

# MEDICAL DEVICE

## SAFETY DATA SHEET

Product name:  
PoloDent Ultrasonic Cleaner

POLO MB OISTERWIJK BV

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

#### 1.1 Product identifier

Product name: PoloDent® Ultrasonic Cleaner  
Article number: 83 00 07

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

Use of substance/mixture: [PC8] Biocidal products (e.g. Disinfectants, pest control);

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

Company: Polo MB Oisterwijk BV  
Laarakkerweg 5  
5061 JR Oisterwijk  
The Netherlands  
www.polodent.com

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

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

STOT SE 3: H336  
Eye Irrit. 2: H319  
Flam. Liq. 3: H226  
Skin Irrit. 2: H315

Most important adverse effects: Flammable liquid and vapour. Causes skin irritation. Causes serious eye irritation. May cause drowsiness or dizziness.

#### 2.2 Label elements

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

Label elements: UFI: 0610-E0JV-7002-VXNE

##### Hazard pictograms:



GHS02: Flame  
GHS07: Exclamation mark

Signal word: Warning

Hazard statements:  
H226 - Flammable liquid and vapour.  
H315 - Causes skin irritation.  
H319 - Causes serious eye irritation.  
H336 - May cause drowsiness or dizziness.

Precautionary statements:  
P403+P233 - Store in a well-ventilated place. Keep container tightly closed.  
P235 - Keep cool.  
P302+350 - IF ON SKIN: Gently wash with plenty of soap and water.  
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P305+351+338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection.  
P261 - Avoid breathing dust/fumes/gas/mist/vapours/spray.  
P304+340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

#### 2.3 Other hazards

Other hazards: In use, may form flammable / explosive vapour-air mixture.

PBT: This product is not identified as a PBT/vPvB substance.

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### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

##### Hazardous ingredients:

Chemical Name	EINECS No.	CAS No.	PBT / WEL	Percent	Classification (CLP)
PROPAN-2-OL	200-661-7	67-63-0	-	10-30%	Flam. Liq. 2: H225; Eye Irrit. 2: H319; STOT SE 3: H336
DIDECYL DIMETHYL AMMONIUM CHLORIDE	230-525-2	7173-51-5	-	< 1%	Skin Corr. 1B: H314; Aquatic Acute 1: H400; Eye Dam. 1: H318; Aquatic Chronic 2: H411; Acute Tox. 4: H302
SODIUM N-LAUROYLSARCOSINATE	205-281-5	137-16-6	-	< 1%	Acute Tox. 1: H330; Eye Dam. 1: H318; Skin Irrit. 2: H315

##### Non-classificated ingredients:

Chemical Name	EINECS No.	CAS No.	PBT / WEL	Percent	Classification (CLP)
SUBTILISIN	232-752-2	9014-01-1	-	< 1%	STOT SE 3: H335; Skin Irrit. 2: H315; Eye Dam. 1: H318; Resp. Sens. 1: H334;

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

<b>Skin contact:</b>	Remove all contaminated clothes and footwear immediately unless stuck to skin. Wash immediately with plenty of soap and water.
<b>Eye contact:</b>	Bathe the eye with running water for 15 minutes. Consult a doctor.
<b>Ingestion:</b>	Wash out mouth with water. Consult a doctor.
<b>Inhalation:</b>	Remove casualty from exposure ensuring one's own safety whilst doing so. Consult a doctor.

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

<b>Skin contact:</b>	There may be irritation and redness at the site of contact.
<b>Eye contact:</b>	There may be irritation and redness. The eyes may water profusely.
<b>Ingestion:</b>	There may be soreness and redness of the mouth and throat.
<b>Inhalation:</b>	There may be irritation of the throat with a feeling of tightness in the chest. Exposure may cause coughing or wheezing.
<b>Delayed / immediate effects:</b>	Immediate effects can be expected after short-term exposure.

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

<b>Immediate / special treatment:</b>	Show this safety data sheet to the doctor in attendance.
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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

**Extinguishing media:** Alcohol resistant foam. Water spray. Carbon dioxide. Dry chemical powder. Use water spray to cool containers.

