

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)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to NOHSC :

Hazardous Substance. Non-Dangerous Goods.

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

Signal word (CLP) : Danger

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- 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

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Subtilisins (proteolytic enzymes)	(CAS No) 9014-01-1 (EC no) 232-752-2 (EC index no) 647-012-00-8	1 - 5	Skin Irrit. 2, H315 Eye Dam. 1, H318 Resp. Sens. 1, H334 STOT SE 3, H335
Alcohols, C12-14-secondary, ethoxylated	(CAS No) 84133-50-6	5 - 10	Skin Irrit. 2, H315 Eye Dam. 1, H318

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.

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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

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Subtilisins (proteolytic enzymes) (9014-01-1)		
United Kingdom	WEL TWA (mg/m ³)	0,00004 mg/m ³
United Kingdom	WEL STEL (mg/m ³)	0,00012 mg/m ³ (calculated)
USA - ACGIH	ACGIH Ceiling (mg/m ³)	0,00006 mg/m ³
USA - NIOSH	NIOSH REL (STEL) (mg/m ³)	0,00006 mg/m ³

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

- Physical state : Liquid
- Colour : Yellow
- Odour : Mild chemical odour
- Odour threshold : No data available
- pH : 7.3
- 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
- Vapour pressure : No data available
- Relative vapour density at 20 °C : No data available
- Relative density : No data available
- Density : 1.055 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
- Oxidising properties : No data available
- Explosive limits : No data available.

9.2. Other information

No additional information available.

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

Prolystica® Ultra Concentrate HP Enzymatic Cleaner	
LD50 oral rat	> 2000 mg/kg
LD50 dermal rat	> 2000 mg/kg

Subtilisins (proteolytic enzymes) (9014-01-1)	
LD50 oral rat	3700 mg/kg
ATE CLP (oral)	3700.000 mg/kg de peso corporal

Alcohols, C12-14-secondary, ethoxylated (84133-50-6)	
LD50 oral rat	2100 mg/kg
ATE CLP (oral)	2100.000 mg/kg de peso corporal

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

Alcohols, C12-14-secondary, ethoxylated (84133-50-6)	
LC50 fishes 1	3.2 mg/l (Exposure time: 96 h - Species: Pimephales promelas)
EC50 Daphnia 1	3.2 mg/l (Exposure time: 48 h - Species: water flea)

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12.2. Persistence and degradability

Prolystica® Ultra Concentrate HP Enzymatic 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

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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

ADG/HazChem Code: Non-Hazardous.

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

Not applicable.

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SECTION 15: Regulatory information

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

15.1.1. Australia

AICS Listed. Hazard Category: Irritant.

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
Key sources of data	:	REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
Other information	:	None.

Full text of H-phrases:

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

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.