

Safety Data Sheet**Section 1 – IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/
UNDERTAKING**

1.1 Product identifiers:

Product names: 3E-Zyme
Product numbers: MED8010, MED8037, MED8024, MED8027 & MED8035
Brand: Medisafe
REACH Number: N/A

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

Identified Uses: Cleaning agent. Enzymatic detergent for cleaning re-usable medical instruments and devices. For use at concentrations between 0.3 to 1% in water at 20°C to 45°C.
Uses Advised against: No Data

1.3 Details of the supplier of the safety data sheet:

Supplier: *Medisafe UK Limited*
Twyford Road,
Bishop's Stortford,
Hertfordshire CM23 3LJ,
United Kingdom.
Tel: +44 (0)1279 461641
Fax: +44 (0)1279 461643
Email: info@medisafeinternational.com
Website: www.medisafeinternational.com

1.4 Emergency telephone number:

For Chemical Emergency please contact your local emergency services

Section 2 – HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture According to Regulation (EC) 1272/2008**Classification H&P Phrases**

Warning *EUH208

2.2 Label Elements

According to Regulation (EC) 1272/2008:

*EUH208: Contains a mixture of: 5-chloro-2-methyl-2H-isothiazol-3-one [ec no 247-500-7] and 2-methyl 2H-isothiazol-3-one [ec no 220-239-6]. May produce an allergic reaction.

2.3 Other hazards: May cause sensitisation by skin contact
PBT: This product is not identified as a PBT/vPvB substance

Section 3 – COMPOSITION/INFORMATION ON INGREDIENTS

The mixture:

Ingredient	% by vol	Classification	Index #	CAS #	EC #
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See Section 15 for the full text of H-phrases referred to in this Section.

Section 4 – FIRST AID MEASURES

General

4.1 First aid measures

Skin:	Wash immediately with plenty of soap and water.
Eye contact:	Bathe the eye with running water for 15 minutes. If irritation persists seek medical advice
Respiratory:	Remove casualty from exposure ensuring one's own safety whilst doing so.
Ingestion:	Wash out mouth with water. Seek medical attention.

4.2 Symptoms

Skin:	There may be mild irritation at the site of contact.
Eye contact:	There may be irritation and redness.
Respiratory:	No Data
Ingestion:	There may be irritation of the throat.
Delayed /Immediate effects:	No Data

4.3 Indication of special treatment

No Data

Section 5 – FIRE-FIGHTING MEASURES

5.1 Extinguishing media:	Non-flammable. Select extinguishing agent appropriate to other materials involved. Carbon dioxide. Dry chemical powder. Alcohol or polymer foam.
5.2 Special hazards:	Not expected to burn in fire until all water has evaporated . Products of combustion include oxides of carbon.
5.3 Advice for fire fighters	Wear self-contained breathing apparatus.

Section 6 – ACCIDENTAL RELEASE MEASURES

- | | |
|--|---|
| 6.1 Personal precautions: | Refer to section 8 of SDS for personal protection details. Turn leaking containers leak- side up to prevent the escape of liquid. |
| 6.2 Environmental precautions: | Do not discharge into drains or rivers. |
| 6.3 Containment & clean up procedures: | Small spillages may be flushed with large amounts of water. |
| 6.4 Reference to other sections: | Refer to section 8 of SDS. |

Section 7 – HANDLING AND STORAGE

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|--------------------------|---|
| 7.1 Handling: | Ensure there is sufficient ventilation of the area. Avoid direct contact with the substance |
| 7.2 Storage: | Keep Polyethylene. Container tightly closed. |
| 7.3 Specific end use(s): | No Data |

Section 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Indicative UK EH40 exposure limits
Exposure WEL mg m⁻³ No data available.

