

## SAFETY DATA SHEET

### REPROZYME MANUAL (IMPROVED FORMULA)

Page: 1

Compilation date: 19/04/2017

Revision No: 1

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

##### 1.1. Product identifier

**Product name:** REPROZYME MANUAL (IMPROVED FORMULA)

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

**Use of substance / mixture:** A concentrated enzymatic preparation for effective cleaning and breakdown of proteinaceous and other organic material from the surfaces of surgical instruments, endoscopes and medical devices.

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

**Company name:** Medimark Scientific Limited

4 East Point

Seal

TN15 0EG

United Kingdom

**Tel:** +44 (0) 8452 223344

**Email:** [info@medi-mark.co.uk](mailto:info@medi-mark.co.uk)

##### 1.4. Emergency telephone number

**Emergency tel:** +44 (0) 8452 223344 (8am-5pm)

(office hours only)

#### Section 2: Hazards identification

##### 2.1. Classification of the substance or mixture

**Classification under CLP:** Skin Sens. 1: H317; -: EUH208

**Most important adverse effects:** Contains amylase, alpha-, lipase enzyme, subtilisin. May produce an allergic reaction.  
May cause an allergic skin reaction.

##### 2.2. Label elements

**Label elements:**

**Hazard statements:** EUH208: Contains amylase, alpha-, lipase enzyme, subtilisin. May produce an allergic reaction.

H317: May cause an allergic skin reaction.

**Hazard pictograms:** GHS07: Exclamation mark



**Signal words:** Warning

**SAFETY DATA SHEET**  
REPROZYME MANUAL (IMPROVED FORMULA)

Page: 2

**Precautionary statements:** P261: Avoid breathing vapours.  
P280: Wear protective gloves.  
P302+352: IF ON SKIN: Wash with plenty of water/.  
P321: Specific treatment (see instructions on this label).

**2.3. Other hazards**

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

**Section 3: Composition/information on ingredients**

**3.2. Mixtures**

**Hazardous ingredients:**

PROPANE-1,2-DIOL - REACH registered number(s): 01-2119457558-25

EINECS	CAS	PBT / WEL	CLP Classification	Percent
200-338-0	57-55-6	Substance with a Community workplace exposure limit.	-	10-20%

PROPAN-2-OL

200-661-7	67-63-0	-	Flam. Liq. 2: H225; Eye Irrit. 2: H319; STOT SE 3: H336	1-5%
-----------	---------	---	---	------

AMYLASE, ALPHA-

232-565-6	9000-90-2	-	Resp. Sens. 1: H334	<1%
-----------	-----------	---	---------------------	-----

SUBTILISIN

232-752-2	9014-01-1	-	STOT SE 3: H335; Skin Irrit. 2: H315; Eye Dam. 1: H318; Resp. Sens. 1: H334; Aquatic Acute 1: H400	<1%
-----------	-----------	---	--	-----

LIPASE ENZYME

232-619-9	9001-62-1	-	Resp. Sens. 1: H334	<1%
-----------	-----------	---	---------------------	-----

1,2-BENZISOTHIAZOLIN-3-ONE

220-120-9	2634-33-5	-	Acute Tox. 4: H302; Skin Irrit. 2: H315; Eye Dam. 1: H318; Skin Sens. 1: H317; Aquatic Acute 1: H400	<1%
-----------	-----------	---	--	-----

**Contains:** 1,2-BENZISOTHIAZOLIN-3-ONE

**Section 4: First aid measures**

**4.1. Description of first aid measures**

**Skin contact:** Wash immediately with plenty of soap and water. If irritation develops seek medical advice.

**Eye contact:** Bathe the eye with running water for 15 minutes.

**Ingestion:** Wash out mouth with water.

**Inhalation:** Remove casualty from exposure ensuring one's own safety whilst doing so.

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

**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:** Exposure may cause coughing or wheezing.

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

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

**Immediate / special treatment:** Not applicable.

**Section 5: Fire-fighting measures**

**5.1. Extinguishing media**

**Extinguishing media:** Suitable extinguishing media for the surrounding fire should be used. Use water spray to cool containers.

