### Materials for protective clothing:

No specific measures are necessary

###### 8.2.2.3. Respiratory protection

###### Respiratory protection:

No specific measures are necessary

###### 8.2.2.4. Thermal hazards

No additional information available

##### 8.2.3. Environmental exposure controls

###### Environmental exposure controls:

Avoid release to the environment.

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### SECTION 9: Physical and chemical properties

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

|   |                             |
|---|-----------------------------|
| Physical state                                  | : Liquid                    |
| Colour  | : colourless to yellowish   |
| Appearance                                      | : Viscous                   |
| Odour   | : odourless                 |
| Odour threshold                                 | : Not available             |
| Melting point                                   | : Not available             |
| Freezing point                                  | : Not available             |
| Boiling point                                   | : Not available             |
| Flammability                                    | : Non flammable.            |
| Explosive properties                            | : Product is not explosive. |
| Oxidising properties                            | : Not oxidising.            |
| Explosive limits                                | : Not available             |
| Lower explosive limit (LEL)                     | : Not available             |
| Upper explosive limit (UEL)                     | : Not available             |
| Flash point                                     | : Not available             |
| Auto-ignition temperature                       | : Not available             |
| Decomposition temperature                       | : Not available             |
| pH  | : 4 – 9                     |
| Viscosity, kinematic                            | : Not available             |
| Viscosity, dynamic                              | : 10000 – 25000 mPa.s 25°C  |
| Solubility                                      | : Water: Miscible           |
| Partition coefficient n-octanol/water (Log Kow) | : Not available             |
| Vapour pressure                                 | : Not available             |
| Vapour pressure at 50 °C                        | : Not available             |
| Density   | : ≈ 1 g/cm <sup>3</sup>     |
| Relative density                                | : Not available             |
| Relative vapour density at 20 °C                | : Not available             |
| Particle characteristics                        | : Not applicable            |

#### 9.2. Other information

##### 9.2.1. Information with regard to physical hazard classes

Not sustained combustibility : Yes

##### 9.2.2. Other safety characteristics

VOC content : 0 %

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

#### 10.2. Chemical stability

Stable under normal conditions.

#### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

#### 10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

#### 10.5. Incompatible materials

No materials to be especially mentioned.

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### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)  
Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)  
Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

| polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8) |              |
|--|--------------|
| LD50 oral rat  | 501 mg/kg    |
| LD50 dermal rat  | > 5000 mg/kg |
| LC50 Inhalation - Rat (Dust/Mist)                            | 0.37 mg/l/4h |
| ATE CLP (vapours)  | 0.5 mg/l/4h  |

Skin corrosion/irritation : Not classified (Based on available data, the classification criteria are not met)  
pH: 4 – 9  
Serious eye damage/irritation : Not classified (Based on available data, the classification criteria are not met)  
pH: 4 – 9  
Respiratory or skin sensitisation : Not classified (Based on available data, the classification criteria are not met)  
Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)  
Carcinogenicity : Not classified (Based on available data, the classification criteria are not met)  
Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)  
STOT-single exposure : Not classified (Based on available data, the classification criteria are not met)  
STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)

| polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8) |  |
|--|--|
| STOT-repeated exposure                                       | Causes damage to organs (respiratory tract) through prolonged or repeated exposure (inhalation). |

Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

#### 11.2.2. Other information

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general : Harmful to aquatic life with long lasting effects.  
Hazardous to the aquatic environment, short-term (acute) : Based on available data, the classification criteria are not met  
Hazardous to the aquatic environment, long-term (chronic) : Harmful to aquatic life with long lasting effects.

| polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8) |                                      |
|--|--------------------------------------|
| LC50 fish 1  | 0.026 mg/l Oncorhynchus mykiss, 96 h |

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| polyhexamethylene biguanide hydrochloride; PHMB (27083-27-8) |   |
|--|---|
| EC50 Daphnia 1   | 0.09 mg/l Daphnia magna, 48 h, (OECD 202 method)                    |
| ErC50 algae  | 0.0191 mg/l Pseudokirchneriella subcapitata, 72h, (OECD 201 method) |
| NOEC chronic crustacea                                       | 0.0084 mg/l Daphnia magna, 21 d, (OECD 211 method)                  |

### 12.2. Persistence and degradability

| Prontosan Wound Gel X         |                                  |
|-------------------------------|----------------------------------|
| Persistence and degradability | The product has not been tested. |

### 12.3. Bioaccumulative potential

| Prontosan Wound Gel X     |                                  |
|---------------------------|----------------------------------|
| Bioaccumulative potential | The product has not been tested. |

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

| Prontosan Wound Gel X  |  |
|--|--|
| This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII  |  |
| This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII |  |

### 12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

### 12.7. Other adverse effects

Other adverse effects : Slightly hazardous to water  
Additional information : Do not flush into surface water or sewer system

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.  
Product/Packaging disposal recommendations : Empty containers should be taken for recycling, recovery or waste in accordance with local regulation. 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.

