

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

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 Revision Number: 6

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled):	ZymeX™ Enzymatic Cleaner
Part/Item Number:	21380, 21381, 21383, 21384, 21390

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use:	Instrument Cleaning Solution Concentrate
Restrictions on Use:	For professional use only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:	Sultan Healthcare
Manufacturer/Supplier Address:	1301 Smile Way York, PA, USA
Manufacturer/Supplier Telephone Number:	1-201-871-1232 or 800-637-8582 (Product Information)-
Email address:	customer.service@sultanhc.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number:	800-535-5053 (INFOTRAC) 1-352-323-3500 (Outside the United States – Call Collect)
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2. HAZARD(S) IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS SDS Classification:

Health	Environmental	Physical
Respiratory Sensitization Category 1	Not hazardous	Not hazardous

EU Classification (1999/45/EC as amended): Not a dangerous preparation

EU Risk (R) Phrases: None

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

2.2 Labeling Elements: Contains Subtilisin



Signal Word: Danger!

Hazard Statements	Precautionary Statements
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.	P261 Avoid breathing mist, vapors or spray. P284 In case of inadequate ventilation wear respiratory protection. P304 + P340 IF INHALED: remove person to fresh air and keep comfortable for breathing. P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER. P501 Dispose of contents and container in accordance with local and national regulations.

2.3 Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.2 Mixture

Hazardous Components	C.A.S. # EC#	IUPAC Name	CLP/GHS / EU Classification (1272/2008) (1999/45/EC)	WT %
Propylene Glycol	57-55-6 / 200-338-0	propane-1,2- diol	Not dangerous Not hazardous	10-20
Isopropyl Alcohol	67-63-0 / 200-661-7	propan-2-ol	F, Xi R11, R36, R67 Flam. Liq. 2 (H225) Eye Irrit. 2 (H319) STOT SE 3 (H336)	1-<10
Triethanolamine	102-71-6 / 203-049-8	<u>2-[bis(2- hydroxyethyl)amino]ethanol</u>	Not dangerous Not hazardous	1-10
Boric Acid	10043-35-3 / 233-139-2	Boric acid	T (Repr Cat 2) R60, R61 Repr. 1B (H360FD)	1-<5
Subtilisin	9014-01-1 / 232-752-2	Subtilisin A Substrate	Xn, Xi R22, R36/37/38, R42, R50 Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Resp. Sens.1 (H334) STOT SE 3 (H335) Aquatic Acute 1 (H400)	0.1-<1

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS and H phrases and EU Classifications and R Phrases.

4. FIRST-AID MEASURES

4.1 Description of First Aid Measures:

Routes of Exposure	First Aid Instructions
Eye	Immediately flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get immediate medical attention.
Skin	Wash skin thoroughly with soap and water. Get medical attention if irritation develops.
Inhalation	None needed under normal use conditions. If irritation develops, remove from exposure and get medical attention. If asthma symptoms or shortness of breath develop, get immediate medical attention.
Ingestion	Do not induce vomiting. Rinse mouth with water and give one glass of water to drink. Never give anything by mouth to an unconscious or convulsing person. Get medical attention.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

May cause eye irritation. Prolonged skin contact may cause irritation. Inhalation of vapors and mists may cause asthma-like symptoms or difficulty in breathing

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

If asthma symptoms or shortness of breath develop, get immediate medical attention.

Note to Physicians (Treatment, Testing, and Monitoring): Treatment of overexposure should be directed at the control of symptoms and clinical conditions.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media

Use media appropriate for surrounding fire





5.2 Special Hazards Arising from the Substance or Mixture:

Cool fire exposed containers and structures with water

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures:	Cool fire exposed containers and structures with water.
Precautions for Fire Fighters:	Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals

Recommended Protective Equipment for Fire Fighters:



EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Wear appropriate protective clothing; gloves and eye protection.

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6.2 Environmental Precautions:

Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning up:

Collect using an inert non-combustible absorbent material and place in appropriate containers for disposal.

6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling:

