



# Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

Date of issue: 04/02/2019

Version: 1.0

## 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
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## 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)	:		
Signal word (CLP)	:	GHS07	GHS08
Hazard statements (CLP)	:	Danger	
	:	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 <sup>3</sup> )	10 mg/m <sup>3</sup>
United Kingdom	WEL STEL (mg/m <sup>3</sup> )	30 mg/m <sup>3</sup> (calculated)
USA - OSHA	OSHA PEL (TWA) (mg/m <sup>3</sup> )	5 mg/m <sup>3</sup>

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

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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.

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

LD50 oral rat	> 2000 mg/kg
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#### Alcohols, C9-11, ethoxylated surfactant (68439-46-3)

LD50 oral rat	1400 mg/kg
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LD50 dermal rabbit	> 2 g/kg
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ATE CLP (oral)	1400.000 mg/kg bodyweight
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#### Glycerin (56-81-5)

LD50 dermal rabbit	> 10 g/kg
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LC50 inhalation rat (mg/l)	> 570 mg/m³ (Exposure time: 1 h)
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#### Subtilisins (proteolytic enzymes) (9014-01-1)

LD50 oral rat	3700 mg/kg
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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])
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EC50 Daphnia 1	> 500 mg/l (Exposure time: 24 h - Species: Daphnia magna)
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#### Citric acid (77-92-9)

LC50 fishes 1	1516 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [Static])
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EC50 Daphnia 1	120 mg/l (Exposure time: 72 h - Species: Daphnia magna)
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### 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.
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### 12.3. Bioaccumulative potential

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

Bioaccumulative potential	Not established.
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<b>Glycerin (56-81-5)</b>	
BCF fish 1	(no bioaccumulation)
Log Pow	-1,76
<b>Citric acid (77-92-9)</b>	
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.
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#### 14.6.2. Transport by sea

IMDG Class	: Non-hazardous.
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#### 14.6.3. Air transport

ICAO/IATA Class	: Non-hazardous.
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#### 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.*