**5.2. Special hazards arising from the substance or mixture**

**Exposure hazards:** Not applicable.

**5.3. Advice for fire-fighters**

**Advice for fire-fighters:** 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:** Do not attempt to take action without suitable protective clothing - see section 8 of SDS.

**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.

**6.4. Reference to other sections**

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

**Section 7: Handling and storage**

**7.1. Precautions for safe handling**

**Handling requirements:** Avoid direct contact with the substance.

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

**Storage conditions:** Store in a cool, well ventilated area. Keep container tightly closed.

**7.3. Specific end use(s)**

**Specific end use(s):** No data available.

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

**8.1. Control parameters**

**Hazardous ingredients:**

**SAFETY DATA SHEET**  
REPROZYME MANUAL (IMPROVED FORMULA)

**PROPANE-1,2-DIOL**

**Workplace exposure limits:**

**Respirable dust**

State	8 hour TWA	15 min. STEL	8 hour TWA	15 min. STEL
EU	-	-	474 mg/m <sup>3</sup>	-

**PROPAN-2-OL**

UK	999 mg/m <sup>3</sup>	1250 mg/m <sup>3</sup>	-	-
----	-----------------------	------------------------	---	---

**DNEL/PNEC Values**

**Hazardous ingredients:**

**1,2-BENZISOTHIAZOLIN-3-ONE**

Type	Exposure	Value	Population	Effect
DNEL	Inhalation (developmental tox)	111	Consumers	Systemic

**8.2. Exposure controls**

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

**Respiratory protection:** Respiratory protection not required. Use in a well ventilated area.

**Hand protection:** Protective gloves.

**Eye protection:** Safety glasses. Ensure eye bath is to hand.

**Skin protection:** Not required.

**Environmental:** Not applicable.

**Section 9: Physical and chemical properties**

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

**State:** Liquid

**Colour:** Green

**Odour:** Characteristic odour

**Solubility in water:** Soluble

**Boiling point/range°C:** >100

**Melting point/range°C:** >0

**Flammability limits %: lower:** No data available.

**upper:** No data available.

**Flash point°C:** No data available.

**Part.coeff. n-octanol/water:** No data available.

**Autoflammability°C:** No data available.

**Vapour pressure:** No data available.

**Relative density:** No data available.

**pH:** 7-8

**VOC g/l:** No data available.

**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.

**SAFETY DATA SHEET**  
REPROZYME MANUAL (IMPROVED FORMULA)

Page: 5

**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.

**10.4. Conditions to avoid**

**Conditions to avoid:** Heat.

**10.5. Incompatible materials**

**Materials to avoid:** Strong oxidising agents. Strong acids.

**10.6. Hazardous decomposition products**

**Haz. decomp. products:** No data available.

**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	gm/kg

**AMYLASE, ALPHA-**

ORL	MUS	LD50	>15	gm/kg
ORL	RAT	LD50	>7500	mg/kg

**SUBTILISIN**

ORL	RAT	LD50	3700	mg/kg
-----	-----	------	------	-------

**1,2-BENZISOTHIAZOLIN-3-ONE**

ORL	MUS	LD50	1150	mg/kg
ORL	RAT	LD50	1020	mg/kg

**Relevant hazards for product:**

Hazard	Route	Basis
Respiratory/skin sensitisation	DRM	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:** Exposure may cause coughing or wheezing.

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

**Section 12: Ecological information**

**SAFETY DATA SHEET**  
REPROZYME MANUAL (IMPROVED FORMULA)

Page: 6

**12.1. Toxicity**

**Ecotoxicity values:** No data available.

**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:** Small amounts of unwanted product may be flushed with water to sewer.

**Disposal of packaging:** Dispose of as normal industrial waste.

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

**Section 14: Transport information**

**Transport class:** This product does not require a classification for transport.

**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**

**Other information**

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

\* indicates text in the SDS which has changed since the last revision.

**Phrases used in s.2 and s.3:** EUH208: Contains <name of sensitising substance>. May produce an allergic reaction.

H225: Highly flammable liquid and vapour.

H302: Harmful if swallowed.

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H318: Causes serious eye damage.

H319: Causes serious eye irritation

## **SAFETY DATA SHEET**

REPROZYME MANUAL (IMPROVED FORMULA)

**Page: 7**

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.

**Legal disclaimer:** The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.

