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

1.1. Product identifier
Product form: Mixture
Trade name: Revital-Ox Bedside Concentrate™
Product code: 2D86

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: Enzymatic Cleaner for Endoscopes and surgical equipment

1.2.2. Uses advised against
No additional information available.

1.3. Details of the supplier of the safety data sheet
STERIS Corporation
P. O. Box 147, St. Louis, MO 63166, US
Telephone Number for Information: 1-800-548-4873 (Customer Service - Healthcare Products)

1.4. Emergency telephone number
Emergency number: US Emergency Telephone No.1-314-535-1395 (STERIS); 1-800-424-9300 (CHEMTREC)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture
GHS-US classification
Skin Irrit. 2 H315
Eye Dam. 2B H320
STOT SE 3 H335

Full text of H-phrases: see Section 16.

2.2. Label elements
GHS-US labelling
Hazard pictograms (GHS-US):

Signal word (GHS-US): Warning
Hazard statements (GHS-US):
H315 - Causes skin irritation.
H320 - Causes eye irritation.
H335 - May cause respiratory irritation.

Precautionary statements (GHS-US):
P261 - Avoid breathing mist, spray, vapours.
P264 - Wash hands thoroughly after handling.
P271 – Use only in well-ventilated area.
P280 - Wear eye protection, protective clothing, protective gloves
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.
P304+P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P335+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 – If eye irritation persists: Get medical attention.
P362+P364 - Take off contaminated clothing and wash it 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>GHS-US classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subtilisins (proteolytic enzymes)</td>
<td>(CAS No) 9014-01-1</td>
<td>0.1 – 1.0</td>
<td>Skin Irrit. 2, H315</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Eye Dam. 1, H318</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Resp. Sens. 1, H334</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT SE 3, H335</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute 1, H400</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic 1, H410</td>
</tr>
<tr>
<td>Alcohols, C12-14-secondary, ethoxylated surfactants</td>
<td>(CAS No) 84133-50-6</td>
<td>1 – 5</td>
<td>Skin Irrit. 2, H315</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Eye Dam. 1, H318</td>
</tr>
</tbody>
</table>
**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/Take off 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 after inhalation: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause allergic skin reaction.
- Symptoms/injuries after skin contact: Prolonged or repeated contact with the skin may cause dermatitis.
- 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 surrounding fire.

5.2. **Special hazards arising from the substance or mixture**
No additional information available.

5.3. **Advice for firefighters**
- Firefighting instructions: Exercise caution when fighting any chemical fire.
- Protective equipment for firefighters: 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, unburned hydrocarbons.

**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. Stop leak if safe to do so. Spilled material may present a slipping hazard.

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: 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: Spills may be picked up with a mop and followed by a water rinse. Small spills may be flushed to a sanitary sewer with copious amounts of water, if in accordance with local, state or national legislation. Residue may be washed down with water. Large spills: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials. Dispose of contents/container to Comply with applicable local, national and international regulations.

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: 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. Keep the packing dry and well sealed to prevent contamination and absorption of humidity. Store away from direct sunlight or other heat sources.

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

<table>
<thead>
<tr>
<th>Subtilisins (proteolytic enzymes) (9014-01-1)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>United Kingdom WEL TWA (mg/m³)</td>
<td>0.00004 mg/m³</td>
</tr>
<tr>
<td>United Kingdom WEL STEL (mg/m³)</td>
<td>0.00012 mg/m³ (calculated)</td>
</tr>
<tr>
<td>USA - ACGIH ACGIH Ceiling (mg/m³)</td>
<td>0.00006 mg/m³</td>
</tr>
<tr>
<td>USA - NIOSH NIOSH REL (STEL) (mg/m³)</td>
<td>0.00006 mg/m³</td>
</tr>
</tbody>
</table>

8.2. Exposure controls

Appropriate engineering controls: Ensure adequate ventilation. Control airborne concentrations below the exposure limits.

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 googles or safety glasses.

Skin and body protection: Wear suitable protective clothing.

Respiratory protection: Work in well-ventilated zones or use proper respiratory protection. In fine dispersion/spraying/misting: Wear suitable respirator equipment.

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>Straw, clear to slight haze</td>
</tr>
<tr>
<td>Odour</td>
<td>Mild chemical</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>7.4 – 8.0</td>
</tr>
<tr>
<td>Relative evaporation rate (butyl acetate=1)</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point</td>
<td>No data available</td>
</tr>
<tr>
<td>Freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
</tbody>
</table>
**Revital-Ox Bedside Concentrate™**

**Safety Data Sheet**

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relative vapour density at 20 °C</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>Approx 1.05 g/ml Specific Gravity</td>
</tr>
<tr>
<td>Solubility</td>
<td>Water: Completely soluble</td>
</tr>
<tr>
<td>Log Pow</td>
<td>No data available</td>
</tr>
<tr>
<td>Log Kow</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Oxidising properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive limits</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**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. Aldehydes.

**SECTION 11: Toxicological information**

**11.1. Information on toxicological effects**

<table>
<thead>
<tr>
<th>Effect</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>Not classified</td>
</tr>
<tr>
<td></td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
</tbody>
</table>

**Revital-Ox Bedside Concentrate**

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 oral rat</td>
<td>Not established</td>
</tr>
<tr>
<td>LD50 dermal rat</td>
<td>Not established</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 oral rat</td>
<td>3700 mg/kg</td>
</tr>
<tr>
<td>ATE CLP (oral)</td>
<td>3700.000 mg/kg body weight</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin corrosion/irritation</td>
<td>Causes skin irritation</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>Mildly irritating</td>
</tr>
<tr>
<td>Respiratory or skin sensitisation</td>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>Not classified</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Not classified</td>
</tr>
<tr>
<td>Specific target organ toxicity (single exposure)</td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
<tr>
<td>Specific target organ toxicity (repeated exposure)</td>
<td>Not classified</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>Not classified</td>
</tr>
<tr>
<td></td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
</tbody>
</table>

**SECTION 12: Ecological information**

**12.1. Toxicity**

No additional information available
12.2. Persistence and degradability

Revital-Ox Bedside Concentrate

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.

Biodegradability

Readily biodegradable >60% TCO₂ reduction by day 29, OECD guideline 301B

Aquatic Toxicity

96 hr LC₅₀ > 750 mg/l (fathead minnow)

12.3. Bioaccumulative potential

Revital-Ox Bedside Concentrate

Bioaccumulative potential

Not established.

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. 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. Ensure all national/local regulations are observed.

Ecology - waste materials

Avoid release to the environment.

SECTION 14: Transport information

In accordance with DOT

No dangerous good in sense of transport regulations.

Additional information

Other information

No supplementary information available.

ADR

Transport document description

Non-hazardous.

Transport by sea

IMDG Class

Non-hazardous.

Air transport

ICAO/IATA Class

Non-hazardous.

SECTION 15: Regulatory information

15.1. US Federal regulations

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

Listed on the United States TSCA (Toxic Substances Control Act) inventory.

Alcohols, C12-14-secondary, ethoxylated (84133-50-6)

Listed on the United States TSCA (Toxic Substances Control Act) inventory.

1-Octanamine, N,N-dimethyl-, N-oxide (2605-78-9)

Listed on the United States TSCA (Toxic Substances Control Act) inventory.

15.2. International regulations

No additional information available.

15.3. US State regulations

This product contains a chemical known to the State of California to cause cancer.
SECTION 16: Other information

Revision Date : 03/22/2018
Other information : None.

Full text of H-phrases:

Aquatic Acute 1 Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1 Hazardous to the aquatic environment — Chronic Hazard, Category 1
Eye Dam. 1 Serious eye damage/eye irritation, Category 1
Eye Dam. 2B Serious eye damage/eye irritation, Category 2B
Eye Irrit. 2 Serious eye damage/eye irritation, Category 2
Resp. Sens. 1 Sensitisation — Respiratory, Category 1
Skin Irrit. 2 Skin corrosion/irritation Category 2
STOT SE 3 Specific target organ toxicity (single exposure) Category 3
H315 Causes skin irritation
H319 Causes serious eye irritation
H320 Causes serious eye damage
H334 May be harmful if inhaled
H335 May cause allergy or asthma symptoms or breathing difficulties if inhaled
H318 May cause respiratory irritation
H400 Very toxic to aquatic life
H410 Very toxic to aquatic life with long lasting effects

NFPA health hazard : 1 - Exposure could cause irritation but only minor residual injury even if no treatment is given.
NFPA fire hazard : 0 - Materials that will not burn.
NFPA reactivity : 0 - Normally stable, even under fire exposure conditions, and are not reactive with water.

SDS US (GHS HazCom 2012) - US

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.