

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Mixture  
 Trade name : Prolystica® 100 PID Prion Inactivating Detergent  
 Product code: : 1P12  
 Product group : Trade product

#### 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 industrial use only  
 Use of the substance/mixture : Prion Inactivating Detergent

##### 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: 1-800-444-9009 (Customer Service-Scientific 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]

Acute Tox. 4 (Oral) H302  
 Skin Corr. 1A H314  
 Eye Dam. 1 H318

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) :

Danger

Hazard statements (CLP) :

H302 - Harmful if swallowed  
 H314 - Causes severe skin burns and eye damage  
 H318 - Causes serious eye damage.

Precautionary statements (CLP) :

P260 - Do not breathe mist, dust, vapours  
 P264 - Wash hands thoroughly after handling  
 P270 - Do not eat, drink or smoke when using this product  
 P280 - Wear protective gloves/protective clothing and eye/face protection  
 P301+P312 - If swallowed, call a doctor if you feel unwell

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according to Regulation (EC) No. 453/2010

P301+P330+P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting  
P303+P361+P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower  
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  
P363 - Wash contaminated clothing 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]
Potassium hydroxide	(CAS No) 1310-58-3 (EC no) 215-181-3 (EC index no) 019-002-00-8	10 - 30	Acute Tox. 4 (Oral), H302 Skin Corr. 1A, H314
Tetrasodium EDTA	(CAS No) 64-02-8 (EC no) 200-573-9 (EC index no) 607-428-00-2	1 - 5	Acute Tox. 4 (Oral), H302 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 to fresh air and keep at rest in a position comfortable for breathing. Immediately get medical attention. If not breathing, give artificial respiration
First-aid measures after skin contact	: Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. If skin irritation occurs: 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. In all cases of doubt, or when symptoms persist, seek medical advice. Remove contact lenses, if present and easy to do. Continue rinsing
First-aid measures after ingestion	: Rinse mouth. Give water to drink if victim completely conscious/alert. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries	: Causes severe skin burns and eye damage
Symptoms/injuries after skin contact	: Severe skin irritant. Effects of skin contact may include: irritation and burn feeling
Symptoms/injuries after eye contact	: Causes serious eye damage. Direct contact may cause severe irritation, pain and burns, possibly severe, and permanent damage including blindness
Symptoms/injuries after ingestion	: May cause burns or irritation of the linings of the mouth, throat, and gastrointestinal tract

### 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. Foam. Dry powder. Carbon dioxide. Water spray. Sand
Unsuitable extinguishing media	: Do not use a heavy water stream

### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Thermal decomposition generates: Fume. Carbon monoxide. Carbon dioxide
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### 5.3. Advice for firefighters

Firefighting instructions	: Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment
Protective equipment for firefighters	: Do not enter fire area without proper protective equipment, including respiratory protection. Use self-contained breathing apparatus
Other information	: Do not mix with: Chlorinated products as this could liberate toxic corrosive chlorine gas

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### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : Do not breathe fumes, vapors. Stop leak if safe to do so. Avoid contact with skin, eyes and clothes

##### 6.1.1. For non-emergency personnel

Protective equipment : Wear suitable protective clothing. Wear protective gloves and eye/face protection. Boots

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 : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Neutralise spill carefully with any weak acid and flush remainder with plenty of water. Collect spillage. Store away from other materials. Local authorities should be advised if significant spillages cannot be contained

#### 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 industrial use only. Provide good ventilation in process area to prevent formation of vapour. Keep container tightly closed to avoid moisture absorption and contamination. Do not breathe gas, fumes, vapour or spray. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Never return unused material to original container

Hygiene measures : Wash hands thoroughly after handling. Take care for general good hygiene and housekeeping. Do not eat, drink or smoke when using this product. Wash contaminated clothing prior to re-use. Separate working clothes from town clothes. Launder separately

#### 7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Comply with applicable regulations. A washing facility/water for eye and skin cleaning purposes should be present. Provide adequate ventilation

Storage conditions : Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use

Incompatible materials : Acids. Oxidizing agents. Organic compounds. Halogenated compounds. Chromium. Magnesium. Zinc. On contact with ordinary metals (steel, galvanized, aluminium) corrosion may occur and generate highly flammable hydrogen gas

Storage temperature : < 24 °C ( < 75°F )

Heat and ignition sources : Store away from excessive heat . Remove all sources of ignition

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

Potassium hydroxide (1310-58-3)		
USA ACGIH	ACGIH Ceiling (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>
USA NIOSH	NIOSH REL (ceiling) (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>
United Kingdom	WEL STEL (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>

#### 8.2. Exposure controls

Appropriate engineering controls : Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Local exhaust ventilation is recommended to maintain vapor level below the threshold limit value (TLV). Ensure adequate ventilation

