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 at rest in a position comfortable for breathing. If not breathing, give artificial respiration. Get medical attention.
- 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>Product identifier</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>(CAS No) 57-55-6</td>
<td>~20</td>
<td>Not classified</td>
</tr>
<tr>
<td></td>
<td>(EC no) 200-338-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohols, C9-11, ethoxylated surfactant</td>
<td>(CAS No) 68439-46-3</td>
<td>1-5</td>
<td>Eye Dam. 1, H318</td>
</tr>
<tr>
<td></td>
<td>(EC no) 614-482-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glycerin</td>
<td>(CAS No) 56-81-5</td>
<td>1-5</td>
<td>Not classified</td>
</tr>
<tr>
<td></td>
<td>(EC no) 200-289-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Citric acid</td>
<td>(CAS No) 77-92-9</td>
<td>1-5</td>
<td>Eye Irrit. 2, H319</td>
</tr>
<tr>
<td></td>
<td>(EC no) 201-069-1</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(REACH No) 01-2119457026-42-0067</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N,N-Dimethyloctadecylamine oxide</td>
<td>(CAS No) 2571-88-2</td>
<td>1-2</td>
<td>Skin Irr. 2, H315, Eye Dam. 1, H318</td>
</tr>
<tr>
<td></td>
<td>(EC no) 219-919-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subtilisins (proteolytic enzymes)</td>
<td>(CAS No) 9014-01-1</td>
<td>0.1</td>
<td>Skin Irr. 2, H315, Eye Dam. 1, H318, Resp. Sens. 1, H334, STOT SE 3, H335</td>
</tr>
<tr>
<td></td>
<td>(EC no) 232-752-2</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(EC index no) 647-012-00-8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Non-Hazardous Components</td>
<td>NA</td>
<td></td>
<td>Up to 100</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.
Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner
Safety Data Sheet
according to Regulation (EC) No. 453/2010

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

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.

Symptoms/injuries: Can occur: gastrointestinal disturbance
Symptoms/injuries after inhalation: Inhaling 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

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 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>Control parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,2-Propylene glycol (57-55-6)</td>
<td></td>
</tr>
<tr>
<td>United Kingdom: WEL TWA (mg/m³)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>United Kingdom: WEL TWA (ppm)</td>
<td>150 ppm</td>
</tr>
<tr>
<td>United Kingdom: WEL STEL (mg/m³)</td>
<td>30 mg/m³</td>
</tr>
<tr>
<td>United Kingdom: WEL STEL (ppm)</td>
<td>450 ppm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Subtilisins (proteolytic enzymes) (9014-01-1)</th>
<th>Control parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>United Kingdom: WEL TWA (mg/m³)</td>
<td>0,00004 mg/m³</td>
</tr>
<tr>
<td>United Kingdom: WEL STEL (mg/m³)</td>
<td>0,00012 mg/m³ (calculated)</td>
</tr>
<tr>
<td>USA - ACGIH: ACGIH Ceiling (mg/m³)</td>
<td>0,00006 mg/m³</td>
</tr>
<tr>
<td>USA - NIOSH: NIOSH REL (STEL) (mg/m³)</td>
<td>0,00006 mg/m³</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Glycerin (56-81-5)</th>
<th>Control parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>United Kingdom: WEL TWA (mg/m³)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>United Kingdom: WEL STEL (mg/m³)</td>
<td>30 mg/m³ (calculated)</td>
</tr>
<tr>
<td>USA - OSHA: OSHA PEL (TWA) (mg/m³)</td>
<td>5 mg/m³</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 goggle
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>Properties</th>
<th>Values</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>

4/2/2019 EN (English) SDS Ref: AU1C33
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
Relative density : 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.

Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner
LD50 oral rat : > 2000 mg/kg

1,2-Propylene glycol (57-55-6)
LD50 oral rat : 20000 mg/kg
LD50 dermal rabbit : 20800 mg/kg
ATE (oral) : 200000,000 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
Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner
Safety Data Sheet
according to Regulation (EC) No. 453/2010

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)
LC50 fishes 1 51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [Static])
EC50 Daphnia 1 > 10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
EC50 other aquatic organisms 1 19000 mg/l (Exposure time: 96 h - Species: Pseudokirchneriella subcapitata)
LC50 fish 2 41 - 47 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [Static])
EC50 Daphnia 2 > 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

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)

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

Persist 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

Bioaccumulative potential: Not established

1,2-Propylene glycol (57-55-6)
BCF fish 1 < 1

Citric acid (77-92-9)
Log Pow -1,72 (at 20 °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. Results of PBT and vPvB assessment

No additional information available

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 regulations
**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

15.1.1. **EU-Regulations**
No REACH Annex XVII restrictions
Contains no REACH candidate substance

15.1.2. **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: 04/02/2019
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
- **H312**: Harmful in contact with skin
### Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner

### Safety Data Sheet

according to Regulation (EC) No. 453/2010

<table>
<thead>
<tr>
<th>H314</th>
<th>Causes severe skin burns and eye damage</th>
</tr>
</thead>
<tbody>
<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.