European List of Waste (LoW) code : 07 06 99 - wastes not otherwise specified

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

| ADR                                 | IMDG          | IATA          | ADN           | RID           |
|-------------------------------------|---------------|---------------|---------------|---------------|
| <b>14.1. UN number or ID number</b> |               |               |               |               |
| Not regulated                       | Not regulated | Not regulated | Not regulated | Not regulated |

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| ADR                                     | IMDG          | IATA          | ADN           | RID           |
|---|---------------|---------------|---------------|---------------|
| <b>14.2. UN proper shipping name</b>    |               |               |               |               |
| Not regulated                           | Not regulated | Not regulated | Not regulated | Not regulated |
| <b>14.3. Transport hazard class(es)</b> |               |               |               |               |
| Not regulated                           | Not regulated | Not regulated | Not regulated | Not regulated |
| <b>14.4. Packing group</b>              |               |               |               |               |
| Not regulated                           | Not regulated | Not regulated | Not regulated | Not regulated |
| <b>14.5. Environmental hazards</b>      |               |               |               |               |
| Not regulated                           | Not regulated | Not regulated | Not regulated | Not regulated |
| No supplementary information available  |               |               |               |               |

### 14.6. Special precautions for user

#### Overland transport

Not regulated

#### Transport by sea

Not regulated

#### Air transport

Not regulated

#### Inland waterway transport

Not regulated

#### Rail transport

Not regulated

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

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

#### 15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

VOC content : 0 %

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on drug precursors)

#### 15.1.2. National regulations

No additional information available



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### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

### SECTION 16: Other information

#### Indication of changes:

2.3, 6, 7, 9, 11, 12.

| Abbreviations and acronyms: |   |
|-----------------------------|---|
| ADN                         | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| ADR                         | European Agreement concerning the International Carriage of Dangerous Goods by Road             |
| ATE                         | Acute Toxicity Estimate   |
| BCF                         | Bioconcentration factor   |
| BLV                         | Biological limit value  |
| BOD                         | Biochemical oxygen demand (BOD)   |
| COD                         | Chemical oxygen demand (COD)  |
| DMEL                        | Derived Minimal Effect level  |
| DNEL                        | Derived-No Effect Level   |
| EC-No.                      | European Community number   |
| EC50                        | Median effective concentration  |
| EN                          | European Standard   |
| IARC                        | International Agency for Research on Cancer   |
| IATA                        | International Air Transport Association   |
| IMDG                        | International Maritime Dangerous Goods  |
| LC50                        | Median lethal concentration   |
| LD50                        | Median lethal dose  |
| LOAEL                       | Lowest Observed Adverse Effect Level  |
| NOAEC                       | No-Observed Adverse Effect Concentration  |
| NOAEL                       | No-Observed Adverse Effect Level  |
| NOEC                        | No-Observed Effect Concentration  |
| OECD                        | Organisation for Economic Co-operation and Development  |
| OEL                         | Occupational Exposure Limit   |
| PBT                         | Persistent Bioaccumulative Toxic  |
| PNEC                        | Predicted No-Effect Concentration   |
| RID                         | Regulations concerning the International Carriage of Dangerous Goods by Rail                    |
| SDS                         | Safety Data Sheet   |
| STP                         | Sewage treatment plant  |
| ThOD                        | Theoretical oxygen demand (ThOD)  |
| TLM                         | Median Tolerance Limit  |
| VOC                         | Volatile Organic Compounds  |
| CAS-No.                     | Chemical Abstract Service number  |

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| Abbreviations and acronyms: |   |
|-----------------------------|---|
| N.O.S.                      | Not Otherwise Specified   |
| vPvB                        | Very Persistent and Very Bioaccumulative  |
| ED                          | Endocrine disrupting properties   |
| DOT                         | Department of Transport   |
| TDG                         | Transportation of Dangerous Goods   |
| REACH                       | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006   |
| GHS                         | Globally Harmonized System of Classification, Labelling and Packaging of Chemicals                  |
| IBC-Code                    | International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk |
| CLP                         | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008                         |
| MARPOL 73/78                | MARPOL 73/78: International Convention for the Prevention of Pollution From Ships                   |
| ADG                         | Transport of Australian Dangerous Goods   |

Other information : Data of sections 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.

| Full text of H- and EUH-statements: |   |
|-------------------------------------|---|
| Acute Tox. 2 (Inhalation)           | Acute toxicity (inhal.), Category 2   |
| Acute Tox. 4 (Oral)                 | Acute toxicity (oral), Category 4   |
| Aquatic Acute 1                     | Hazardous to the aquatic environment – Acute Hazard, Category 1                             |
| Aquatic Chronic 1                   | Hazardous to the aquatic environment – Chronic Hazard, Category 1                           |
| Aquatic Chronic 3                   | Hazardous to the aquatic environment – Chronic Hazard, Category 3                           |
| Carc. 2                             | Carcinogenicity, Category 2   |
| EUH208                              | Contains polyhexamethylene biguanide hydrochloride; PHMB. May produce an allergic reaction. |
| Eye Dam. 1                          | Serious eye damage/eye irritation, Category 1   |
| 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.  |
| Skin Sens. 1B                       | Skin sensitisation, category 1B   |
| STOT RE 1                           | Specific target organ toxicity – Repeated exposure, Category 1                              |

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|  |      |  |
|--|------|--|
| <b>Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:</b> |      |  |
| Aquatic Chronic 3  | H412 |  |

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should therefore not be construed as guaranteeing any specific property of the product.