

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

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3



SECTION 1: Identification of the substance/mixture and company

1.1. Product Identifier

Product code: F50026

Name: Ultraclean Sonozyme 3

UFI XPX4-A063-300S-4TDE

1.2. Product Uses

A tri-enzymatic detergent for ultrasonic and manual cleaning of medical devices {pH neutral}.

1.3. Supplier

Ultrawave
Eastgate Business Park
Wentloog Avenue,
Cardiff,
CF3 2EY
Phone: +44 (0)29 20 837337
Web: www.ultrawave.co.uk
Fax:
Email: sales@ultrawave.co.uk

1.4. Emergency telephone number

Emergency Telephone Number: +44 (0)29 20 837337

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: Not Classified

2.2. Label elements

Warning

According to 1272/2008



H319 Causes serious eye irritation

EUH208 Contains subtilisins. May produce an allergic reaction

P264 Wash hands thoroughly after handling.

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.

P302 + P352 IF ON SKIN: Wash with plenty of water.

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

P405 Store locked up.

2.3. Other hazards

SECTION 3: Composition/ information on ingredients

Material	CAS number	Level	EC No (where available)	EU REACH reg. no. (where available)	Hazards (see section 16)	
Citric acid	5949-29-1	1-5%	201-069-1	01-2119457026-42	Eye Irrit. 2	H319
Anionic surfactant	Mixture	1-5%			Eye Dam. 1, Skin Irrit. 2	H315 H318
Nonionic surfactant	120313-48-6	1-5%			Aquatic Acute 1, Skin Irrit. 2	H315 H400 H411
Subtilisins	9014-01-1	0-1%	232-752-2	01-2119480434-38	Acute Tox. 4, Aquatic Acute 1, Eye Dam. 1, Resp Sens. 1	H302 H315 H318 H334 H335 H400 EUH208

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 water and 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 severe irritation and damage.

Skin hazard: Will cause irritation.

Respiratory hazard: Not a hazard in normal use. 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

No specific hazards arising from the mixture. May produce toxic fumes under extreme heating in 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, flush to foul sewer with a large quantity of water.

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. Recommended storage temperature 5-25°C.

7.3. Product Uses

Add cold or tepid water to the bath (not exceeding 45°C). Add Sonozyme 3 to obtain a dilution of 5ml/l, that's 40ml in 8 litres of water. Operate the Ultrasonic bath as directed in the user guide. After processing, rinse the cleaned devices with water. The fluid in the bath should be changed and re-dosed at the start of each clinical session (twice a day) or more frequently if visibly contaminated. Please refer to product safety data sheet before use.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Workplace exposure limits

Subtilisins 0.04µg/m³ WEL 8 hour TWA (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 nitrile or neoprene gloves. Exact choice of glove depends on specific risk assessments.
Body protection: As necessary to prevent contact.
Respiratory protection: Use in a well ventilated area, 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: Blue
Odour: Characteristic Melting point/ freezing point: N/a
pH (typical): 7.8 1% in water (typical). Flammability N/a
Initial boiling point: >100°C Flash point: N/a
Auto-ignition temp: N/a Viscosity: Free flowing.
Vapour pressure: No data
Explosive properties: N/a
Lower upper explosion limits: N/a
Oxidising properties: None
Solubility: Miscible with water.
Relative density at 20° C (typical): 1.031 (typical)
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** None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

- Acute toxicity: Contains an ingredient classified as Acute Tox. Section 3. Mixture is not classified as Acute Tox.
- Skin corrosion/ irritation: Based on available data, the classification criteria are not met.
- Serious eye damage/ irritation: Mixture is classified as Eye Irrit. 2. See section 2.
- Respiratory or skin sensitisation: Contains an ingredient classified as sensitising. Section 3. Mixture is not classified as sensitising.
- Germ cell mutagenicity: Does not contain any ingredients classified as mutagenic.
- Carcinogenicity: Does not contain any ingredients classified as carcinogenic.
- Reproductive toxicity: Does not contain any ingredients classified as toxic for reproduction.
- STOT single exposure: contains an ingredient classified as STOT SE. Section 3. Mixture is not classified as STOT SE.
- STOT repeated exposure: Does not contain any ingredients classified as STOT RE.
- Aspiration toxicity: Does not contain any ingredients classified as Asp Tox.

Routes of exposure/ symptoms

- Eye contact: Will cause severe irritation and damage.
- Skin contact: Will cause irritation.
- Inhalation: Not a hazard in normal use. Breathing spray mist may cause irritation.
- Ingestion: Moderate toxicity, will cause irritation and damage to gastro-intestinal tract due to acidity.

11.2. Information on other hazards No data.

SECTION 12: Ecological information

- 12.1. Toxicity** Not classified as dangerous for the environment/ aquatic toxicant
- 12.2. Persistence and degradability** All organic ingredients are biodegradable when well diluted. Surfactants used comply with biodegradation criteria, see section 15.1.
- 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).
- Large quantities, dispose via a licensed chemical waste contractor.
- 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** not classified
- 14.2. UN proper shipping name** N/a ()
- 14.3. Transport hazard class(es)** N/a **14.4. Packing group** Na
- 14.5. Environmental hazards** Not classified as environmentally hazardous for transport
- 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:

Anionic surfactants <5% Enzymes

Nonionic surfactants <5%

Preservative

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)

H319 Causes serious eye irritation

H315 Causes skin irritation

H318 Causes serious eye damage

H400 Very toxic to aquatic life

H411 Toxic to aquatic life with long lasting effects

H335 May cause respiratory irritation

H302 Harmful if swallowed

EUH208 Contains subtilisins. May produce an allergic reaction

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled

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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.

