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

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

1.2.2. Uses advised against
- No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer:
- STERIS Corporation
  - P. O. Box 147, St. Louis, MO 63166, US
  - Telephone Number for Information: 1-800-548-4873 (Customer Service-Healthcare Products)
  - US Emergency Telephone No.1-314-535-1395 (STERIS); 1-800-424-9300 (CHEMTREC)

Supplier:
- Device Technologies Australia Pty Ltd
  - 1 Garigal Road
  - Belrose NSW 2085, Australia
  - Telephone: 1-800-429-551
  - Fax: 612-9975-5711

- Device Technologies New Zealand Limited
  - 47 Arrenway Drive, Albany, Auckland, 0632
  - New Zealand
  - Tel: 0508 338 423, Fax: 649 9913 2009.

1.4. Emergency telephone number
- Emergency number: 1 800 429 551 (24 hours) Australia
  - 0508 338 423 (New Zealand)
  - 1-703-741-5970 (CHEMTREC International)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to NOHSC:

Classification according to Regulation (EC) No. 1272/2008 [CLP]
- Skin Corr. 2 H315
- Eye Dam. 2B H320
- Resp. Sens. 1 H334
- STOT SE 3 H335

Full text of H-phrases: see section 16

Adverse physicochemical, human health and environmental effects
- No additional information available
2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP):

Signal word (CLP): Danger
Hazard statements (CLP):
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 (CLP):
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

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

<table>
<thead>
<tr>
<th>Name</th>
<th>CAS No</th>
<th>EC No</th>
<th>%</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,2-Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>~20</td>
<td>Not classified</td>
</tr>
<tr>
<td>Alcohols, C9-11, ethoxylated surfactant</td>
<td>68439-46-3</td>
<td>614-482-0</td>
<td>1-5</td>
<td>Eye Dam. 1, H318</td>
</tr>
<tr>
<td>Glycerin</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>1-5</td>
<td>Not classified</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>1-5</td>
<td>Eye Irrit. 2, H319</td>
</tr>
<tr>
<td>N,N-Dimethyloctadecylamine oxide</td>
<td>2571-88-2</td>
<td>219-919-5</td>
<td>1-2</td>
<td>Skin Irrit. 2, H315</td>
</tr>
<tr>
<td>Subtilisins (proteolytic enzymes)</td>
<td>9014-01-1</td>
<td>232-752-2</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>
<tr>
<td>Other Non-Hazardous Components</td>
<td>NA</td>
<td></td>
<td>Up to 100</td>
<td>NA</td>
</tr>
</tbody>
</table>

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 you feel unwell, seek medical advice (show the label where possible)

First-aid measures after inhalation: Remove 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/Take off immediately all contaminated clothing. Rinse skin with water/shower. 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 after inhalation:** Inhaling vapours 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 |

| For non-emergency personnel | 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 |

| For emergency responders | 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 vapour. Avoid all eye and skin contact and do not breathe vapour 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 |
Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner
Safety Data Sheet
according to Regulation (EC) No. 453/2010

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>Substances</th>
<th>United Kingdom WEL TWA (mg/m³)</th>
<th>United Kingdom WEL STEL (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,2-Propylene glycol (57-55-6)</td>
<td>10 mg/m³</td>
<td>30 mg/m³</td>
</tr>
<tr>
<td>Subtilisins (proteolytic enzymes) (9014-01-1)</td>
<td>0,00004 mg/m³ (calculated)</td>
<td>0,00006 mg/m³ (calculated)</td>
</tr>
<tr>
<td>Glycerin (56-81-5)</td>
<td>10 mg/m³</td>
<td>30 mg/m³ (calculated)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Liquid</td>
</tr>
<tr>
<td>Appearance</td>
<td>Clear to slightly hazy liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>Colorless to straw</td>
</tr>
<tr>
<td>Odour</td>
<td>Floral odour</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>7.5 - 8.1</td>
</tr>
<tr>
<td>pH solution</td>
<td>8 (1 % solution)</td>
</tr>
<tr>
<td>Relative evaporation rate (butylacetate=1)</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point</td>
<td>No data available</td>
</tr>
<tr>
<td>Freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>No data available</td>
</tr>
</tbody>
</table>
### Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner

#### Safety Data Sheet

according to Regulation (EC) No. 453/2010

**Flash point**: No data available

**Self ignition temperature**: No data available

**Decomposition temperature**: No data available

**Flammability (solid, gas)**: No data available

**Vapour pressure**: No data available

**Relative vapour density at 20 °C**: No data available

**Density**: (Approximately) 1.035 g/ml Specific Gravity

**Solubility**: Water: completely soluble

**Log Pow**: No data available

**Viscosity, kinematic**: No data available

**Viscosity, dynamic**: No data available

**Explosive properties**: No data available

**Oxidising 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.

LD50 oral rat: > 2000 mg/kg

LD50 oral rat (1,2-Propanediol): 20000 mg/kg

LD50 dermal rabbit: 20800 mg/kg

ATE (oral): 20000,000 mg/kg bodyweight

ATE (dermal): 20800,000 mg/kg bodyweight

**Glycerin (56-81-5)**

LD50 dermal rabbit: > 10 g/kg

LC50 inhalation rat (mg/l): > 570 mg/m³ (Exposure time: 1 h)

**Skin corrosion/irritation**: Causes skin and eye 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

**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

Reproductive toxicity : Not classified  
Based on available data, the classification criteria are not met

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Inhalation of vapours or spray/mists may cause allergy or asthma symptoms or breathing difficulties. May cause respiratory irritation.