The exposure limits of EH40 are consistent with Directive 2000/39/EC

8.2 Exposure controls

- | | |
|-----------------------|---|
| PPE: | PVC gloves, Safety glasses, Protective clothing with elasticated cuffs and closed neck. |
| Engineering measures: | Ensure there is sufficient ventilation of the area. |
| Eye protection: | Safety glasses |
| Respiratory: | Respiratory protection not required. |
| Skin protection: | PVC gloves & Protective clothing with elasticated cuffs and closed neck. |
| Ingestion: | No data available. |
| Industrial hygiene: | Prevent from entering in public sewers or the immediate environment. |

Section 9- PHYSICAL & CHEMICAL PROPERTIES

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|---------------------------------|--------------------------|
| Appearance: | Blue Liquid |
| Odour & odour threshold: | Barely perceptible odour |
| pH: | 7-9 |
| Melting/freezing point: | No Data Available |
| Initial boiling point & boiling | >100 |

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range:

Flammability (solid, gas):	Not applicable.
Flash point:	>100
Explosive properties:	No Data Available
Upper/lower	Not applicable.
Vapour pressure:	No Data Available
Vapour density:	No Data Available
Evaporation rate:	No Data Available
Relative density:	No Data Available
Solubility:	Soluble
Partition ratio (K_{ow})	No Data Available
Auto-ignition temperature	No Data Available
Decomposition temperature:	No Data Available
Viscosity:	No Data Available
Oxidising properties:	Non-oxidising (by EC criteria)

Section 10- STABILITY & REACTIVITY

10.1	Reactivity:	Stable under recommended transport or storage conditions.
10.2	Chemical stability:	Stable under normal conditions.
10.3	Possibility of hazardous reactions:	Hazardous reactions will not occur under normal transport or storage conditions. Decomposition may occur on exposure to conditions or materials listed below.
10.4	Materials to avoid:	Strong bases. Strong oxidising agents.
10.5	Incompatible	Strong bases. Strong oxidising agents.
10.6	Hazardous	In combustion emits toxic fumes of carbon dioxide / carbon

Section 11- TOXICOLOGICAL INFORMATION

Acute toxicity:	No data available.
Skin contact:	There may be mild irritation at the site of contact.
Skin absorption:	There may be irritation and redness.
Eye contact:	There may be irritation and redness.
Inhalation:	Not applicable
Ingestion:	There may be irritation of the throat.
Germ cell mutagenicity:	No data available.
Carcinogenicity:	No data available.
Reproductive toxicity:	No data available.

Section 12- ECOLOGICAL INFORMATION

Mobility:	Soluble in water.
Eco toxicity:	No data available.

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Persistence: Biodegradable.

Section 13- DISPOSAL CONSIDERATIONS

Transfer to a suitable container and arrange for collection by specialised disposal company.

Dispose of as normal industrial waste.

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

Contact a licensed professional for disposal consideration. Observe all federal, state and local environmental regulations.

Section 14- TRANSPORT INFORMATION

DOT:

Shipping Name: This product does not require a classification for transport.

UN#:

Class:

Packing Group:

Hazard Label:

Marine pollutant

IATA:

Shipping Name:

IATA UN#:

Class:

Packing Group:

Hazard Label:

Section 15 – REGULATORY INFORMATION

Classification of components of the mixture

All the raw materials/chemicals sourced for use in this product are pre-registered for REACH (where applicable) or have undergone the registration process and therefore said to be REACH compliant.

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

Medical Devices Directive

The product is not classifiable as a medical device, or

The product is registered as a Class 1 device according to 93/42/EEC and later amendments.

Class 1

According to Rule 1, by applying all 18 Rules of Annex IX of MDD 93/42/EEC. It is non-invasive and is intended to be used in conjunction with a washer/disinfectant.

US Regulatory Information

SARA listed: No Data Available

Section 16 – OTHER INFORMATION

Revision history:

		This safety data sheet is prepared in accordance with Commission Regulation (EU) No 453/2010.
Iss 1	01/08/2012	First issue of the MSDS
Iss 2	27/03/2015	Updated Template including CHIP regs
Iss 3	22/04/2015	SDS issued on old MSDS template CLP Regs added.
Iss 4	13/03/2017	SDS issued on new SDS template grid style format CHIP regs removed.

Disclaimer:

This Safety Data Sheet is not a technical specification and does not guarantee any properties or performance. It has been published for the purpose of giving guidance to the user in the safe storage, transportation, use and disposal of the product, and conforms to Regulation (EC) No. 453/2010.

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[END OF SAFETY DATA SHEET]