

STERIS Enzymatic Presoak and Cleaner

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations Date of issue: 03/21/2016 Version: 1.0

SECTION 1: Identification

Product Identifier

Product Form: Mixture

Product Name: Klenzyme® Enzymatic Presoak and Cleaner

Product Code: 1673

Intended Use of the Product

Use of the substance/mixture: Enzymatic Presoak and Cleaner.

For professional use only.

Name, Address, and Telephone of the Responsible Party

Company

STERIS Corporation Official Mailing Address:

P.O. Box 147

St. Louis, MO 63166 USA

Street Address: 7501 Page Avenue St. Louis, MO 63133 USA

Telephone Number for Information: 1-800-548-4873 (Customer Service-Healthcare Products)

web: www.steris.com

email: asksteris_msds@steris.com

Emergency Telephone Number

Emergency Number : 1-314-535-1395 or CHEMTREC: 1-800-424-9300

SECTION 2: Hazards Identification

Classification of the Substance or Mixture

Classification (GHS-US) Eye Irrit. 2A H319 Resp. Sens. 1 H334 Full text of H-phrases: see section 16

Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)





Signal Word (GHS-US)

Danger Hazard Statements (GHS-US) H319 - Causes serious eye irritation.

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

P261 - Avoid breathing vapors, mist, spray. Precautionary Statements (GHS-US)

P264 - Wash hands, forearms, and exposed areas thoroughly after handling.

P280 - Wear eye protection, protective gloves, protective clothing. P284 - [In case of inadequate ventilation] wear respiratory protection.

P304+P340 - IF INHALED: Remove person to fresh air and keep at rest in a position

comfortable for breathing.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing.

P337+P313 - If eye irritation persists: Get medical advice/attention.

P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER, a doctor.

P405 - Store locked up.

P501 - Dispose of contents/container in accordance with local, regional, national, territorial,

provincial, and international regulations.

Other Hazards

Other Hazards: Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions. Hazards Not Otherwise Classified (HNOC): Contains Subtilisins (proteolytic enzymes)(9014-01-1). May produce an allergic reaction

Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: Composition/Information On Ingredients

Not applicable

3.2. **Mixture**

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Name	Product identifier	%	Classification (GHS-US)
Triethanolamine	(CAS No) 102-71-6	7-13	Not classified
Sodium tetraborate decahydrate	(CAS No) 1303-96-4	1-5	Eye Irrit. 2A, H319
Subtilisins (proteolytic enzymes)	(CAS No) 9014-01-1	0.1-1	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Resp. Sens. 1, H334 STOT SE 3, H335

Full text of H-phrases: see section 16

SECTION 4: First Aid Measures

4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. IF exposed or concerned: Get medical advice/attention. First-aid Measures After Inhalation: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. When symptoms occur: go into open air and ventilate

suspected area. Call a POISON CENTER or doctor/physician if you feel unwell.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. Obtain medical attention if irritation persists.

First-aid Measures After Ingestion: Call a POISON CENTER/doctor/physician if you feel unwell. Rinse mouth. Do NOT induce vomiting.

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

Symptoms/Injuries: Causes irritation. Exposure may produce an allergic reaction.

Symptoms/Injuries After Inhalation: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Symptoms/Injuries After Skin Contact: May cause skin irritation.

Symptoms/Injuries After Eye Contact: Causes serious eye irritation. Symptoms may include: Redness, pain, swelling, itching, burning, tearing, and blurred vision.

Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects.

Chronic Symptoms: Not applicable.

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

If medical advice is needed, have product container or label at hand.

SECTION 5: Fire-Fighting Measures

5.1. Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: Do not use a heavy water stream. A heavy water stream may spread burning liquid.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not flammable.

Explosion Hazard: Product is not explosive. Contains substances that are combustible dusts. If dried, allowed to accumulate may form combustible dust concentrations in air that could ignite and cause an explosion. Take appropriate precautions.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Do not allow run-off from fire fighting to enter drains or water sources. Do not breathe fumes from fires or vapors from decomposition. Exercise caution when fighting any chemical fire.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Aldehydes.

