

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
 Trade name : Prolystica[®] 2X Concentrate Enzymatic Presoak and Cleaner
 Product code : 1C33

1.2. Relevant identified uses of the substance or mixture and uses advised against

Industrial/Professional use spec : Product for hospital and professional use only. Not for home use.
 Use of the substance/mixture : Enzymatic Presoak and Cleaner

1.3. Details of the supplier of the safety data sheet

STERIS Corporation
 P. O. Box 147, St. Louis, MO 63166, US
 Telephone Number for Information: 1-800-548-4873 (Customer Service-Healthcare Products)

1.4. Emergency telephone number

Emergency number : US Emergency Telephone No.1-314-535-1395 (STERIS); 1-800-424-9300 (CHEMTREC)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification

Skin Corr. 2 H315
 Eye Dam. 2B H320
 Resp. Sens. 1 H334
 STOT SE 3 H335

2.2. Label elements

GHS-US labelling

Hazard pictograms (GHS-US) :



GHS07

GHS08

Signal word (GHS-US) :

Danger

Hazard statements (GHS-US) :

H315 - Causes skin irritation
 H320 - Causes eye irritation
 H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
 H335 - May cause respiratory irritation

Precautionary statements (GHS-US) :

P260 - Do not breathe mist, spray, vapours
 P261 - Avoid breathing dust/fume/gas/mist/vapours/spray
 P264 - Wash thoroughly after handling
 P280 - Wear protective gloves/protective clothing/eye protection/face protection
 P284 - In case of inadequate ventilation, wear respiratory protection
 P301+P330+P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting
 P302+P352 - IF ON SKIN: Wash with plenty of soap and water
 P304+P340 - IF INHALED: Remove person to fresh air and keep 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
 P312 - Call a POISON CENTER or doctor/physician if you feel unwell
 P303+P361+P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower
 P332+P313 - If skin irritation occurs: Get medical advice/attention.

2.3. Other hazards

No additional information available.

2.4. Unknown acute toxicity (GHS-US)

No data available.

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SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable.

Full text of H-phrases: See section 16.

3.2. Mixture

Name	Product identifier	%	GHS-US classification
Ethanolamine	(CAS No) 141-43-5	1 - 5	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation), H332 Skin Corr. 1A, H314 STOT SE 3, H335
Alcohols, C9-11, ethoxylated	(CAS No) 68439-46-3	1 - 5	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318
Glycerin	(CAS No) 56-81-5	1 - 5	Not classified
Citric acid	(CAS No) 77-92-9	1 - 5	Eye Irrit. 2A, H319
N,N-Dimethyloctadecylamine oxide	(CAS No) 2571-88-2	1 - 2	Skin Irrit. 2, H315 Eye Dam. 1, H318
Subtilisins (proteolytic enzymes)	(CAS No) 9014-01-1	0.1 - 1	Skin Irrit. 2, H315 Eye Dam. 1, H318 Resp. Sens. 1, H334 STOT SE 3, H335

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 you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Remove patient to fresh air and keep at rest in a position comfortable for breathing. If not breathing, give artificial respiration. Get medical attention.
First-aid measures after skin contact	: Immediately flush skin with plenty of water for at least 15 minutes. Remove immediately all contaminated clothing. Rinse skin with water. Get medical advice/attention.
First-aid measures after eye contact	: In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately get medical attention.
First-aid measures after ingestion	: If victim completely conscious/alert. Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician. Give water or milk if the person is fully conscious.

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

Symptoms/injuries	: Causes skin and eye irritation.
Symptoms/injuries after inhalation	: Inhalation of vapors or spray/mists may cause allergy or asthma symptoms or breathing difficulties. May cause respiratory irritation.
Symptoms/injuries after skin contact	: Causes skin irritation.
Symptoms/injuries after eye contact	: Causes eye irritation.
Symptoms/injuries after ingestion	: Can occur: Gastrointestinal disturbance.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for primary source of fire.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Hazardous decomposition products may be released during prolonged heating like smokes, carbon monoxide and dioxide, nitrogen oxides (NOx).

5.3. Advice for firefighters

Firefighting instructions	: Exercise caution when fighting any chemical fire.
Protective equipment for firefighters	: Use self-contained breathing apparatus. Do not enter fire area without proper protective equipment, including respiratory protection. Wear a self contained breathing apparatus.
Other information	: Hazardous decomposition products may be released during prolonged heating like smokes, carbon monoxide and dioxide, nitrogen oxides (NOx).

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Do not breathe fumes, vapors. Avoid contact with skin, eyes and clothes.

