

**Endozime Premium with A.P.A. EU Safety Data Sheet**  
according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Date of issue: 06/19/2019  
Version: 1.0

Section 1 – Identification of the substance/mixture and of the company/undertaking			
1.1 <u>Product identifier:</u> Product Form: mixture Trade Name: Endozime Premium with A.P.A. Registration number: Substances contained in the mixture are registered by the suppliers.		1.4 <u>Emergency Telephone Number</u> 0035318308266	
1.2 <u>Relevant identified uses of the substance or mixture and uses advised against</u>  <b>Recommended use:</b> Medical Instrument Cleaning <b>Uses advised against:</b> No information available	1.3. <u>Details of the supplier of the safety data sheet</u>		NPIC Number 01 8092166  Hours of work 9am - 5pm Mon- Friday
	<b>Supplied by</b> Murray Surgical Limited Unit 23a Moyle Road Dublin Ind. Estate Glasnevin, Dublin 11	<b>Manufactured by</b> The Ruhof Corporation 393 Sagamore Avenue Mineola, NY 11501-1919  USA	
Section 2 – Hazards Identification			
Section 2.1 – Classification of the substance or mixture			
Classification according to Regulation (EC) No. 1272/2008 and its amendments			
This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.			
2.2. Label Elements			
Hazard Pictogram: Not Applicable	Precautionary Statements: P501 - Dispose of contents/ container to an approved waste disposal plant.		
Signal Word: Not Applicable	<b>Additional information:</b>		
Hazard Statements: Not Applicable	EUH208 Contains Subtilisin. May produce an allergic reaction. EUH208 Contains Lipase. May produce an allergic reaction. EUH208 Contains Amylase. May produce an allergic reaction. <b>Regulation (EC) No 648/2004 on detergents / Labelling for contents:</b> non-ionic surfactants, perfumes, preservation agents, enzymes < 5%		
Section 3 – Composition/Information on Ingredients			
3.1. <u>Substance:</u> Not Applicable    3.2 <u>Mixture</u>			
Name	Product Identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Propan-2-ol	(CAS No) 67-63-0 (EC no) 200-661-7 REACH No 01-2119457558-25	1-<5	Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336
Alcohols, C9-11, ethoxylated	(CAS No) 68439-46-3 (EC no) 614-482-0	0,1-<1	Eye Dam. 1, H318
Subtilisins (proteolytic enzymes)	(CAS No) 9014-01-1 (EC no) 232-752-2 REACH No 01-2119480434-38	0,1-<1	Skin Irrit. 2, H315 Eye Dam. 1, H318 Resp. Sens. 1, H334 STOT SE 3, H335
Lipase	(CAS No) 9000-62-1 (EC no) 232-619-9 REACH No 01-2119972939-13	0,1-0,5	Resp. Sens. 1, H334
Amylase	(CAS No) 9000-90-2 (EC no) 232-565-6 (EC index no) 647-015-00-4	0,1-0,5	Resp. Sens. 1, H334
Full text of H-statements: see section 16			
Section 4 – First Aid Measures			
4.1. <u>Description of first-aid measures</u>			
<b>General Advice</b>	No specific measures required.		
<b>Eye Contact</b>	Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.		
<b>Skin Contact</b>	Rinse off with water. If symptoms persist, consult a doctor.		
<b>Inhalation</b>	If irritation occurs move to fresh air. If symptoms persist, call a doctor.		
<b>Ingestion</b>	Do NOT induce vomiting. Drink plenty of water. If symptoms persist, call a physician.		
4.2. <u>Most important symptoms and effects, both acute and delayed</u>			
Most Important Symptoms/Effects	No further relevant information available.		
4.3. <u>Indication of immediate medical attention and special treatment needed</u>			
Notes to Physician	No further relevant information available.		
Section 5 – Fire Fighting Measures			
5.1. <u>Extinguishing media</u> Suitable Extinguishing Media CO2, powder or water spray.		5.3. <u>Advice for firefighters</u> Special protective equipment for fire-fighters No further relevant information available.	
5.2. <u>Special hazards arising from the substance or mixture</u> Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases None in particular.			
Section 6 – Accidental Release Measures			
6.1. <u>Personal precautions, protective equipment and emergency procedures</u> Use personal protective equipment.		6.3. <u>Methods and materials for containment and cleaning up</u> Soak up with inert absorbent material.	
6.2. <u>Environmental precautions</u> No special measures required.		6.4. <u>Reference to other sections:</u> See Section 12 for additional information.	
Section 7 – Handling and Storage			
7.1. <u>Precautions for Safe Handling</u>		7.2. <u>Conditions for safe storage, including any incompatibilities</u>	

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No special precautions are necessary if used correctly.  
**Information about fire - and explosion protection:** No special measures required.