SECTION 6: Accidental Release Measures

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Handle in accordance with good industrial hygiene and safety practice. Avoid all contact with skin, eyes, or clothing. Avoid breathing vapor, mist, or spray.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clear up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material, then place in suitable container. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8: Exposure Controls and Personal Protection. See Section 13, Disposal Considerations

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SECTION 7: Handling And Storage

7.1. Precautions for Safe Handling

Precautions for Safe Handling: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear recommended personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing vapors, mist, spray. Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work. Wash contaminated clothing before reuse.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Protect from moisture.

Storage Conditions: Store in a dry, cool and well-ventilated place. Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Incompatible Products: Strong acids. Strong bases. Strong oxidizers.

7.3. Specific End Use(s)

Enzymatic Presoak and Cleaner. For professional use only.

SECTION 8: Exposure Controls/Personal Protection

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established Exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), OSHA (PEL), Canadian provincial governments, or the Mexican government.

Subtilisins (proteolytic enzy		
USA ACGIH	ACGIH Ceiling (mg/m³)	0.00006 mg/m³
USA NIOSH	NIOSH REL (STEL) (mg/m³)	0.00006 mg/m ³
Alberta	OEL Ceiling (mg/m³)	0.00006 mg/m ³
British Columbia	OEL Ceiling (mg/m³)	0.00006 mg/m ³
Manitoba	OEL Ceiling (mg/m³)	0.00006 mg/m ³
New Brunswick	OEL Ceiling (mg/m³)	0.00006 mg/m³ (proteolytic enzymes)
Newfoundland & Labrador	OEL Ceiling (mg/m³)	0.00006 mg/m³
Nova Scotia	OEL Ceiling (mg/m³)	0.00006 mg/m³
Nunavut	OEL Ceiling (mg/m³)	0.00006 mg/m³ (Proteolytic enzymes)
Northwest Territories	OEL Ceiling (mg/m³)	0.00006 mg/m³ (Proteolytic enzymes)
Ontario	OEL Ceiling (mg/m³)	0.00006 mg/m³
Prince Edward Island	OEL Ceiling (mg/m³)	0.00006 mg/m³
Québec	PLAFOND (mg/m³)	0.00006 mg/m³ (Proteolytic enzymes)
Saskatchewan	OEL Ceiling (mg/m³)	0.00006 mg/m³
Yukon	OEL Ceiling (mg/m³)	0.00006 mg/m³ (Proteolytic enzymes)
Triethanolamine (102-71-6)		
USA ACGIH	ACGIH TWA (mg/m³)	5 mg/m³
Alberta	OEL TWA (mg/m³)	5 mg/m ³
British Columbia	OEL TWA (mg/m³)	5 mg/m³
Manitoba	OEL TWA (mg/m³)	5 mg/m ³
New Brunswick	OEL TWA (mg/m³)	5 mg/m³
Newfoundland & Labrador	OEL TWA (mg/m³)	5 mg/m³
Nova Scotia	OEL TWA (mg/m³)	5 mg/m³
Ontario	OEL TWA (mg/m³)	3.1 mg/m ³
Ontario	OEL TWA (ppm)	0.5 ppm
Prince Edward Island	OEL TWA (mg/m³)	5 mg/m³
Québec	VEMP (mg/m³)	5 mg/m³
Saskatchewan	OEL STEL (mg/m³)	10 mg/m ³
Saskatchewan	OEL TWA (mg/m³)	5 mg/m³
Sodium tetraborate decahy	drate (1303-96-4)	
USA ACGIH	ACGIH TWA (mg/m³)	2 mg/m³ (inhalable fraction)
USA ACGIH	ACGIH STEL (mg/m³)	6 mg/m³ (inhalable fraction)
USA NIOSH	NIOSH REL (TWA) (mg/m³)	5 mg/m³
Alberta	OEL STEL (ppm)	3 ppm
Alberta	OEL TWA (mg/m³)	1 mg/m ³
British Columbia	OEL STEL (mg/m³)	6 mg/m³ (inhalable)
British Columbia	OEL TWA (mg/m³)	2 mg/m³ (inhalable)
Manitoba	OEL STEL (mg/m³)	6 mg/m³ (inhalable fraction)
Manitoba	OEL TWA (mg/m³)	2 mg/m³ (inhalable fraction)
New Brunswick	OEL TWA (mg/m³)	5 mg/m ³
Newfoundland & Labrador	OEL STEL (mg/m³)	6 mg/m³ (inhalable fraction)
Newfoundland & Labrador	OEL TWA (mg/m³)	2 mg/m³ (inhalable fraction)
Nova Scotia	OEL STEL (mg/m³)	6 mg/m³ (inhalable fraction)
Nova Scotia	OEL TWA (mg/m³)	2 mg/m³ (inhalable fraction)
Nunavut	OEL STEL (mg/m³)	10 mg/m ³
Nunavut	OEL TWA (mg/m³)	5 mg/m³
Northwest Territories	OEL STEL (mg/m³)	10 mg/m³
Northwest Territories	OEL TWA (mg/m³)	5 mg/m³
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Ontario	OEL STEL (mg/m³)	6 mg/m³ (inhalable)
Ontario	OEL TWA (mg/m³)	2 mg/m³ (inhalable)
Prince Edward Island	OEL STEL (mg/m³)	6 mg/m³ (inhalable fraction)
Prince Edward Island	OEL TWA (mg/m³)	2 mg/m³ (inhalable fraction)
Québec	VEMP (mg/m³)	5 mg/m³
Saskatchewan	OEL STEL (mg/m³)	6 mg/m³ (inhalable fraction)
Saskatchewan	OEL TWA (mg/m³)	2 mg/m³ (inhalable fraction)