6.1.1. For non-emergency personnel

Protective equipment : Wear protective gloves and eye/face protection. For further information refer to Section 8: "Exposure controls/personal protection".

Emergency procedures : Stop leak if safe to do so. Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Comply with applicable local, national and international regulation. Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials. Residue may be washed down with water. Product may be flushed to a sanitary sewer with copious amounts of water, if in accordance with local, state, or national legislation.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Product for hospital and professional use only. Read label before use. Provide good ventilation in process area to prevent formation of vapor. Avoid all eye and skin contact and do not breathe vapor and mist. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

Hygiene measures : Take care for general good hygiene and housekeeping. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Provide adequate ventilation. A washing facility/water for eye and skin cleaning purposes should be present.

Storage conditions : Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.

Incompatible materials : Strong oxidizing agents.

Storage temperature : < 32 °C (< 90 °F).

Storage area : Store in dry, cool, well-ventilated area.

Special rules on packaging : Correctly labelled.

7.3. Specific end use(s)

No additional information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Ethanolamine (141-43-5)		
USA ACGIH	ACGIH TWA (ppm)	3 ppm
USA ACGIH	ACGIH STEL (ppm)	6 ppm
USA - IDLH	US IDLH (ppm)	30 ppm
USA - NIOSH	NIOSH REL (TWA) (mg/m ³)	8 mg/m ³
USA - NIOSH	NIOSH REL (TWA) (ppm)	3 ppm
USA - NIOSH	NIOSH REL (STEL) (mg/m ³)	15 mg/m ³
USA - NIOSH	NIOSH REL (STEL) (ppm)	6 ppm
USA OSHA	OSHA PEL (TWA) (mg/m ³)	6 mg/m ³

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Ethanolamine (141-43-5)		
USA OSHA	OSHA PEL (TWA) (ppm)	3 ppm

Subtilisins (proteolytic enzymes) (9014-01-1)		
USA - NIOSH	NIOSH REL (STEL) (mg/m ³)	0.00006 mg/m ³
USA ACGIH	ACGIH Ceiling (mg/m ³)	0.00006 mg/m ³

Glycerin (56-81-5)		
USA - OSHA	OSHA PEL (TWA) (mg/m ³)	5 mg/m ³

8.2. Exposure controls

- Appropriate engineering controls : Ensure adequate ventilation. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.
- Personal protective equipment : Avoid all unnecessary exposure. Personal protective equipment should be selected based upon the conditions under which this product is handled or used. Protective clothing. Gloves. Protective goggles.



- Hand protection : Wear rubber gloves or latex-free gloves.
- Eye protection : Wear chemical splash goggles.
- Skin and body protection : Wear suitable protective clothing.
- Respiratory protection : Work in well-ventilated zones or use proper respiratory protection.
- Other information : Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

- Physical state : Liquid
- Appearance : Clear to slightly hazy
- Color : Colorless to straw
- Odor : Floral odor
- Odor threshold : No data available
- pH : 7.5 - 8.1
- pH solution : 8 (1% solution)
- Relative evaporation rate (butyl acetate=1) : No data available
- Melting point : No data available
- Freezing point : No data available
- Boiling point : No data available
- Flash point : No data available
- Auto-ignition temperature : No data available
- Decomposition temperature : No data available
- Flammability (solid, gas) : No data available
- Vapor pressure : No data available
- Relative vapor density at 20 °C : No data available
- Relative density : No data available
- Density : (Approximately) 1.035 g/ml Specific Gravity
- Solubility : Water: Completely soluble
- Log Pow : No data available
- Log Kow : No data available
- Viscosity, kinematic : No data available
- Viscosity, dynamic : No data available
- Explosive properties : No data available

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Oxidizing properties : No data available
Explosive limits : No data available.

9.2. Other information

No additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available.

10.2. Chemical stability

Stable under normal conditions of use.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Heat. Light.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products may be released during prolonged heating like smokes, carbon monoxide and dioxide. Nitrogen oxides (NOx).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Causes skin and eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause respiratory irritation.

