# Prolystica® Ultra Concentrate HP Enzymatic Cleaner

**Safety Data Sheet**

according to Regulation (EC) No. 453/2010

Date of issue: 02/22/2018

Version: 1.0

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

### 1.1. Product identifier

| Product form | : Mixture |
| Trade name | Prolystica® Ultra Concentrate HP Enzymatic Cleaner |
| Product code | 1C16 |

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

- Use of the substance/mixture: Enzymatic Cleaner

### 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)

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## 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]**

- Oral Tox. 5: H303  
- Derm Tox. 5: H313  
- Skin Irrit. 2: H315  
- Eye Dam. 2B: H320  
- Inhalation Tox. 5: H333  
- Resp. Sens. 1: H334  
- STOT SE 2: 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):  
  - GHS07  
  - GHS08  
  - Danger

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02/22/2018  
EN (English)  
SDS ID: 1C16AU  
Page 1
Hazard statements (CLP) : H303 - May be harmful if swallowed.
H313 - May be harmful in contact with skin.
H315 - Causes skin irritation.
H320 - Cause eye irritation.
H333 - May be harmful if inhaled.
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 foam of the concentrated product.
H335 - May cause respiratory irritation.
Precautionary statements (CLP) : P261 - Avoid breathing dust, mist, spray, vapours.
P264 - Wash hand thoroughly after handling.
P271 – Use only in well-ventilated area.
P280 - Wear eye protection, protective clothing, protective gloves.
P284 - Wear respiratory protection.
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.
P304+P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position 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.
P310 - Immediately call a POISON CENTER or doctor/physician.
P332+P313 - If skin irritation occurs: Get medical attention.
P337+P313 - If eye irritation persists: Get medical attention.
P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
P362+P364 - Take off contaminated clothing and wash it before reuse.

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>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 Irr. 2, H315 Eye Dam. 1, H318 Resp. Sens. 1, H334 STOT SE 3, H335</td>
</tr>
<tr>
<td>Alcohols, C12-14-secondary, ethoxylated</td>
<td>(CAS No) 84133-50-6</td>
<td>5 - 10</td>
<td>Skin Irrit. 2, H315 Eye Dam. 1, H318</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 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/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 : May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
Symptoms/injuries after skin contact : Prolonged or repeated contact with the skin may cause dermatitis.
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 surrounding fire.

5.2. Special hazards arising from the substance or mixture
No additional information available.

5.3. Advice for firefighters
Firefighting instructions: Exercise caution when fighting any chemical fire.
Protective equipment for firefighters: 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, unburned hydrocarbons.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
General measures: Do not breathe fumes, vapours. Avoid contact with skin, eyes and clothes. Stop leak if safe to do so. Spilled material may present a slipping hazard.

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: 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: Spills may be picked up with a mop and followed by a water rinse. Small spills may be flushed to a sanitary sewer with copious amounts of water, if in accordance with local, state or national legislation. Residue may be washed down with water. Large spills: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials. Dispose of contents/container to comply with applicable local, national and international regulations.

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: 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. Keep the packing dry and well sealed to prevent contamination and absorption of humidity. Store away from direct sunlight or other heat sources.
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
Prolystica® Ultra Concentrate HP Enzymatic Cleaner
Safety Data Sheet
according to Regulation (EC) No. 453/2010

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:
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>Colour</td>
<td>Yellow</td>
</tr>
<tr>
<td>Odour</td>
<td>Mild chemical odour</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>7.3</td>
</tr>
<tr>
<td>Relative evaporation rate (butyl acetate=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>Auto-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>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>1.055 g/ml Specific Gravity</td>
</tr>
<tr>
<td>Solubility</td>
<td>Water: Completely soluble</td>
</tr>
<tr>
<td>Log Pow</td>
<td>No data available</td>
</tr>
<tr>
<td>Log Kow</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Oxidising properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive limits</td>
<td>No data available</td>
</tr>
</tbody>
</table>

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 smoke, carbon monoxide and dioxide. Aldehydes.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