8.2. **Exposure Controls**

Appropriate Engineering Controls

: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment

Gloves. Protective goggles. Protective clothing. Insufficient ventilation: wear respiratory protection.









Materials for Protective Clothing

Hand Protection Eve Protection

Skin and Body Protection

Respiratory Protection

Other Information

Chemically resistant materials and fabrics

Wear chemically resistant protective gloves.

Chemical safety goggles.

Wear appropriate personal protective equipment. Wash contaminated clothing before reuse.

If exposure limits are exceeded or irritation is experienced, approved respiratory protection

should be worn.

When using, do not eat, drink or smoke.

SECTION 9: Physical And Chemical Properties

Information on Basic Physical and Chemical Properties

Physical State Liquid **Appearance** Amber Spicy, floral Odor Odor Threshold No data available 7.5 - 8

Evaporation rate Melting Point Freezing Point **Boiling Point** Flash Point

Solubility

Auto-ignition Temperature **Decomposition Temperature** Flammability (solid, gas) Vapor Pressure

Relative Vapor Density at 20 °C Specific Gravity

Partition coefficient: n-octanol/water Viscosity

Explosion Data - Sensitivity to Mechanical Impact

Explosion Data - Sensitivity to Static Discharge

No data available 1.086 g/ml

No data available

Complete in water No data available No data available

Not expected to present an explosion hazard due to mechanical impact. Not expected to present an explosion hazard due to static discharge.

Other Information

: < 1 % VOC content

SECTION 10: Stability And Reactivity

Reactivity:

Hazardous reactions will not occur under normal conditions.

Chemical Stability:

Stable under normal conditions.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

Conditions to Avoid:

Direct sunlight. Extremely high or low temperatures. Humidity. Incompatible materials.

Incompatible Materials:

Strong acids. Strong bases. Strong oxidizers.

10.6 Hazardous Decomposition Products:

Thermal decomposition generates: Carbon oxides (CO, CO₂). Aldehydes.

SECTION 11: Toxicological Information

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11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Subtilisins (proteolytic enzymes) (9014-01-1)	
LD50 Oral Rat	3700 mg/kg
ATE (Oral)	1,800.00 mg/kg body weight
Triethanolamine (102-71-6)	
LD50 Oral Rat	6400 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
Sodium tetraborate decahydrate (1303-96-4)	
LD50 Oral Rat	3493 mg/kg
LD50 Dermal Rabbit	> 10000 mg/kg

Skin Corrosion/Irritation: Not classified (pH: 7.5 - 8)

Serious Eye Damage/Irritation: Causes serious eye irritation. (pH: 7.5 - 8)

Respiratory or Skin Sensitization: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Germ Cell Mutagenicity: Not classified Teratogenicity: No data available Carcinogenicity: Not classified

Triethanolamine (102-71-6)	
IARC group	3
National Toxicology Program (NTP) Status	Evidence of Carcinogenicity.