Avoid contact with the eyes, skin and clothing. Avoid breathing mists. Wear appropriate protective clothing and equipment. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, dry, well ventilated area away from incompatible materials. Protect from physical damage.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Isopropyl Alcohol	United States	400 ppm TWA US OSHA PEL 200 ppm TWA ACGIH TLV, 400 ppm STEL
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	Germany	200 ppm TWA DFG MAK
	United Kingdom	400 ppm TWA UK OEL, 500 ppm STEL
	France	400 ppm TWA INRS VLCT
	Spain	400 ppm TWA VLA-ED, 500 ppm VAL-EC
	Italy	None Established
	European Union	None Established
Triethanolamine	United States	5 mg/m ³ TWA ACGIH TLV
	Germany	5 mg/m ³ TWA DFG MAK (inhalable)
	United Kingdom	None Established
	France	None Established
	Spain	5 mg/m ³ TWA VLA-ED
	Italy	None Established
	European Union	None Established
Boric Acid	United States	2 mg/m ³ TWA ACGIH TLV (inhalable), 6 mg/m ³ STEL (inhalable)
	Germany	None Established
	United Kingdom	None Established
	France	2 mg/m ³ TWA VLA-ED, 6 mg/m ³ VLA-EC
	Spain	None Established
	Italy	None Established
	European Union	None Established
Propylene Glycol	United States	10 mg/m ³ AIHA WEEL
	Germany	None Established
	United Kingdom	150 ppm TWA UK OEL (particulates)
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Subtilisin	United States	0.00006 mg/m ³ TWA ACGIH TLV Ceiling
	Germany	None Established
	United Kingdom	0.00004 mg/m ³ TWA UK OEL
	France	None Established
	Spain	0.00006 mg/m ³ VLA-EC
	Italy	None Established
	European Union	None Established
Biological Exposure Limits: None Established		

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate general or local exhaust ventilation to maintain exposure levels below the occupational exposure limits.

Individual Protection Measures (PPE)



Specific Eye/face Protection: Chemical safety glasses recommended.

Specific Skin Protection: Wear impervious gloves such as rubber. Consult glove supplier for thickness and breakthrough times.

Specific Respiratory Protection: None required under normal use conditions.

Specific Thermal Hazards: Not applicable

Recommended Personal Protective Equipment

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Clear, green-colored liquid	Explosive limits:	Not applicable
Odor:	Mint	Vapor pressure:	Not available
Odor threshold:	Not available	Vapor density:	Not available
pH:	7.0	Relative density:	1.03 @ 35°C
Melting/freezing point:	Not available	Solubility:	Complete
Initial boiling point and range:	Not available	Partition coefficient: n-octanol/water:	Not available
Flash point:	>200°F	Auto-ignition temperature:	Not available
Evaporation rate:	Not available	Decomposition temperature:	Not available
Flammability:	Not flammable	Viscosity:	Not available
Explosive Properties:	None	Oxidizing Properties:	Not available

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: Will not polymerize

10.2 Chemical Stability: Stable.

10.3 Possibility of Hazardous Reactions: Triethanolamine can decompose at elevated temperature.

10.4 Conditions to Avoid: Avoid high temperatures.

10.5 Incompatible materials: Avoid oxidizing agents

10.6 Hazardous Decomposition Products: Thermal decomposition may produce carbon and nitrogen oxides and hydrogen cyanide.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: May cause irritation with redness and tearing.

Skin: Prolonged or repeated skin contact may cause irritation.

Ingestion: Swallowing may cause nausea, vomiting and diarrhea.

Inhalation: Inhalation of mists may cause upper respiratory tract irritation. Sensitization may occur. Symptoms include shortness of breath, wheezing or labored cough.

Chronic Health Effects: Boric acid has been shown to cause adverse reproductive effects in laboratory animals.

Carcinogenicity: There is inadequate evidence of carcinogenicity of isopropyl alcohol and triethanolamine in human and animals. In a life-time bioassay in which mice consumed 48-96 mg/kg/day as boric acid in the diet, there was no evidence of carcinogenicity. None of the components are listed as a carcinogen by IARC, NTP, OSHA, ACGIH or the EU Substances Directive.

Mutagenicity: Isopropyl Alcohol: Negative in mammalian gene mutation assay and in-vivo mammalian bone marrow cytogenetic test. Triethanolamine: Negative in the AMES test and chromosomal aberration test in Chinese hamster cells.

Medical Conditions Aggravated by Exposure: Employees with pre-existing skin disorders may be at increased risk from exposure.

Acute Toxicity Data:

Isopropyl Alcohol: Oral rat LD50 5,045 mg/kg, Skin rabbit LD50 12,800 mg/kg

Triethanolamine: Oral rat LD50 8.0 g/kg, Skin rabbit LD50 >20,000 mg/kg

Boric Acid: Oral rat LD50 2660 mg/kg, Skin rabbit LD50 >2000 mg/kg, inhalation rat LC50 >2 mg/cu m/4 hr

Propylene Glycol: Oral rat LD50 21000 mg/kg, Skin rabbit LD50 20,800 mg/kg

Subtilisin: Oral rat LD50 1800 mg/kg

Reproductive Toxicity Data: Boric Acid: In a reproductive test, rabbits were administered 63, 125 or 250 mg/kg of boric acid. Developmental effects were seen at the highest dose only, including an increased incidence of reabsorptions and malformations. No evidence of developmental toxicity was observed at lower doses. The NOAEL for maternal and developmental toxicity was 125 mg/kg.

