Safety Data Sheet conforms to Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 2020/878, US 29CFR1910.1200, Canada Hazardous Products Regulation

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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 17404
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)

2. HAZARD(s) IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS SDS Classification:		
Health	**Environmental**	**Physical**
Respiratory Sensitization Category 1 Toxic to Reproduction Category 1B	Not hazardous	Not hazardous

OSHA Specific Hazards: None

2.2 Label Elements:

Signal Word: Danger

Contains: Subtilisin

Hazard Phrases	Precautionary Phrases
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H360 May damage fertility or the unborn child.	P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. 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. P308 + P313 IF exposed or concerned: Get medical attention. P405 Store locked up. 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. #	EINECS # / REACH Registration #	Classification	WT %
Isopropyl Alcohol	67-63-0	200-661-7 /	Flam. Liq. 2 (H225) Eye Irrit. 2 (H319) STOT SE 3 (H336)	1-<10
Triethanolamine	102-71-6	203-049-8 /	Not hazardous	1-10
Boric Acid	10043-35-3	233-139-2 /	Repr. 1B (H360FD) EU Specific concentration: >= 5.5%	1-<5
Subtilisin	9014-01-1	232-752-2 /	Acute Tox. 4 (H302) LD50 1800 mg/kg Skin Irrit. 2 (H315) Eye Dam. 1 (H318) Resp. Sens.1 (H334) STOT SE 3 (H335) Aquatic Acute 1 (H400) M Factor 1 Aquatic Chronic 2 (H411)	0.1-<1

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS Classifications.

4. FIRST-AID MEASURES

4.1 Description of First Aid Measures:	
Eye	Flush eyes with large quantities of water for several minutes, holding the eyelids apart. Get 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. May damage fertility or the unborn child.	
4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:	
If asthma symptoms or shortness of breath develop, get immediate medical attention.	

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use media appropriate for surrounding fire
5.2 Special Hazards Arising from the Substance or Mixture:	
Not classified as flammable or combustible. Thermal decomposition may produce carbon and nitrogen oxides, and hydrogen cyanide.	
5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures/Precautions for Fire Fighters:	Cool fire exposed containers with water spray. Firefighters should wear full emergency equipment and approved positive pressure self-containing breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:
Ventilate the area. Avoid contact with skin, eyes or clothing. Avoid breathing vapors, mist, or spray. Wear appropriate protective clothing as described in Section 8.
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.

Empty containers retain product residues can be hazardous. Follow all SDS precautions when handling empty containers.

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:

2-Propanol	200 ppm TWA, 400 ppm STEL ACGIH TLV 400 ppm TWA OSHA PEL 400 ppm TWA, 500 ppm STEL UK OEL 400 ppm STEL France OEL 200 ppm TWA, 400 ppm STEL DFG MAK 200 ppm TWA, 400 ppm STEL Belgium OEL
Triethanolamine	5 mg/m^3 TWA, ACGIH TLV 5 mg/m^3 TWA, 5 mg/m^3 STEL DFG MAK (Inhalable) 5 mg/m^3 TWA, Belgium OEL
Boric Acid	2 mg/m^3 TWA, 6 mg/m^3 STEL ACGIH TLV (Inhalable) 10 mg/m^3 TWA, 1 mg/m^3 STEL DFG MAK (Inhalable) 2 mg/m^3 TWA, 6 mg/m^3 STEL (Inhalable) Belgium OEL
Subtilisin	0.00006 mg/m^3 Ceiling ACGIH TLV (as 100% crystalline active pure enzyme) 0.00004 mg/m^3 TWA UK OEL 0.00006 mg/m^3 Ceiling Belgium OEL (Note "M")

Biological Exposure Limits: 2-Propanol – End of shift at end of work week. Acetone in urine 40 mg/L.

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 should be needed under normal use. If exposure limits are exceeded an approved respirator or supplied air respirator appropriate should be used. Respirator selection and use should be based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice.