Reproductive Toxicity: Not applicable

Specific Target Organ Toxicity (Single Exposure): Not classified Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Symptoms/Injuries After Skin Contact: May cause skin irritation.

Symptoms/Injuries After Eye Contact: Causes serious eye irritation. Redness, pain, swelling, itching, burning, tearing, and blurred vision.

Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects.

Chronic Symptoms: Not applicable

SECTION 12: Ecological Information

12.1. Toxicity

Subtilisins (proteolytic enzymes) (9014-01-1)		
LC50 Fish 1	14.6 mg/l	
EC50 Daphnia 1	0.306 mg/l	
ErC50 (algae)	0.513 (0.513 - 1.48) mg/l	
NOEC chronic fish	2 mg/l	
Triethanolamine (102-71-6)		
LC50 Fish 1	10600 (10600 - 13000) mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])	
LC 50 Fish 2	1000 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])	

12.2. Persistence and Degradability

Not applicable

12.3. Bioaccumulative Potential

Triethanolamine (102-71-6)	
BCF fish 1	3.9
Log Pow	-2.53

12.4. Mobility in Soil

No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: Disposal Considerations

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations.

Ecology – Waste Materials: Avoid release to the environment.

SECTION 14: Transport Information

14.1 In Accordance with DOT

Not regulated for transport

14.2 In Accordance with IMDG

Not regulated for transport

14.3 In Accordance with IATA

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Not regulated for transport

14.4 In Accordance with TDG

Not regulated for transport

SECTION 15: Regulatory Information

15.1 US Federal Regulations

Klenzyme® Enzymatic Presoak and Cleaner

SARA Section 311/312 Hazard Classes Immediate (acute) health hazard Delayed (chronic) health hazard

Subtilisins (proteolytic enzymes) (9014-01-1)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Triethanolamine (102-71-6)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Sodium tetraborate decahydrate (1303-96-4)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2 US State Regulations

Triethanolamine (102-71-6)

- U.S. Massachusetts Right To Know List
- U.S. New Jersey Right to Know Hazardous Substance List
- U.S. Pennsylvania RTK (Right to Know) List

Sodium tetraborate decahydrate (1303-96-4)

- U.S. Massachusetts Right To Know List
- U.S. New Jersey Right to Know Hazardous Substance List
- U.S. Pennsylvania RTK (Right to Know) List

15.3. Canadian Regulations

Klenzyme® Enzymatic Presoak and Cleaner

Subtilisins (proteolytic enzymes) (9014-01-1)

Listed on the Canadian DSL (Domestic Substances List)

Triethanolamine (102-71-6)

Listed on the Canadian DSL (Domestic Substances List)

Listed on the Canadian IDL (Ingredient Disclosure List)

Sodium tetraborate decahydrate (1303-96-4)

Listed on the Canadian DSL (Domestic Substances List)

Listed on the Canadian IDL (Ingredient Disclosure List)

This product has been classified in accordance with the hazard criteria of the Hazardous Products Regulations (HPR) and the SDS contains all of the information required by HPR.

SECTION 16: Other Information

Revision : 03/21/2016

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication

Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

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Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Resp. Sens. 1	Respiratory sensitisation Category 1
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
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

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Klenzyme®

NFPA fire hazard

Enzymatic Presoak and Cleaner

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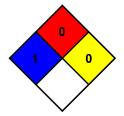
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NFPA health hazard : 1 - Exposure could cause irritation but only minor residual injury even if no treatment is given.

: 0 - Materials that will not burn.

NFPA reactivity : 0 - Normally stable, even under fire exposure conditions,

and are not reactive with water.



Party Responsible for the Preparation of This Document

STERIS Corporation

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS NA, Mex GHS

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