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

**Exposure hazards:** Flammable. In combustion emits toxic fumes. Forms explosive air-vapour mixture.

### 5.3 Advice for firefighters

**Advice for firefighters:** Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes.

## SECTION 6: Accidental release measures

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

**Personal precautions:** Refer to section 8 of SDS for personal protection details. If outside do not approach from downwind. If outside keep bystanders upwind and away from danger point. Mark out the contaminated area with signs and prevent access to unauthorised personnel. Turn leaking containers leak-side up to prevent the escape of liquid. Eliminate all sources of ignition.

### 6.2 Environmental precautions

**Environmental precautions:** Do not discharge into drains or rivers. Contain the spillage using bunding.

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

**Clean-up procedures:** Absorb into dry earth or sand. Transfer to a closable, labelled salvage container for disposal by an appropriate method. Do not use equipment in clean-up procedure which may produce sparks.

### 6.4 Reference to other sections

**Reference to other sections:** Refer to section 8 of SDS. Refer to section 13 of SDS.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

**Handling requirements:** Avoid direct contact with the substance. Ensure there is sufficient ventilation of the area. Do not handle in a confined space. Avoid the formation or spread of mists in the air. Smoking is forbidden. Use non-sparking tools.

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

**Storage conditions:** Store in a cool, well ventilated area. Keep container tightly closed. Keep away from sources of ignition. Prevent the build up of electrostatic charge in the immediate area. Ensure lighting and electrical equipment are not a source of ignition.

### 7.3 Specific end use(s)

**Specific end use(s):** PC8: Biocidal products (e.g. Disinfectants, pest control).

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## SECTION 8: Exposure controls / personal protection

### 8.1 Control parameters

**Hazardous ingredients:** PROPAN-2-OL

**Workplace exposure limits:**

Chemical Name	State	8 hour TWA	15 min STEL
PROPAN-2-OL	UK	999 mg/m <sup>3</sup>	1250 mg/m <sup>3</sup>

**Respirable dust:**

Chemical Name	State	8 hour TWA	15 min STEL
PROPAN-2-OL	UK	-	-

### DNEL / PNEC Values

**Hazardous ingredients:** SODIUM N-LAUROYLSARCOSINATE

Type	Exposure	Value	Population	Effect
DNEL	Oral	0.15 mg/kg	General Population	Systemic
DNEL	Inhalation	5 mg/m <sup>3</sup>	General Population	Systemic
PNEC	Fresh water	29.7 µg/L	-	-
PNEC	Marine water	3 µg/L	-	-

### 8.2 Exposure controls

**Engineering measures:** Ensure there is sufficient ventilation of the area.

**Respiratory protection:** Respiratory protection not required.

**Hand protection:** Protective gloves.

**Eye protection:** Safety glasses.

**Skin protection:** Protective clothing.

**Environmental:** No special requirement.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

**State:** Liquid

**Colour:** Yellow

**Odour:** Alcoholic

**Flash point (°C):** 27°C

**pH:** 5.0-6.0

### 9.2 Other information

**Other information:** No data available.

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

**Reactivity:** Stable under recommended transport or storage conditions.

### 10.2 Chemical stability

**Chemical stability:** Stable under normal conditions. Stable at room temperature.

### 10.3 Possibility of hazardous reactions

**Hazardous reactions:** Hazardous reactions will not occur under normal transport or storage conditions. Decomposition may occur on exposure to conditions or materials listed below.

