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
                               : P267 - 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
Prolystica® 100 PID Prion Inactivating Detergent
Safety Data Sheet
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

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium hydroxide</td>
<td>(CAS No) 1310-58-3</td>
<td>10 - 30</td>
<td>Acute Tox. 4 (Oral), H302 Skin Corr. 1A, H314</td>
</tr>
<tr>
<td></td>
<td>(EC index no) 019-002-00-8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tetrasodium EDTA</td>
<td>(CAS No) 64-02-8</td>
<td>1 - 5</td>
<td>Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318</td>
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<tr>
<td></td>
<td>(EC no) 200-573-9</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(EC index no) 607-428-00-2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 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


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
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


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)

<table>
<thead>
<tr>
<th>Source</th>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA ACGIH</td>
<td>ACGIH Ceiling (mg/m³)</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>USA NIOSH</td>
<td>NIOSH REL (ceiling) (mg/m³)</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>WEL STEL (mg/m³)</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

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
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.

01/10/2018 EN (English) SDS Ref: 1P12UK
10.5. Incompatible materials

10.6. Hazardous decomposition products
Carbon monoxide. Carbon dioxide

SECTION 11: Toxicological information

11.1. Information on toxicological effects

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prolystica® 100 PID Prion Inactivating Detergent</strong></td>
<td></td>
</tr>
<tr>
<td>LD50 oral rat</td>
<td>860 mg/kg</td>
</tr>
<tr>
<td>ATE (oral)</td>
<td>500,000 mg/kg bodyweight</td>
</tr>
<tr>
<td><strong>Tetrasodium EDTA (64-02-8)</strong></td>
<td></td>
</tr>
<tr>
<td>ATE (oral)</td>
<td>500,000 mg/kg bodyweight</td>
</tr>
<tr>
<td><strong>Potassium hydroxide (1310-58-3)</strong></td>
<td></td>
</tr>
<tr>
<td>LD50 oral rat</td>
<td>214 mg/kg</td>
</tr>
<tr>
<td>ATE (oral)</td>
<td>500,000 mg/kg bodyweight</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation: Causes severe skin burns and eye damage

Serious eye damage/irritation: Causes serious eye damage

Respiratory or skin sensitisation: Not classified

Germ cell mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive toxicity: Not classified

Specific target organ toxicity (single exposure): Not classified

Specific target organ toxicity (repeated exposure): Not classified

Aspiration hazard: Not classified

Potential Adverse human health effects and symptoms: Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prolystica® 100 PID Prion Inactivating Detergent</strong></td>
<td></td>
</tr>
<tr>
<td>LC50 fishes 1</td>
<td>&gt; 750 mg/l (10% Solution)</td>
</tr>
<tr>
<td><strong>Tetrasodium EDTA (64-02-8)</strong></td>
<td></td>
</tr>
<tr>
<td>LC50 fishes 1</td>
<td>41 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [Static])</td>
</tr>
<tr>
<td>EC50 Daphnia 1</td>
<td>610 mg/l (Exposure time: 24 h - Species: Daphnia magna)</td>
</tr>
<tr>
<td>EC50 other aquatic organisms 1</td>
<td>1,01 mg/l (Exposure time: 72 h - Species: Desmodesmus subsicusatus)</td>
</tr>
<tr>
<td>LC50 fish 2</td>
<td>59,8 mg/l (Exposure time: 96 h - Species: Pimephales promelas [Static])</td>
</tr>
<tr>
<td><strong>Potassium hydroxide (1310-58-3)</strong></td>
<td></td>
</tr>
<tr>
<td>LC50 fishes 1</td>
<td>80 mg/l (Exposure time: 96 h - Species: Gambusia affinis [Static])</td>
</tr>
</tbody>
</table>

12.2. Persistence and degradability

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prolystica® 100 PID Prion Inactivating Detergent</strong></td>
<td></td>
</tr>
<tr>
<td>Persistence and degradability</td>
<td>The surfactant(s) contained in this preparation complies 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</td>
</tr>
</tbody>
</table>
12.3. Bioaccumulative potential

<table>
<thead>
<tr>
<th>Prolystica® 100 PID Prion Inactivating Detergent</th>
<th>Bioaccumulative potential</th>
<th>Not established</th>
</tr>
</thead>
</table>

| 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 : 80
Transport category (ADR) : 2
Tunnel restriction code : E
Limited quantities (ADR) : 1L
Excepted quantities (ADR) : E2
EAC code : 2R
Prolystica® 100 PID Prion Inactivating Detergent
Safety Data Sheet
according to Regulation (EC) No. 453/2010

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 |
| 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.