

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

### **1.1. Product identifier**

ProntOral Mouth Rinse

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

#### **Use of the substance/mixture**

For oral cavity and pharynx decolonization including MDRO by physical cleansing  
[MDRO: Multi-Drug-Resistant-Organisms]

### **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 Service-Bereiche / Logistik und Supply Chain  
Telephone: +49 (0) 5661 / 71-4422  
E-Mail: logistics.service@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)  
England and Wales: NHS Direct - 0845 4647; Scotland: NHS 24 - 08454 24 24 24

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## **SECTION 2: Hazards identification**

### **2.1. Classification of the substance or mixture according to 1272/2008/EC**

Hazard categories:  
Hazardous to the aquatic environment: Aquatic Chronic 3  
Hazard Statements:  
Harmful to aquatic life with long lasting effects.

### **2.2. Label elements**

#### **Hazard statements**

H412 Harmful to aquatic life with long lasting effects.

#### **Precautionary statements**

P273 Avoid release to the environment.

#### **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.

### **2.3. Other hazards**

Not known.

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## **SECTION 3: Composition/information on ingredients**

### **3.2. Mixtures**

#### **Chemical characterization**

Aqueous solution

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### Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
27083-27-8	Polyhexamethylene biguanide hydrochloride			0,1 - < 0,25 %
		616-207-00-X		
	Carc. 2, Acute Tox. 4, STOT RE 1, Eye Dam. 1, Skin Sens. 1B, Aquatic Acute 1 (M-Factor = 10), Aquatic Chronic 1 (M-Factor = 10); H351 H302 H372 H318 H317 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

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.

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

Contact with eyes may cause irritation.

Repeated or prolonged skin contact may cause allergic reactions with susceptible persons.

### 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).

### 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.

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**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 oral cavity and pharynx decolonization including MDRO by physical cleansing  
[MDRO: Multi-Drug-Resistant-Organisms]

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**SECTION 8: Exposure controls/personal protection**

**8.1. Control parameters**

**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.

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**SECTION 9: Physical and chemical properties**

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

Physical state:	Liquid
Colour:	Colourless - yellowish
Odour:	characteristic

pH-Value (at 20 °C):	approx. 5 - 8
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**Changes in the physical state**

Flash point:	n.a.
Lower explosion limits:	n.a.
Upper explosion limits:	n.a.
Ignition temperature:	n.a.
Density (at 20 °C):	approx. 1,0 g/cm <sup>3</sup>
Water solubility: (at 20 °C)	Miscible

**9.2. Other information**

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No data available.

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## **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.

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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.

No toxicological data available.

Polyhexamethylene biguanide hydrochloride 20%

LD50/oral/rat: > 2000 mg/kg

#### **Irritation and corrosivity**

Based on available data, the classification criteria are not met.

#### **Sensitising effects**

Based on available data, the classification criteria are not met.

#### **STOT-single exposure**

Based on available data, the classification criteria are not met.

#### **Severe effects after repeated or prolonged exposure**

Based on available data, the classification criteria are not met.

#### **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.

#### **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.

Repeated or prolonged skin contact may cause allergic reactions with susceptible persons.

#### **Further information**

No toxicological data available.

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## **SECTION 12: Ecological information**

### **12.1. Toxicity**

Ecological data are not available.

Harmful to aquatic life with long lasting effects.

### **12.2. Persistence and degradability**

No data available.

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**12.3. Bioaccumulative potential**

No data available.

**12.4. Mobility in soil**

No data available.

**12.5. Results of PBT and vPvB assessment**

No data available.

**12.6. Other adverse effects**

Low hazard to waters.

**Further information**

Do not flush into surface water or sanitary sewer system.

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**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

**Advice on disposal**

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 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.

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**SECTION 14: Transport information**

**Land transport (ADR/RID); Marine transport (IMDG); Air transport (ICAO); Inland waterways transport (ADN):**

**14.1. UN number:**

No hazardous material as defined by the transport regulations.

**14.2. UN proper shipping name:**

No hazardous material as defined by the transport regulations.

**14.3. Transport hazard class(es):**

No hazardous material as defined by the transport regulations.

**14.4. Packing group:**

No hazardous material as defined by the transport regulations.

**14.5. Environmental hazards**

No hazardous material as defined by the transport regulations.

**14.6. Special precautions for user**

No hazardous material as defined by the transport regulations.

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

No hazardous material as defined by the transport regulations.

**Air transport (ICAO)**

**14.1. UN number:**

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**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 %

**National regulatory information**

Water contaminating class (D): 1 - slightly water contaminating

**15.2. Chemical safety assessment**

For this substance a chemical safety assessment has not been carried out.

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## 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 intérieure

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

LD = Lethal dose

LC = Lethal concentration

EC = Effect concentration

IC = Median immobilisation concentration or median inhibitory concentration

### 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.

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)

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