

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:

STERIS Ireland Limited
 IDA Business and Technology Park
 Tullamore
 County Offaly
 R35 X865
 Ireland.
 Product/Technical Information Phone No: +44 (0) 116 276 8636
 Email: asksteris_msds@steris.com

1.4. Emergency telephone number

Emergency number : +44 (0) 1895 622 639

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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) :



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.
 H335 - May cause respiratory irritation.

Precautionary statements (CLP) :

P260 - Do not breathe mist, spray, vapours.
 P261 - Avoid breathing fume/gas/mist/vapours/spray.
 P264 - Wash thoroughly after handling.
 P280 - Wear protective gloves/protective clothing/eye protection/face protection.

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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 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.
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

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|---|---|---------|---|
| Alcohols, C9-11, ethoxylated surfactant | (CAS No) 68439-46-3 (EC no) 614-482-0 | 1 - 5 | Eye Dam. 1, H318 |
| Glycerin | (CAS No) 56-81-5 (EC no) 200-289-5 | 1 - 5 | Not classified |
| Citric acid | (CAS No) 77-92-9 (EC no) 201-069-1 (REACH No) 01-2119457026-42-0067 | 1 - 5 | Eye Irrit. 2, H319 |
| N,N-Dimethyloctadecylamine oxide | (CAS No) 2571-88-2 (EC no) 219-919-5 | 1 - 2 | Skin Irrit. 2, H315 Eye Dam. 1, H318 |
| Subtilisins (proteolytic enzymes) | (CAS No) 9014-01-1 (EC no) 232-752-2 (EC index no) 647-012-00-8 | 0,1 - 1 | Skin Irrit. 2, H315 Eye Dam. 1, H318 Resp. Sens. 1, H334 STOT SE 3, H335 |

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 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 : Causes skin and eye irritation.
- Symptoms/injuries after inhalation : Inhalation of vapours 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.
- 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, nitrogen oxides (NOx).

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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, vapours. 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.
- 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

| Glycerin (56-81-5) | | |
|---|---------------------------------------|--|
| United Kingdom | WEL TWA (mg/m ³) | 10 mg/m ³ |
| United Kingdom | WEL STEL (mg/m ³) | 30 mg/m ³ (calculated) |
| USA - OSHA | OSHA PEL (TWA) (mg/m ³) | 5 mg/m ³ |
| 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 |

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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

- Physical state : Liquid
- Appearance : Clear to slightly hazy
- Colour : Colourless to straw
- Odour : Floral odour
- Odour threshold : No data available
- pH : 7,5 - 8,1
- pH solution : 8 (1% solution)
- Relative evaporation rate (butylacetate=1) : No data available
- Melting point : No data available
- Freezing point : No data available
- Boiling point : No data available
- 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.

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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. 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.

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| | |
|---------------|--------------|
| LD50 oral rat | > 2000 mg/kg |
|---------------|--------------|

Alcohols, C9-11, ethoxylated surfactant (68439-46-3)

| | |
|--------------------|---------------------------|
| LD50 oral rat | 1400 mg/kg |
| LD50 dermal rabbit | > 2 g/kg |
| ATE CLP (oral) | 1400.000 mg/kg bodyweight |

Glycerin (56-81-5)

| | |
|----------------------------|--|
| LD50 dermal rabbit | > 10 g/kg |
| LC50 inhalation rat (mg/l) | > 570 mg/m ³ (Exposure time: 1 h) |

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

| | |
|---------------|------------|
| LD50 oral rat | 3700 mg/kg |
|---------------|------------|

Skin corrosion/irritation : Causes skin 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

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) : May cause respiratory irritation.

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
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

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) |

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) |

12.2. Persistence and degradability

Prolystica® 2X Concentrate Enzymatic Presoak and 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® 2X Concentrate Enzymatic Presoak and Cleaner

| | |
|---------------------------|------------------|
| Bioaccumulative potential | Not established. |
|---------------------------|------------------|

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| Glycerin (56-81-5) | |
|--------------------|----------------------|
| BCF fish 1 | (no bioaccumulation) |
| Log Pow | -1,76 |

| Citric acid (77-92-9) | |
|-----------------------|------------------|
| Log Pow | -1,72 (at 20 °C) |

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.

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

- IMDG Class : Non-hazardous.

14.6.3. Air transport

- ICAO/IATA Class : Non-hazardous.

14.6.4. Inland waterway transport

No additional information available.

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. EU-Regulations

No REACH Annex XVII restrictions
Contains no REACH candidate substance.

15.1.2. National regulations

No additional information available.

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

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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 |
| H314 | Causes severe skin burns and eye damage |
| H315 | Causes skin irritation |
| H318 | Causes serious eye damage |
| H319 | Causes serious eye irritation |
| H320 | Causes eye irritation |
| H332 | Harmful if inhaled |
| H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled |
| H335 | May cause respiratory irritation |

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.