Keep out of the reach of children. Keep in properly labeled containers.  
**7.3. Specific end use(s) Exposure Scenario** No information available. **Other Guidelines** No information available.

## Section 8 – Exposure controls/personal protection

### 8.1. Control parameters

Substance	Occupational Exposure Limit Value (8-hour reference period)		Occupational Exposure Limit Value (15-minute reference period)	
	ppm	mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>
<b>Propan-2-ol</b> (CAS No) 67-63-0 (EC no) 200-661-7	200	-	400	-
<b>Subtilisins</b> (proteolytic enzymes) (CAS No) 9014-01-1 (EC no) 232-752-2	-	0.00006	-	0.00006

**8.2. Exposure controls**  
**Personal protective equipment**  
**General protective and hygienic measures:** The usual precautionary measures are to be adhered to when handling chemicals.  
**Eye Protection** Not required under normal conditions of use.  
**Skin and Body Protection** Not required under normal conditions of use.

**Hand Protection** Not required under normal conditions of use.  
**Respiratory Protection** No respiratory protection normally required. In case of inadequate ventilation wear respiratory protection.

Device	Filter type	Condition	Standard
Dust mask	Type P1	Dust protection EN	143, EN 149

## Section 9 – Physical and chemical properties

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

Physical State	Odour	Appearance	pH	Melting Point/Range	Boiling Point
Liquid	Tropical	Blue	6-8	No data available	>100C
Flash Point	Flammability Limits	Vapor Pressure	Specific Gravity	Water Solubility	Flammable Properties
Not Flammable	No data available	No data available	1.00-1.01	Soluble	Not Flammable

**9.2. Other information** **VOC Content (%)** No information available **Flammability Limits in Air** No data available

## Section 10 – Stability and reactivity

**10.1. Reactivity** No data available.  
**10.2. Chemical stability** Stable under normal conditions.  
**10.3. Possibility of hazardous reactions** None under normal processing.

**10.4. Conditions to avoid** None known based on information supplied.  
**10.5. Incompatible materials** No information available.  
**10.6. Hazardous decomposition products** None under normal use.

## Section 11 – Toxicological information

**11.1. Information on toxicological effects**  
**Inhalation** Based on available data, the classification criteria are not met.  
**Eye Contact** Based on available data, the classification criteria are not met.  
**Skin Contact** Based on available data, the classification criteria are not met.  
**Ingestion** There is no data available for this product.

**Delayed and immediate effects and also chronic effects from short and long-term exposure**  
**Carcinogenicity** Based on available data, the classification criteria are not met.  
**Chronic Toxicity** Based on available data, the classification criteria are not met.

## Section 12 – Ecological information

### 12.1. Toxicity

<b>Ecotoxicity</b>	The product is not expected to be hazardous to the environment.
<b>Persistence and Degradability</b>	No information available.
<b>Bioaccumulation</b>	The product does not contain any substances expected to be bioaccumulating.
<b>Other Adverse Effects</b>	No information available.

### 12.2. Persistence and degradability

The surfactant(s) contained in this preparation complies (comply) with the biodegradability criteria as 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 or at the request of a detergent manufacturer.

**12.3. Bioaccumulative potential:** No information available.  
**12.4. Mobility in soil** Adsorbs on soil.

**12.5. Results of PBT and vPvB assessment** No information available.  
**12.6. Other adverse effects** None known

## Section 13 – Disposal considerations

**13.1. Waste treatment methods: Waste from Residues / Unused Products** Dispose of in accordance with local regulations. **Contaminated Packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal.

## Section 14 – Transport information

<b>14.1 UN number</b> N/A	<b>Ground:</b> Non-Hazardous	<b>14.4 Packing group</b> N/A	<b>Product Regulated for Transport</b> No
<b>14.2 UN proper shipping name</b> N/A	<b>Sea: IMDG Class:</b> Non-Hazardous	<b>14.5 Environmental hazards</b> N/A	<b>14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:</b> N/A
<b>14.3 Transport hazard class(es)</b>	<b>Air: ICAO/IATA Class:</b> Non-Hazardous	<b>14.6 Special precautions for user</b> N/A	

## Section 15 – Regulatory information

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

**EU Legislation:** The UN Globally Harmonized System (GHS) Safety Data Sheet format (Annex IV) is implemented as Annex II of REACH EU No 2015/830 of 20th May 2015 amending regulation (EC) No 1907/2006. Detergent Regulation (EC) No. 648/2004

## Section 16 – Other information

**Full text of H-phrases referred to under Sections 3:** **H225** Highly flammable liquid and vapour; **H319** Causes serious eye irritation; **H336** May cause drowsiness or dizziness; **H318** Causes serious eye damage; **H315** Causes skin irritation; **H334** May cause allergy or asthma symptoms or breathing difficulties if inhaled; **H335** May cause respiratory irritation.

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### General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet