



# 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:

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]

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

# Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

### 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 dust/fume/gas/mist/vapours/spray  
P264 - Wash thoroughly after handling  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
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]
1,2-Propylene glycol	(CAS No) 57-55-6 (EC no) 200-338-0	~ 20	Not classified
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
Other Non-Hazardous Components	NA	Up to 100	NA

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 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

# Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

- |                                      |                                                                                                                                                                                                                                                                |
|--------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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) |
|--------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|

### 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, vapors. 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 |
|--------------------|---------------------------------------------------------------------------------------------------------------|

# Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

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

1,2-Propylene glycol (57-55-6)		
United Kingdom	WEL TWA (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup>
United Kingdom	WEL TWA (ppm)	150 ppm
United Kingdom	WEL STEL (mg/m <sup>3</sup> )	30 mg/m <sup>3</sup>
United Kingdom	WEL STEL (ppm)	450 ppm
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>
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>

### 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 liquid
Colour	: Colorless 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

# Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

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

### 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
---------------	--------------

#### 1,2-Propylene glycol (57-55-6)

LD50 oral rat	20000 mg/kg
LD50 dermal rabbit	20800 mg/kg
ATE (oral)	20000,000 mg/kg bodyweight
ATE (dermal)	20800,000 mg/kg bodyweight

#### Glycerin (56-81-5)

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

Skin corrosion/irritation	: Causes skin and eye 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

# Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

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

## SECTION 12: Ecological information

### 12.1. Toxicity

1,2-Propylene glycol (57-55-6)	
LC50 fishes 1	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [Static])
EC50 Daphnia 1	> 10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
EC50 other aquatic organisms 1	19000 mg/l (Exposure time: 96 h - Species: Pseudokirchneriella subcapitata)
LC50 fish 2	41 - 47 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [Static])
EC50 Daphnia 2	> 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
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)
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)

### 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
1,2-Propylene glycol (57-55-6)	
BCF fish 1	< 1
Citric acid (77-92-9)	
Log Pow	-1,72 (at 20 °C)
Glycerin (56-81-5)	
BCF fish 1	(no bioaccumulation)
Log Pow	-1,76

### 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

# Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

### 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

Non-Hazardous

##### 14.6.3. Air transport

Non-Hazardous

##### 14.6.4. Inland waterway transport

Non-Hazardous

#### 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

AICS Listed or Exempt. Hazard Category : Irritant

##### 15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Contains no REACH candidate substance

##### 15.1.2. National regulations – New Zealand

HSNO Approval Number: HSR002526

HSNO Group Standard Name: Cleaning Products (Corrosive) Group Standard 2006

#### 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

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

# Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner

## Safety Data Sheet

according to Regulation (EC) No. 453/2010

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.*