Specific Target Organ Toxicity (STOT):

Single Exposure: Boric acid: During LD50 studies with rats and mice, acute symptoms included depression, ataxia, convulsions, fall in body temperature and violet-red color of the skin and mucous membranes. Triethanolamine: Toxic effects in oral studies in rats and guinea pigs were observed to the gastrointestinal tract. It was determined the effects were due to the alkalinity of the material.

Repeated Exposure: Isopropyl Alcohol: In a 13 week inhalation study with rats, effects of narcosis were found at 5,000 ppm. These effects were reversible at the cessation of exposure. A 73 week chronic study found male reproductive effects at 2,500 and 5,000 ppm and liver effects at 2,500 ppm. Triethanolamine: In a 90-day sub-acute feeding study with rats, the max dose producing no effect was 0.08 g/kg. Microscopic lesions and deaths occurred at 0.73 g/kg and 0.17 g/kg produced alterations in liver and kidney weights.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Isopropyl Alcohol: 96 hr LC50 Pimephales promelas (fathead minnow) 6.12 g/L
Triethanolamine: 96 hr LC50 Pimephales promelas (fathead minnow) 11.8 g/L/
Boric Acid: 48 hr LC50 Daphnia magna 115 mg/L, 96 hr LC50 Catostomus latipinnis (Flannelmouth sucker) 125 mg/L
Propylene Glycol: Selenastrum capricornutum (green algae) 18,100 mg/L, 48 hr LC50 Daphnia magna 43,500 mg/L, 96 hr LC50 Pimephales promelas (Fathead minnow) 46,500 mg/L

12.2 Persistence and Degradability.

Isopropyl Alcohol: Readily biodegradable (95% after 21 days). Triethanolamine: readily biodegradable (82% after 8 days).
Subtilisin: Readily biodegradable

12.3 Bio-accumulative Potential:

Triethanolamine: BCF <0.4

12.4 Mobility in Soil:

Boric acid occurring naturally in soil.

12.5 Other Adverse Effects: None known

12.6 Results of PBT/vPvB Assessment: Not applicable

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with local and national environmental regulations.

Properties (Physical/Chemical) Affecting Disposal: None known.

Waste Treatment Recommendations: Do not flush to sewer.

14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	None	Not Regulated	None	None	No
ADR/RID	None	Not Regulated	None	None	No
IMDG	None	Not Regulated	None	None	Marine Pollutant-No
IATA/ICAO	None	Not Regulated	None	None	No

14.6 Special precautions for user: Not applicable

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable – product is transported only in packaged form.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): None

Toxic Substances Control Act (TSCA): All of the ingredients in this product are listed on the EPA TSCA Inventory.

Clean Water Act (CWA): Not Listed

Clean Air Act (CAA): Not Listed

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	Yes	Pressure Hazard:	No
Delayed Hazard:	Yes	Reactivity Hazard:	No
Fire Hazard:	No		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None		

State Regulations

California: This product contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm:

Components	C.A.S. #	WT %
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None		
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International Regulations

EU REACH: The substances in this product comply with the EU REACH regulation as applicable.

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3:

Repr Cat. 2 Reproductive Toxicity Category 2

T Toxic

F Flammable

Xi Irritant

Xn Harmful

R11 Highly flammable.

R22 Harmful if swallowed.

R36 Irritating to eyes.

R36/37/38 Irritating to eyes, respiratory system and skin.

R42 May cause sensitization by inhalation.

R50 Very toxic to aquatic organisms.

R60 May impair fertility.

R61 May cause harm to the unborn child.

R67 Vapors may cause drowsiness and dizziness.

Flam. Liq. 2 Flammable Liquid Category 2

Acute Tox. 4 Acute Toxicity Category 4

Skin Irrit. 2 Skin Irritation Category 2

Eye Irrit. 2 Eye Irritant Category 2

Resp. Sens. 1 Respiratory Sensitization Category 1

Repr 1B Reproductive Toxicity Category 1B

STOT SE 3 Specific Target Organ Toxicity (Single Exposure) Category 3

Aquatic Acute 1 Acute Aquatic Toxicity Category 1

H225 Highly flammable liquid and vapor.

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

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

H335 May cause respiratory irritation.

H336 May cause drowsiness or dizziness.

H360FD May damage fertility. May damage the unborn child.

H400 Very toxic to aquatic life.

Supersedes: 29 July 2013

Revision Summary: Comprehensive review, new format.

Date of SDS Preparation/Revision: 02 September, 2014

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau ESIS, Country websites for occupational exposure limits.