

# SAFETY DATA SHEET according to regulation (EC) No.1907/2006

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2

# dentisan®

INNOVATION, EDUCATION, COMPLIANCE

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

### 1.1. Product Identifier

Product code: DS025

Name: Bioclear

UFI FFT4-H0CN-300J-Q2SK

### 1.2. Product Uses

Disinfection for Dental Unit Water Lines by immersion (off-line, in-situ soaking treatment) for non-invasive medical devices.

### 1.3. Supplier

Dentisan  
Unit 3, St. Modwen Park,  
Andressey Way,  
Derby  
DE21 6YH  
Phone: 01332 268526  
Web: [www.dentisan.co.uk](http://www.dentisan.co.uk)  
Fax: 01332 295941  
Email: [info.dentisan@getinge.com](mailto:info.dentisan@getinge.com)

### 1.4. Emergency telephone number

Emergency Telephone Number: 01332 292402

## SECTION 2: Hazards identification (Undiluted product)

### 2.1. Classification of the mixture

According to 1272/2008

Health Hazards: Eye Irrit. 2

Physical Hazards: Not Classified

Environmental Hazards: Aquatic Chronic 2

### 2.2. Label elements

Warning

According to 1272/2008



H319 Causes serious eye irritation

EUH208 Contains PHMB. May produce an allergic reaction

H411 Toxic to aquatic life with long lasting effects

P264 Wash hands thoroughly after handling.

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 If eye irritation persists: Get medical advice/attention.

P405 Store locked up.

### 2.3. Other hazards

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

<b>Material</b>	<b>CAS number</b>	<b>Level</b>	<b>EC No (where available)</b>	<b>EU REACH reg. no. (where available)</b>	<b>Hazards (see section 16)</b>
Polyhexamethylene biguanide hydrochloride	32289-58-0	0-1%			Acute Tox. 4, Aquatic Acute 1, Aquatic Chronic 1, Carc. 2, Eye Dam. 1, Skin Sens. 1, STOT RE 1 H351 H302 H372 H318 H400 H410 H317

## **SECTION 4: First aid measures**

### **4.1. Description of first aid measures**

Eye contact: Immediately flush eyes with water, holding eyelids apart, for at least 10 minutes. Seek medical assistance immediately.

Skin contact: Remove contaminated clothing, wash skin with soap and water. Seek medical attention if irritation persists.

Inhalation: If irritation occurs, remove to fresh air, keep warm and at rest, seek medical attention immediately.

Ingestion: Do not induce vomiting. If conscious, give water to drink. Seek medical assistance immediately.

First aider PPE: As required to prevent contact. See section 8.2.

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

Eye hazard: Will cause irritation.

Skin hazard: Not classified as skin irritant. Can produce an allergic reaction in sensitive individuals.

Respiratory hazard: Breathing spray mist may cause irritation.

Other hazards:

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

No special treatment or attention required additional to section 4.2.

## **SECTION 5: Fire fighting measures**

Flammability hazard: Not combustible.

### **5.1. Extinguishing media**

No special requirements. As appropriate for the fire.

### **5.2. Special hazards arising from the mixture**

May cause toxic fumes in a fire.

### **5.3. Advice for firefighters**

No special measures arising from the mixture.

## **SECTION 6: Accidental release measures**

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

Take precautions to avoid contact. Use Personal Protective Equipment as detailed in section 8

Spillage may make floors slippery. Keep the area clear. Observe regulations.

### **6.2. Environmental precautions**

Prevent spills from entering water courses.

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

Small quantities, mop up or use an inert absorbent.

Large quantities, contain and absorb or pump into suitable containers for disposal.

### **6.4. Reference to other sections**

Observe the advice given in sections 8 and 13

## **SECTION 7: Handling and storage**

Shelf life: 24 months in original sealed containers.

### **7.1. Precautions for safe handling**

Do not mix with other products. Observe good industrial hygiene.

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

Store in a cool, dry place protected from frost and away from acids and strong oxidising agents. Store upright in original containers.

### **7.3. Product Uses**

Follow the instructions supplied with the product.

Please refer to product safety datasheet before use. Use only as directed.

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

### **8.1. Control parameters**

Workplace exposure limits

None set in UK EH40

### **8.2. Exposure controls**

These measures are suggested on the basis of general use methods and may not be appropriate to all potential uses of the product. The user is responsible for carrying out a full risk assessment of their specific processes and systems of work.

Eye protection: Wear eye protection appropriate to the process according to BS EN 166.

Hand protection: Wear pvc or latex gloves. Exact choice of glove depends on specific risk assessments.

Body protection: As necessary to prevent contact.

Respiratory protection: Avoid breathing spray mist, wear a protective mask to EN149 if necessary.

Other protection:

Personal protective equipment:



Exact PPE requirements should be determined from a specific risk assessment of the processes being carried out.

Environmental protection: Prevent mixture from entering water courses.

## **SECTION 9: Physical and chemical properties**

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

Physical State: Liquid

Colour: Green

Odour: None

Melting point/ freezing point: N/a

pH (typical): 8 as supplied (typical).

Flammability N/a

Initial boiling point: >100°C.