Aspiration hazard : Not classified  
Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity

1,2-Propylene glycol (57-55-6)

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 fishes 1</td>
<td>51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [Static])</td>
</tr>
<tr>
<td>EC50 Daphnia 1</td>
<td>&gt; 10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)</td>
</tr>
<tr>
<td>EC50 other aquatic organisms 1</td>
<td>19000 mg/l (Exposure time: 96 h - Species: Pseudokirchneriella subcapitata)</td>
</tr>
<tr>
<td>LC50 fish 2</td>
<td>41 - 47 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [Static])</td>
</tr>
<tr>
<td>EC50 Daphnia 2</td>
<td>&gt; 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])</td>
</tr>
</tbody>
</table>

Citric acid (77-92-9)

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 fishes 1</td>
<td>1516 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [Static])</td>
</tr>
<tr>
<td>EC50 Daphnia 1</td>
<td>120 mg/l (Exposure time: 72 h - Species: Daphnia magna)</td>
</tr>
</tbody>
</table>

Glycerin (56-81-5)

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 fishes 1</td>
<td>51 - 57 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [Static])</td>
</tr>
<tr>
<td>EC50 Daphnia 1</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

1,2-Propylene glycol (57-55-6)

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCF fish 1</td>
<td>&lt; 1</td>
</tr>
</tbody>
</table>

Citric acid (77-92-9)

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Log Pow</td>
<td>-1,72 (at 20 °C)</td>
</tr>
</tbody>
</table>

Glycerin (56-81-5)

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCF fish 1</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. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

: 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.
**Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner**

**Safety Data Sheet**

generated by Regulation (EC) No. 453/2010

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**Ecology - waste materials**: Avoid release to the environment

### SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

**14.1. UN number**

No dangerous good in sense of transport regulations

**14.2. UN proper shipping name**

Not applicable

**14.3. Transport hazard class(es)**

Not applicable

**14.4. Packing group**

Not applicable

**14.5. Environmental hazards**

- Dangerous for the environment: No
- Marine pollutant: No
- Other information: No supplementary information available

**14.6. Special precautions for user**

**14.6.1. Overland transport**

- Transport category (ADR): Non-Hazardous

**14.6.2. Transport by sea**

Non-Hazardous

**14.6.3. Air transport**

Non-Hazardous

**14.6.4. Inland waterway transport**

Non-Hazardous

**14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable

### SECTION 15: Regulatory information

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

**15.1.1. Australia**

- AICS Listed or Exempt. Hazard Category: Irritant

**15.1.2. EU-Regulations**

- No REACH Annex XVII restrictions
- Contains no REACH candidate substance

**15.1.3. National regulations – New Zealand**

- HSNO Approval Number: HSR002526
- HSNO Group Standard Name: Cleaning Products (Corrosive) Group Standard 2006

**15.2. Chemical safety assessment**

No chemical safety assessment has been carried out

### SECTION 16: Other information

**Revision Date**: 10/04/2018

**Other information**: None

Full text of H- and EUH- phrases:

- **Acute Tox. 4 (Dermal)**: Acute toxicity (dermal), Category 4
- **Acute Tox. 4 (Inhalation:dust,mist)**: Acute toxicity (inhalation:dust,mist), Category 4
- **Acute Tox. 4 (Oral)**: Acute toxicity (oral), Category 4
- **Eye Dam. 1**: Serious eye damage/eye irritation, Category 1
- **Eye Dam. 2B**: Causes serious eye damage
- **Eye Irrit. 2**: Serious eye damage/eye irritation, Category 2
- **Resp. Sens. 1**: Sensitisation — Respiratory, Category 1
- **Skin Corr. 1B**: Skin corrosion/irritation, Category 1B
- **Skin Irrit. 2**: Skin corrosion/irritation, Category 2
- **STOT SE 3**: Specific target organ toxicity (single exposure), Category 3
- **H302**: Harmful if swallowed
### Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner

**Safety Data Sheet**

according to Regulation (EC) No. 453/2010

<table>
<thead>
<tr>
<th>H312</th>
<th>Harmful in contact with skin</th>
</tr>
</thead>
<tbody>
<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>

SDS EU (REACH Annex II)

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.