

Endozime Sponge EU Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Date of issue: 06/21/2019
Version: 1.0

Section 1 - Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier: Product Form: mixture Trade Name: Endozime Sponge Registration number: Substances contained in the mixture are registered by the suppliers.		1.4 Emergency Telephone Number 0035318308266				
1.2 Relevant identified uses of the substance or mixture and uses advised against Recommended use: Medical Instrument Cleaning Uses advised against: No information available	1.3. Details of the supplier of the safety data sheet					
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px; text-align: center;"> Supplied by Murray Surgical Limited 23a Moyle Road Dublin Ind. Estate Glasnevin, Dublin 11 </td> <td style="width: 50%; padding: 5px; text-align: center;"> Manufactured by The Ruhof Corporation 393 Sagamore Avenue Mineola, NY 11501-1919 USA </td> </tr> <tr> <td colspan="2" style="padding: 5px; text-align: center;"> Email: info@murraysurgical.ie </td> </tr> </table>		Supplied by Murray Surgical Limited 23a Moyle Road Dublin Ind. Estate Glasnevin, Dublin 11	Manufactured by The Ruhof Corporation 393 Sagamore Avenue Mineola, NY 11501-1919 USA	Email: info@murraysurgical.ie		NPIC Number 01 8092166 Hours of work 9am - 5pm Mon- Friday
Supplied by Murray Surgical Limited 23a Moyle Road Dublin Ind. Estate Glasnevin, Dublin 11	Manufactured by The Ruhof Corporation 393 Sagamore Avenue Mineola, NY 11501-1919 USA					
Email: info@murraysurgical.ie						

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	
Hazard Statements: Not Applicable	Additional information: EUH208 Contains Subtilisin. May produce an allergic reaction. Regulation (EC) No 648/2004 on detergents / Labelling for contents: non-ionic surfactants, preservation agents, enzymes < 5%

Section 3 - Composition/Information on Ingredients

3.1. Substance: Not Applicable 3.2 Mixture

Name	Product Identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
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

Full text of H-statements and additional information: see section 16

Section 4 - First Aid Measures

4.1. Description of first-aid measures

General Advice	No specific measures required.
Eye Contact	Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
Skin Contact	Rinse off with water. If symptoms persist, consult a doctor.
Inhalation	If irritation occurs move to fresh air. If symptoms persist, call a doctor.
Ingestion	Do NOT induce vomiting. Drink plenty of water. If symptoms persist, call a physician.

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

Most Important Symptoms/Effects	No further relevant information available.
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4.3. Indication of immediate medical attention and special treatment needed

Notes to Physician	No further relevant information available.
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Section 5 - Fire Fighting Measures

5.1. Extinguishing media Suitable Extinguishing Media CO2, powder or water spray.	5.3. Advice for firefighters Special protective equipment for fire-fighters No further relevant information available.
5.2. Special hazards arising from the substance or mixture Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases None in particular.	

Section 6 - Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures Use personal protective equipment. 6.2. Environmental precautions No special measures required.	6.3. Methods and materials for containment and cleaning up Soak up with inert absorbent material. 6.4. Reference to other sections: See Section 12 for additional information.
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Section 7 - Handling and Storage

7.1. Precautions for Safe Handling No special precautions are necessary if used correctly. Information about fire - and explosion protection: No special measures required.	7.2. Conditions for safe storage, including any incompatibilities 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.
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Sendoze Sponge EU Safety Data Sheet

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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 ³	ppm	mg/m ³
Subtilisins (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	Odor	Appearance	pH	Melting Point/Range	Boiling Point
Red polyether-urethane foam sponge with red liquid	Floral	Red	6-8	No data available	>100°C
Flash Point	Flammability Limits	Vapor Pressure	Specific Gravity	Water Solubility	Flammable Properties
No data available	No data available	No data available	1.01-1.03	Soluble	Not Flammable

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

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

12.5. Results of PBT and vPvB assessment No information available.

12.4. Mobility in soil Adsorbs on soil.

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

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

The percentages reflected in section 3 of this SDS represents the levels of hazardous components in the mixture.

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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