Flash point: None.

Auto-ignition temp: None.

Viscosity: Free flowing.

Vapour pressure: 17.5mm Hg at 20°C.

Explosive properties: None.

Lower upper explosion limits: N/a

Oxidising properties: None.

Solubility: Miscible with water.

Relative density at 20° C (typical): 1.000

Relative vapour density: No data

### **9.2. Other information**

## **SECTION 10: Stability and reactivity**

- 10.1. Reactivity** Incompatible with strong oxidising agents and acids.
- 10.2. Chemical stability** Stable under recommended storage conditions.
- 10.3. Possibility of hazardous reactions** No hazardous reactions are expected to occur.
- 10.4. Conditions to avoid** Extremes of temperature.
- 10.5. Incompatible materials** Incompatible with strong oxidising agents and acids.
- 10.6. Hazardous decomposition products** May produce toxic fumes in fire.

## **SECTION 11: Toxicological information**

### **11.1. Information on toxicological effects**

- Acute toxicity: Contains an ingredient classified as Acute Tox. 4 (section 3). Mixture is not classified as Acutely Toxic.
- Skin corrosion/ irritation: Based on available data, the classification criteria are not met.
- Serious eye damage/ irritation: Mixture is classified as Eye Irritant 2. See section 2.
- Respiratory or skin sensitisation: Contains PHMB, may cause sensitisation by skin contact.
- Germ cell mutagenicity: Does not contain any ingredients classified as mutagenic.
- Carcinogenicity: Contains an ingredient classified as a Carc 2 (section 3). Mixture is not classified as carcinogenic.
- Reproductive toxicity: Does not contain any ingredients classified as toxic for reproduction.
- STOT single exposure: Does not contain any ingredients classified as STOT SE.
- STOT repeated exposure: Contains an ingredient classified as STOT RE (section 3). Mixture is not classified as STOT RE.
- Aspiration toxicity: Does not contain any ingredients classified as Asp Tox.

### **Routes of exposure/ symptoms**

- Eye contact: Will cause irritation.
- Skin contact: Not classified as skin irritant. Can produce an allergic reaction in sensitive individuals.
- Inhalation: Breathing spray mist may cause irritation.
- Ingestion: Low toxicity, may cause irritation to gastro-intestinal tract.

### **11.2. Information on other hazards** No data.

## **SECTION 12: Ecological information**

- 12.1. Toxicity** This product has microbiocidal properties. Large quantities may affect biological treatment plants.
- 12.2. Persistence and degradability** May affect aquatic organisms due to biocidal activity if released into water courses untreated.
- 12.3. Bioaccumulative potential** Not expected to bioaccumulate
- 12.4. Mobility in soil** This product has high water solubility
- 12.5. Results of PBT and vPvB assessment** Contains no ingredients classified as PBT or vPvB.
- 12.6. Endocrine disrupting properties** No known endocrine disrupting properties.
- 12.7. Other adverse effects** No other adverse effects are anticipated.

## **SECTION 13: Disposal considerations**

### **13.1. Waste treatment methods**

- Process effluent can normally be discharged to foul sewer (subject to consent limits).
- Empty cleaned containers can be recycled where facilities exist or sent for landfill or incineration where permitted.

## **SECTION 14: Transport information**

- 14.1. UN number** 3082
- 14.2. UN proper shipping name** Environmentally hazardous substance, liquid, N.O.S. (PHMB)
- 14.3. Transport hazard class(es)** 9      **14.4. Packing group** 3
- 14.5. Environmental hazards** Product is environmentally hazardous (LQ)
- 14.6. Special precautions for user** No specific precautions.
- 14.7. Maritime transport in bulk according to IMO instruments** Not available for bulk transport.

## **SECTION 15: Regulatory information**

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

Contents according to (EC) regulation No.648/2004 on detergents:

Nonionic surfactants <5%  
Disinfectant

The surfactant(s) contained in this preparation comply with the biodegradability criteria laid down in Regulation (EC) No 648/2004 on detergents.

Data to support this assertion are held at the disposal of the competent authorities of the member states and will be made available to them at their direct request.

**15.2. Chemical safety assessment** A chemical safety assessment has not been carried out.

## **SECTION 16: Other information**

Hazard statements relating to ingredients (see section 3)

H351 Suspected of causing cancer

H372 Causes damage to respiratory system through prolonged or repeated exposure- inhalation

H318 Causes serious eye damage

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long lasting effects

H317 May cause an allergic skin reaction

H302 Harmful if swallowed

Note on Polyhexamethylene biguanide hydrochloride:

The classification of the substance corresponds to the future harmonised classification which shall apply on 01/01/2015 at the latest (5th ATP to the CLP regulation EC No 944/2013 of 2nd Oct 2013).

CAS No 27083-27-8 is also used to describe PHMB and supported within the BPR review programme.

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This product should be stored, handled and used in accordance with good industrial practice and in conformity with legal regulations. The information in this data sheet is based on the present state of our knowledge and is intended to describe products from the point of view of safety requirements and thus should not be construed as guaranteeing specific properties. It is for users to satisfy themselves of the suitability of this product for their own applications.