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### SECTION 10 (continued): Stability and reactivity

#### 10.4 Conditions to avoid

**Conditions to avoid:** Heat. Sources of ignition.

#### 10.5 Incompatible materials

**Materials to avoid:** Aluminium. Copper.

#### 10.6 Hazardous decomposition products

**Haz. decomp. products:** In combustion emits toxic fumes.

### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

##### Hazardous ingredients:

##### PROPAN-2-OL

IVN	RAT	LD50	1088 mg/kg
ORL	MUS	LD50	3600 mg/kg
ORL	RAT	LD50	5045 mg/kg
SCU	MUS	LDLO	6 mg/kg

##### DIDECYLDIMETHYLAMMONIUM CHLORIDE

DERMAL	RBT	LD50	3342 mg/kg
ORAL	RAT	LD50	238 mg/kg

##### SODIUM N-LAUROYLSARCOSINATE

DUST/MIST	RAT	LC50/4 h	0.05-0.5 mg/l
ORAL	RAT	LD50	>5000 mg/kg

##### Non-classified ingredients:

##### SUBTILISIN

ORAL	RAT	LD50	3700 mg/kg
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##### Relevant hazards for product:

Hazard	Route	Basis
Skin corrosion/irritation	DRM	Hazardous: calculated
Serious eye damage/irritation	OPT	Hazardous: calculated
STOT-single exposure	-	Hazardous: calculated

#### Symptoms / routes of exposure:

**Skin contact:** There may be irritation and redness at the site of contact.

**Eye contact:** There may be irritation and redness. The eyes may water profusely.

**Ingestion:** There may be soreness and redness of the mouth and throat.

**Inhalation:** There may be irritation of the throat with a feeling of tightness in the chest. Exposure may cause coughing or wheezing.

**Delayed / immediate effects:** Immediate effects can be expected after short-term exposure.

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**SECTION 12:  
Ecological information****12.1 Toxicity****Hazardous ingredients:****DIDECYLDIMETHYLAMMONIUM CHLORIDE**

Daphnia magna	LC50/48 h	0.062 mg/l
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**SODIUM N-LAUROYLSARCOSINATE**

Daphnia magna	EC50/48 h	29.7 mg/l
ZEBRAFISH (Brachydanio rerio)	LC50/96 h	107 mg/l

**12.2 Persistence and degradability**

**Persistence and degradability:** Biodegradable.

**12.3 Bioaccumulative potential**

**Bioaccumulative potential:** No bioaccumulation potential.

**12.4 Mobility in soil**

**Mobility:** Readily absorbed into soil.

**12.5 Results of PBT and vPvB assessment**

**PBT identification:** This product is not identified as a PBT/vPvB substance.

**12.6 Other adverse effects**

**Other adverse effects:** Negligible ecotoxicity.

**SECTION 13:  
Disposal considerations****13.1 Waste treatment methods**

**Disposal operations:** Transfer to a suitable container and arrange for collection by specialised disposal company.

**NB:** The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

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### SECTION 14: Transport information

#### 14.1 UN number

UN number: UN1993

#### 14.2 UN proper shipping name

Shipping name: FLAMMABLE LIQUID, N.O.S.  
(PROPAN-2-OL)

#### 14.3 Transport hazard class(es)

Transport class: 3

#### 14.4 Packing group

Packing group: III

#### 14.5 Environmental hazards

Environmentally hazardous: No

Marine pollutant: No

#### 14.6 Special precautions for user

Special precautions: No special precautions.

Tunnel code: D/E

Transport category: 3

### SECTION 15: Regulatory information

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

Specific regulations: Not applicable.

#### 15.2 Chemical safety assessment

Chemical safety assessment: A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

### SECTION 16: Other information

#### 16.1 Other information

Other information: This safety data sheet is prepared in accordance with Commission Regulation (EU) No 2015/830.

Phrases used in s.2 and s.3:

- H225 - Highly flammable liquid and vapour.
- H226 - Flammable liquid and vapour.
- H302 - Harmful if swallowed.
- H314 - Causes severe skin burns and eye damage.
- H315 - Causes skin irritation.
- H318 - Causes serious eye damage.
- H319 - Causes serious eye irritation.
- H330 - Fatal if inhaled.
- H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H335 - May cause respiratory irritation.
- H336 - May cause drowsiness or dizziness.
- H400 - Very toxic to aquatic life.
- H411 - Toxic to aquatic life with long lasting effects.

Legal disclaimer: The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication however no guarantee is made to its accuracy, reliability or completeness. This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process. It is the user's responsibility to satisfy him/herself as to the suitability of such information for his /her own particular use.