#### Acute toxicity
- Not classified
  - Based on available data, the classification criteria are not met.

<table>
<thead>
<tr>
<th>Substance</th>
<th>LD50 oral rat</th>
<th>LD50 dermal rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prolystica® Ultra Concentrate HP Enzymatic Cleaner</td>
<td>&gt; 2000 mg/kg</td>
<td>&gt; 2000 mg/kg</td>
</tr>
<tr>
<td>Subtilisins (proteolytic enzymes) (9014-01-1)</td>
<td>3700 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Alcohols, C12-14-secondary, ethoxylated (84133-50-6)</td>
<td>2100 mg/kg</td>
<td>2100.000 mg/kg de peso corporal</td>
</tr>
</tbody>
</table>

#### Skin corrosion/irritation
- Not classified
  - Based on available data, the classification criteria are not met

#### Serious eye damage/irritation
- May cause eye irritation.
  - pH: 7.3

#### Respiratory or skin sensitisation
- May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

#### 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
  - 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

## SECTION 12: Ecological information

### 12.1. Toxicity

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50 fishes 1</th>
<th>EC50 Daphnia 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohols, C12-14-secondary, ethoxylated (84133-50-6)</td>
<td>3.2 mg/l (Exposure time: 96 h - Species: Pimephales promelas)</td>
<td>3.2 mg/l (Exposure time: 48 h - Species: water flea)</td>
</tr>
</tbody>
</table>
12.2. Persistence and degradability

The surfactant(s) contained in this preparation complies 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.

12.4. Mobility in soil

No additional information available.

12.5. Other adverse effects

Avoid release to the environment.

12.6. 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.

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

No additional information available.

14.6.2. Transport by sea

No additional information available.

14.6.3. Air transport

No additional information available.

14.6.4. Inland waterway transport

Not subjected to ADN : No additional information available.

14.6.5. Rail transport

Carriage Prohibited (RID) : No additional information available.

14.6.6. Australia


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

15.1.2. EU-Regulations
Contains no REACH candidate substance.

15.1.3. National regulations
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 : 02/22/2018


Other information : None.

Full text of H-phrases:

<table>
<thead>
<tr>
<th>Acute Tox. 5 (oral)</th>
<th>Acute toxicity (oral), Category 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox. 5 (dermal)</td>
<td>Acute toxicity (dermal), Category 5</td>
</tr>
<tr>
<td>Acute Tox. 5 (inhalation)</td>
<td>Acute toxicity (inhalation), Category 5</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>Hazardous to the aquatic environment — Acute Hazard, Category 1</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>Hazardous to the aquatic environment — Chronic Hazard, Category 1</td>
</tr>
<tr>
<td>Eye Dam. 1</td>
<td>Serious eye damage/eye irritation, Category 1</td>
</tr>
<tr>
<td>Eye Dam. 2B</td>
<td>Serious eye damage/eye irritation, Category 2B</td>
</tr>
<tr>
<td>Resp. Sens. 1</td>
<td>Sensitisation — Respiratory, Category 1</td>
</tr>
<tr>
<td>Skin Irrit. 2</td>
<td>Skin corrosion/irritation Category 2</td>
</tr>
<tr>
<td>STOT SE 2</td>
<td>Specific target organ toxicity (single exposure) Category 2</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>Specific target organ toxicity (single exposure) Category 3</td>
</tr>
<tr>
<td>H303</td>
<td>May be harmful if swallowed</td>
</tr>
<tr>
<td>H313</td>
<td>May be harmful in contact with skin</td>
</tr>
<tr>
<td>H315</td>
<td>Causes skin irritation</td>
</tr>
<tr>
<td>H320</td>
<td>Causes serious eye damage</td>
</tr>
<tr>
<td>H333</td>
<td>Causes eye irritation</td>
</tr>
<tr>
<td>H334</td>
<td>May be harmful if inhaled</td>
</tr>
<tr>
<td>H335</td>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled</td>
</tr>
<tr>
<td>H318</td>
<td>May cause respiratory irritation</td>
</tr>
<tr>
<td>H400</td>
<td>Very toxic to aquatic life</td>
</tr>
<tr>
<td>H410</td>
<td>Very toxic to aquatic life with long lasting effects</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.