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](GHS07.png) ![GHS08](GHS08.png)
   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+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.
Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner
Safety Data Sheet
according to the federal final rule of hazard communication revised on 2012 (HazCom 2012)

SECTION 3: Composition/information on ingredients

3.1. Substance
Not applicable.
Full text of H-phrases: See section 16.

3.2. Mixture

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>GHS-US classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanolamine</td>
<td>(CAS No) 141-43-5</td>
<td>1 - 5</td>
<td>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</td>
</tr>
<tr>
<td>Alcohol, C9-11, ethoxylated</td>
<td>(CAS No) 68439-46-3</td>
<td>1 - 5</td>
<td>Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318</td>
</tr>
<tr>
<td>Glycerin</td>
<td>(CAS No) 56-81-5</td>
<td>1 - 5</td>
<td>Not classified</td>
</tr>
<tr>
<td>Citric acid</td>
<td>(CAS No) 77-92-9</td>
<td>1 - 5</td>
<td>Eye Irrit. 2A, H319</td>
</tr>
<tr>
<td>N,N-Dimethyloctadecylamine oxide</td>
<td>(CAS No) 2571-88-2</td>
<td>1 - 2</td>
<td>Skin Irrit. 2, H315, Eye Dam. 1, H318</td>
</tr>
<tr>
<td>Subtilisins (proteolytic enzymes)</td>
<td>(CAS No) 9014-01-1</td>
<td>0.1 - 1</td>
<td>Skin Irrit. 2, H315, Eye Dam. 1, H318, Resp. Sens. 1, H334 STOT SE 3, H335</td>
</tr>
</tbody>
</table>

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).
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

<table>
<thead>
<tr>
<th>Ethanolamine (141-43-5)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>USA ACGIH ACGIH TWA (ppm)</td>
<td>3 ppm</td>
</tr>
<tr>
<td>USA ACGIH ACGIH STEL (ppm)</td>
<td>6 ppm</td>
</tr>
<tr>
<td>USA - IDLH US IDLH (ppm)</td>
<td>30 ppm</td>
</tr>
<tr>
<td>USA - NIOSH NIOSH REL (TWA) (mg/m³)</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>USA - NIOSH NIOSH REL (TWA) (ppm)</td>
<td>3 ppm</td>
</tr>
<tr>
<td>USA - NIOSH NIOSH REL (STEL) (mg/m³)</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>USA - NIOSH NIOSH REL (STEL) (ppm)</td>
<td>6 ppm</td>
</tr>
<tr>
<td>USA OSHA OSHA PEL (TWA) (mg/m³)</td>
<td>6 mg/m³</td>
</tr>
</tbody>
</table>
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
Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner

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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/m³ (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
Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner
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according to the federal final rule of hazard communication revised on 2012 (HazCom 2012)

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)**
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 fishes</td>
<td>1516 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [Static])</td>
</tr>
<tr>
<td>EC50 Daphnia</td>
<td>120 mg/l (Exposure time: 72 h - Species: Daphnia magna)</td>
</tr>
</tbody>
</table>

**Ethanolamine (141-43-5)**
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 fishes</td>
<td>227 mg/l (Exposure time: 96 h - Species: Pimephales promelas [Flow-through])</td>
</tr>
<tr>
<td>EC50 Daphnia</td>
<td>65 mg/l (Exposure time: 48 h - Species: Daphnia magna)</td>
</tr>
<tr>
<td>EC50 other aquatic organisms</td>
<td>15 mg/l (Exposure time: 72 h - Species: Desmodesmus subspicatus)</td>
</tr>
<tr>
<td>LC50 fish</td>
<td>3684 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [Static])</td>
</tr>
</tbody>
</table>

**Glycerin (56-81-5)**
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 fishes</td>
<td>51 - 57 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [Static])</td>
</tr>
<tr>
<td>EC50 Daphnia</td>
<td>&gt; 500 mg/l (Exposure time: 24 h - Species: Daphnia magna)</td>
</tr>
</tbody>
</table>

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)**
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Log Pow</td>
<td>-1.72 (at 20 °C)</td>
</tr>
</tbody>
</table>

**Ethanolamine (141-43-5)**
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Log Pow</td>
<td>-1.91 (at 25 °C)</td>
</tr>
</tbody>
</table>

**Glycerin (56-81-5)**
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCF fish</td>
<td>(no bioaccumulation)</td>
</tr>
<tr>
<td>Log Pow</td>
<td>-1.76</td>
</tr>
</tbody>
</table>

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.
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.
SECTION 16: Other information

Full text of H-phrases:

<table>
<thead>
<tr>
<th>H227</th>
<th>Combustible liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>H312</td>
<td>Harmful in contact with skin</td>
</tr>
<tr>
<td>H314</td>
<td>Causes severe skin burns and eye damage</td>
</tr>
<tr>
<td>H315</td>
<td>Causes skin irritation</td>
</tr>
<tr>
<td>H318</td>
<td>Causes serious eye damage</td>
</tr>
<tr>
<td>H319</td>
<td>Causes serious eye irritation</td>
</tr>
<tr>
<td>H320</td>
<td>Causes eye irritation</td>
</tr>
<tr>
<td>H332</td>
<td>Harmful if inhaled</td>
</tr>
<tr>
<td>H334</td>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled</td>
</tr>
<tr>
<td>H335</td>
<td>May cause respiratory irritation</td>
</tr>
</tbody>
</table>

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)-Steries 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.