Prolystica [®] 2X Concentrate Enzymatic Presoak and Cleaner	
LD50 oral rat	> 2000 mg/kg
Ethanolamine (141-43-5)	
LD50 oral rat	1720 mg/kg
LD50 dermal rabbit	1 ml/kg
ATE CLP (oral)	500,000 mg/kg bodyweight
ATE CLP (dermal)	1,100,000 mg/kg bodyweight
ATE CLP (dust,mist)	1,500 mg/l/4h
NOAEL (oral, rat, 90 days)	>= mg/kg bodyweight/day
Glycerin (56-81-5)	
LD50 dermal rabbit	> 10 g/kg
LC50 inhalation rat (mg/l)	> 570 mg/m ³ (Exposure time: 1h)
Subtilisins (proteolytic enzymes) (9014-01-1)	
LD50 oral rat	3700 mg/kg
Alcohols, C9-11, ethoxylated (68439-46-3)	
LD50 oral rat	1400 mg/kg
LD50 dermal rabbit	> 2 g/kg
ATE CLP (oral)	1400,000 mg/kg bodyweight

Skin corrosion/irritation : Causes skin irritation
pH: 7.5 - 8.1
Serious eye damage/irritation : Causes eye irritation
pH: 7.5 - 8.1
Respiratory or skin sensitisation : May cause allergy or asthma symptoms or breathing difficulties if inhaled
Based on available data, the classification criteria are not met
Germ cell mutagenicity : Not classified
Based on available data, the classification criteria are not met
Carcinogenicity : Not classified
Based on available data, the classification criteria are not met

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Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (single exposure)	: May cause respiratory irritation Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Inhalation of vapors or spray/mists may cause allergy or asthma symptoms or breathing difficulties. May cause respiratory irritation Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

Citric acid (77-92-9)	
LC50 fishes 1	1516 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [Static])
EC50 Daphnia 1	120 mg/l (Exposure time: 72 h - Species: Daphnia magna)
Ethanolamine (141-43-5)	
LC50 fishes 1	227 mg/l (Exposure time: 96 h - Species: Pimephales promelas [Flow-through])
EC50 Daphnia 1	65 mg/l (Exposure time: 48 h - Species: Daphnia magna)
EC50 other aquatic organisms 1	15 mg/l (Exposure time: 72 h - Species: Desmodesmus subspicatus)
LC50 fish 2	3684 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [Static])
Glycerin (56-81-5)	
LC50 fishes 1	51 - 57 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [Static])
EC50 Daphnia 1	> 500 mg/l (Exposure time: 24 h - Species: Daphnia magna)

12.2. Persistence and degradability

Prolystica [®] 2X Concentrate Enzymatic Presoak and Cleaner	
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

Prolystica [®] 2X Concentrate Enzymatic Presoak and Cleaner	
Bioaccumulative potential	Not established.
Citric acid (77-92-9)	
Log Pow	-1.72 (at 20 °C)
Ethanolamine (141-43-5)	
Log Pow	-1.91 (at 25 °C)
Glycerin (56-81-5)	
BCF fish 1	(no bioaccumulation)
Log Pow	-1.76

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 in a safe manner in accordance with local/national regulations. Do not re-use empty containers.
Additional information	: Empty containers should be thoroughly rinsed with large quantities of clean water. Empty containers should be taken for recycling, recovery or waste in accordance with local regulation.
Ecology - waste materials	: Avoid release to the environment.

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SECTION 14: Transport information

In accordance with DOT

No dangerous good in sense of transport regulations.

Additional information

Other information : No supplementary information available.

ADR

Transport document description : Non-hazardous.

Transport by sea

IMDG Class : Non-hazardous.

Air transport

ICAO/IATA Class : Non-hazardous.

SECTION 15: Regulatory information

15.1. US Federal regulations

Citric acid (77-92-9)

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

Ethanolamine (141-43-5)

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

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

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

Alcohols, C9-11, ethoxylated (68439-46-3)

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

N,N-Dimethyloctadecylamine oxide (2571-88-2)

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

15.2. International regulations

No additional information available.

15.3. US State regulations

This product contains a chemical known to the State of California to cause cancer.

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SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhalation) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation, Category 2A
Flam. Liq. 4	Flammable liquids Category 4
Resp. Sens. 1	Sensitisation — Respiratory, Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H227	Combustible liquid
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H320	Causes eye irritation
H332	Harmful if inhaled
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335	May cause respiratory irritation

NFPA health hazard

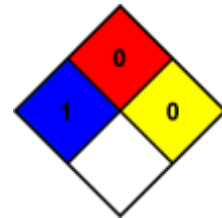
: 1 - Exposure could cause irritation but only minor residual injury even if no treatment is given.

NFPA fire hazard

: 0 - Materials that will not burn.

NFPA reactivity

: 0 - Normally stable, even under fire exposure conditions, and are not reactive with water.



SDS US (GHS HazCom 2012)-Series US

The information on this sheet is not a specification and does not guarantee specific properties. The information is intended to provide general knowledge as to health and safety based upon our knowledge of the handling, storage and use of the product. It is not applicable to unusual or non-standard uses of the product or where instruction or recommendations are not followed.