

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

STERIS Corporation
 P. O. Box 147, St. Louis, MO 63166, US
 Telephone Number for Information: 1-800-548-4873 (Customer Service - Healthcare Products)

1.4. Emergency telephone number

Emergency number : US Emergency Telephone No.1-314-535-1395 (STERIS); 1-800-424-9300 (CHEMTREC)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification

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.

2.2. Label elements

GHS-US labelling

Hazard pictograms (GHS-US) :



Signal word (GHS-US) :

Danger

Hazard statements (GHS-US) :

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 aerosol foam of the concentrated product.
 H335 - May cause respiratory irritation.

Precautionary statements (GHS-US) :

P261 - Avoid breathing dust, mist, spray, vapors.
 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.

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2.3. Other hazards

No additional information available.

2.4. Unknown acute toxicity (GHS-US)

No data available.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable.

3.2. Mixture

Name	Product identifier	%	GHS-US classification
Subtilisins (proteolytic enzymes)	(CAS No) 9014-01-1	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.

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, vapors. Avoid contact with skin, eyes and clothes. Stop leak if safe to do so. Spilled material may present a slipping hazard.

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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 vapor. Avoid all eye and skin contact and do not breathe vapor 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

Subtilisins (proteolytic enzymes) (9014-01-1)		
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.

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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
Color : Yellow
Odor : Mild chemical odor
Odor 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
Vapor pressure : No data available
Relative vapor 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.

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.

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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 bodyweight

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

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

Serious eye damage/irritation : Causes 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)

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

Prolystica® Ultra Concentrate HP Enzymatic Cleaner	
Bioaccumulative potential	Not established.

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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

Additional information

- In accordance with DOT
Non-Hazardous
Other information : No supplementary information available.

ADR

- Transport document description : No additional information available

Transport by sea

No additional information available

Air transport

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

Subtilisins (proteolytic enzymes) (9014-01-1)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

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

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. International regulations

Not applicable.

15.3. US State regulations

Not applicable.

SECTION 16: Other information

- Revision Date : 08/11/2015
- Other information : 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 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.

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

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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

NFPA health hazard

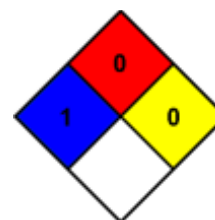
: 1 - Exposure could cause irritation but only minor residual injury even if no treatment is given.

NFPA fire hazard

: 0 - Materials that will not burn.

NFPA reactivity

: 0 - Normally stable, even under fire exposure conditions, and are not reactive with water.



SDS US (GHS HazCom 2012)

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