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

### 1.1. Product identifier

<table>
<thead>
<tr>
<th>Product form</th>
<th>: Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade name</td>
<td>: Prolystica® Ultra Concentrate Enzymatic Cleaner</td>
</tr>
<tr>
<td>Product code</td>
<td>: 1C03</td>
</tr>
</tbody>
</table>

### 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**: Instrument 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 Irrit. 2 H315
- Eye Dam. 2B H320
- Resp. Sens. 1 H334

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):

- GHS07
- GHS08

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. This may occur with prolonged or frequent exposure to dried dusts or aerosol form of the concentrated product

Precautionary statements (CLP):
- P261 - Avoid breathing mist, spray, vapours
- P280 - Wear protective gloves/protective clothing and eye/face protection
- P284 - In case of inadequate ventilation, wear respiratory protection
- P304+P313 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
- P305+P351+P338 - If in eyes: Get medical advice/attention
- P302+P352 - IF ON SKIN: Wash with plenty of soap and water
- P305+P351+P338 - IF INhaled: Remove person to fresh air and keep comfortable for breathing. If not breathing, give artificial respiration. Get medical attention
- P332+P313 - If skin irritation occurs: Get medical advice/attention
- P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor
- P362+P364 - Take off contaminated clothing and wash it before reuse
- P501 - Dispose of contents/container to comply with applicable local, national and international regulation

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 (EC no) 200-338-0</td>
<td>~ 26</td>
<td>Not classified</td>
</tr>
<tr>
<td>Alcohols, C12-14-secondary, ethoxylated</td>
<td>(CAS No) 84133-50-6 (EC no) 617-534-0</td>
<td>10-30</td>
<td>Skin Irrit. 2, H315, Eye Dam. 1, H318</td>
</tr>
<tr>
<td>Subtilisins (proteolytic enzymes)</td>
<td>(CAS No) 9014-01-1 (EC no) 232-752-2 (EC index no) 647-012-00-8</td>
<td>1-5</td>
<td>Skin Irrit. 2, H315, Eye Dam. 1, H318, Resp. Sens. 1, H334, STOT SE 3, H335</td>
</tr>
<tr>
<td>Glycerine</td>
<td>(CAS No) 56-81-5 (EC no) 200-338-2</td>
<td>5-10</td>
<td>Not classified</td>
</tr>
<tr>
<td>Other Non-Hazardous Components</td>
<td>NA</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

03/29/2019 EN (English) SDS Ref: 1C03AU 2/7
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 eye and skin irritation.
Symptoms/injuries after inhalation: In case of repeated or prolonged exposure: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause respiratory irritation.
Symptoms/injuries after skin contact: Irritating to eyes and skin.
Symptoms/injuries after eye contact: Irritating to eyes.
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, Aldehydes.

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

03/29/2019 EN (English) SDS Ref: 1C03AU 3/7
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>1,2-Propylene glycol (57-55-6)</th>
<th>1,2-Propylene glycol (57-55-6)</th>
</tr>
</thead>
<tbody>
<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>Subtilisins (proteolytic enzymes) (9014-01-1)</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>

8.2. Exposure controls

Appropriate engineering controls: Ensure adequate ventilation. Control airborne concentrations below the exposure limits. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

Personal protective equipment: Personal protective equipment should be selected based upon the conditions under which this product is handled or used. Protective clothing, Gloves, Protective goggles. Avoid all unnecessary exposure.

Hand protection: Wear rubber gloves or latex-free gloves
Eye protection: Safety glasses
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>Physical state</th>
<th>Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Clear</td>
</tr>
<tr>
<td>Colour</td>
<td>Amber</td>
</tr>
<tr>
<td>Odour</td>
<td>Mild chemical odor</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>6,5 - 7,5 Approximately</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>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Self ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density at 20 °C</td>
<td>No data available</td>
</tr>
</tbody>
</table>
### Relative density
- No data available

### Density
- 1.035 g/ml

### Solubility
- Water: completely soluble

### Log Pow
- No data available

### Viscosity, kinematic
- No data available

### Viscosity, dynamic
- No data available

### Explosive 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. Aldehydes.

### 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.

<table>
<thead>
<tr>
<th>Prolystica® Ultra Concentrate Enzymatic Cleaner</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 oral rat</td>
<td>&gt; 2000 mg/kg</td>
</tr>
</tbody>
</table>

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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 oral rat</td>
<td>20000 mg/kg</td>
</tr>
<tr>
<td>LD50 dermal rabbit</td>
<td>20800 mg/kg</td>
</tr>
<tr>
<td>ATE (oral)</td>
<td>20000.000 mg/kg bodyweight</td>
</tr>
<tr>
<td>ATE (dermal)</td>
<td>20800.000 mg/kg bodyweight</td>
</tr>
</tbody>
</table>

**Glycerine (56-81-5)**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 oral rat</td>
<td>12600 mg/kg</td>
</tr>
</tbody>
</table>

**Alcohols, C12-14-secondary, ethoxylated (84133-50-6)**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 oral rat</td>
<td>2100 mg/kg</td>
</tr>
<tr>
<td>ATE (oral)</td>
<td>2100,000 mg/kg bodyweight</td>
</tr>
</tbody>
</table>

##### Skin corrosion/irritation
- Causes skin irritation
  - pH: 6.5 - 7.5

##### Serious eye damage/irritation
- Causes eye irritation
  - pH: 6.5 - 7.5

##### 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
Prolystica® Ultra Concentrate Enzymatic Cleaner
Instrument Cleaner
Safety Data Sheet
according to Regulation (EC) No. 453/2010

Specific target organ toxicity (single exposure): Not classified
Based on available data, the classification criteria are not met

Specific target organ toxicity (repeated exposure): Not classified
Based on available data, the classification criteria are not met

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

Potential adverse human health effects and symptoms: Harmful if swallowed

SECTION 12: Ecological information

12.1. Toxicity

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

<table>
<thead>
<tr>
<th>Parameter</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>

Alcohols, C12-14-secondary, ethoxylated (84133-50-6)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 fishes 1</td>
<td>3.2 mg/l (Exposure time: 96 h - Species: Pimephales promelas)</td>
</tr>
<tr>
<td>EC50 Daphnia 1</td>
<td>3.2 mg/l (Exposure time: 48 h - Species: water flea)</td>
</tr>
</tbody>
</table>

12.2. Persistence and degradability

Prolystica® Ultra Concentrate Enzymatic Cleaner

Persistence and degradability:
The surfactant(s) contained in this preparation 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® Ultra Concentrate Enzymatic Cleaner

Bioaccumulative potential: Not established

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

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

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. Ensure all national/local regulations are observed.

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
Prolystica® Ultra Concentrate Enzymatic Cleaner
Instrument Cleaner
Safety Data Sheet
according to Regulation (EC) No. 453/2010

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
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: HSR002530
HSNO Group Standard Name: Cleaning Products (Subsidiary Hazards) Group Standard 2006

15.2. Chemical safety assessment
No chemical safety assessment has been carried out

SECTION 16: Other information

Revision Date : 03/29/2019
Other information : None

Full text of H- and EUH-phrases:

Eye Dam. 1 Serous eye damage/eye irritation, Category 1
Eye Dam. 2B Serious eye damage/eye irritation, Category 2B
Resp. Sens. 1 Sensitisation — Respiratory, Category 1
Skin Irrit. 2 Skin corrosion/irritation, Category 2
STOT SE 3 Specific target organ toxicity (single exposure), Category 3
H315 Causes skin irritation
H318 Causes serious eye damage
H320 Causes eye irritation
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335 May cause respiratory irritation
H400 Very toxic to aquatic life

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.