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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. The following pictograms represent the minimum requirements for personal protective equipment. Protective clothing. Gloves. Protective goggles



### Hand protection

: Wear protective gloves, rubber or plastic gloves

### Eye protection

: Chemical goggles or face shield

### Skin and body protection

: Wear suitable protective clothing. Rubber apron, boots

### Respiratory protection

: Work in well-ventilated zones or use proper respiratory protection. Wear appropriate mask

### Environmental exposure controls

: Avoid discharge to the environment

### 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
Colour	: Clear to pale straw
Odour	: Slight chemical odor
Odour threshold	: No data available
pH	: > 13 (concentrate)
pH solution	: 12,3 - 12,8 (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	: ca. 1,27 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 polymerisation does not occur

### 10.4. Conditions to avoid

Incompatible materials. Keep away from heat. Direct sunlight

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### 10.5. Incompatible materials

On contact with ordinary metals (steel, galvanized, aluminium) corrosion may occur and generate highly flammable hydrogen gas. Acids. Oxidizing agent. Organic materials. Halogenated compounds. Magnesium. Zinc. Chromium

### 10.6. Hazardous decomposition products

Carbon monoxide. Carbon dioxide

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Harmful if swallowed

Prolystica® 100 PID Prion Inactivating Detergent	
LD50 oral rat	860 mg/kg
ATE (oral)	500,000 mg/kg bodyweight

Tetrasodium EDTA (64-02-8)	
ATE (oral)	500,000 mg/kg bodyweight

Potassium hydroxide (1310-58-3)	
LD50 oral rat	214 mg/kg
ATE (oral)	500,000 mg/kg bodyweight

Skin corrosion/irritation	: Causes severe skin burns and eye damage pH: > 13 (concentrate)
Serious eye damage/irritation	: Causes serious eye damage Causes severe skin burns and eye damage pH: > 13 (concentrate)
Respiratory or skin sensitisation	: Not classified Based on available data, the classification criteria are not met
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
Potential Adverse human health effects and symptoms	: Based on available data, the classification criteria are not met

## SECTION 12: Ecological information

### 12.1. Toxicity

Prolystica® 100 PID Prion Inactivating Detergent	
LC50 fishes 1	> 750 mg/l ( 10% Solution )

Tetrasodium EDTA (64-02-8)	
LC50 fishes 1	41 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [Static])
EC50 Daphnia 1	610 mg/l (Exposure time: 24 h - Species: Daphnia magna)
EC50 other aquatic organisms 1	1,01 mg/l (Exposure time: 72 h - Species: Desmodesmus subspicatus)
LC50 fish 2	59,8 mg/l (Exposure time: 96 h - Species: Pimephales promelas [Static])

Potassium hydroxide (1310-58-3)	
LC50 fishes 1	80 mg/l (Exposure time: 96 h - Species: Gambusia affinis [Static])

### 12.2. Persistence and degradability

Prolystica® 100 PID Prion Inactivating Detergent	
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

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Bioaccumulative potential : Not established

#### Potassium hydroxide (1310-58-3)

Log Pow : 0,65

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Other adverse effects

: Avoid release to the environment

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations  
Additional information : Dispose of empty containers and wastes safely. Hazardous waste (corrosive) based on pH  
Ecology - waste materials : Avoid release to the environment

## SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

### 14.1. UN number

UN-No : 1814  
UN-No.(IATA) : 1814  
UN-No. (IMDG) : 1814

### 14.2. UN proper shipping name

Proper Shipping Name : POTASSIUM HYDROXIDE SOLUTION  
Transport document description : UN 1814 POTASSIUM HYDROXIDE SOLUTION, 8, II

### 14.3. Transport hazard class(es)

Class (UN) : 8  
Class (IATA) : 8  
Class (IMDG) : 8  
Hazard labels (UN) : 8



### 14.4. Packing group

Packing group (UN) : II

### 14.5. Environmental hazards

Other information : No supplementary information available

### 14.6. Special precautions for user

Special transport precautions : 4 x 1 gal package not approved for air shipment. Road/Rail: ADR/RID Class: UN1814, Potassium Hydroxide Solution, 8, 42(b) ADR

#### 14.6.1. Overland transport

Hazard identification number (Kemler No.) : 80  
Classification code (UN) : C5  
Orange plates :



Transport category (ADR) : 2  
Tunnel restriction code : E  
Limited quantities (ADR) : 1L  
Excepted quantities (ADR) : E2  
EAC code : 2R

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### 14.6.2. Transport by sea

No additional information available

### 14.6.3. Air 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 : 01/10/2018

Sources of Key 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- and EUH-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage

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.*