Specific Thermal Hazards: Not applicable

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:			
Appearance:	Clear, green-colored liquid	**Explosive limits:**	Not applicable
Color:	Green	**Physical State:**	Liquid
Odor:	Mint	**Vapor pressure (mmHg):**	Not determined
Odor threshold:	Not determined	**Relative Vapor Pressure @20ºC:** (Air = 1)	Not determined
pH:	7.0	**Density (Relative):**	1.03 @ 35°C
Melting/freezing point:	Not determined	**Solubility:**	Complete
Initial boiling point and range:	Not determined	**Partition coefficient: n-octanol/water:**	Not determined
Flash point:	>200°F	**Auto-ignition temperature:**	Not applicable
Evaporation rate: (n-BuAc = 1)	Not determined	**Decomposition temperature:**	Not applicable
Flammability:	Not flammable	**Kinematic Viscosity**	Not determined

9.2.1 Properties, Safety Characteristics and Test Results for Physical Hazards: None determined.

9.2.2 Other Safety Characteristics: None determined

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: None expected under normal use. Boric acid has been shown to cause adverse reproductive effects in laboratory animals.

Eye Irritation / Damage: Based on available data, the classification criteria are not met.

Corrosivity: Based on available data, the classification criteria are not met.

Sensitization: Subtilisinis classified as a respiratory sensitizer.

Carcinogenicity: Based on available data, the classification criteria are not met. 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 CLP

Mutagenicity: Based on available data, the classification criteria are not met. Isopropyl Alcohol: Negative in mammalian gene mutation assay and in-vivo mammalian bone marrow cytogenetic test. Ttriethanolamine: Negative in the AMES test and chromosomal aberration test in Chinese hamster cells.

Aspiration Hazard: Based on available data, the classification criteria are not met.

Acute Toxicity Data:

ATE Product: Oral LD50: 533 mg/kg

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

Subtilisin: Oral rat LD50 1800 mg/kg

Reproductive Toxicity Data: Product is classified for reproductive toxicity based on US cutoff for Boric Acid. Does not meet the classification criteria in the EU. 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 Single Exposure (STOT-SE): Based on available data, the classification criteria are not met. 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.

Specific Target Organ Toxicity Repeated Exposure (STOT-RE): Based on available data, the classification criteria are not met. 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.

11.2 Information on Other Hazards

11.2.1 Endocrine Disrupting Properties: None known

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

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 Results of PBT/vPvB Assessment: Not required

12.6 Endocrine disrupting Properties: None known.

12.7 Other Adverse Effects: None known

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	N/A	Not Regulated	N/A	N/A	N/A
ADR/RID	N/A	Not Regulated	N/A	N/A	N/A
IMDG	N/A	Not Regulated	N/A	N/A	N/A
IATA/ICAO	N/A	Not Regulated	N/A	N/A	N/A

14.6 Special precautions for user: Not applicable

14.7 Transport in Bulk According to IMO Instruments: 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): This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

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

Clean Water Act (CWA): This material is not regulated under the Clean Water Act

Clean Air Act (CAA): This material is not regulated under the Clean Air Act

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

SARA Section 311/312 (40 CFR 370) Hazard Categories: See OSHA Hazard Classification in Section 2.

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372): None.

State Regulations

California: This product does not contain substances known to the state of California to cause cancer and/or reproductive toxicity.

International Regulations

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

15.2 Chemical Safety Assessment: None required

16. OTHER INFORMATION

HMIS Hazard Rating:
Health –2 Flammability – 1 Reactivity – 0

Full text of Classification abbreviations used in Section 2 and 3:
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
Eye Dam. 1 Eye Damage Category 1
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- Hazardous to the Aquatic Environment – Acute Hazard Category 1
Aquatic Chronic 2 - Hazardous to the Aquatic Environment – Long-Term Hazard Category 2

H225 Highly flammable liquid and vapor.
H302 Harmful if swallowed.
H315 Causes skin irritation.

H318 Causes serious eye damage.
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.
H411 Toxic to aquatic life with long lasting effects

Supersedes: 16 February 2018

Revision Summary: Three year update. Remove EU classifications. Revise format. Changes to all Sections.

Date of SDS Preparation/Revision: 29 March 2021

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