



Revital-Ox™ Bedside Concentrate Pre-Cleaning Kit

Safety Data Sheet

According to amending Regulation (EC) No. 1907/2006 (REACH)

Date of issue: 06/06/2023

Version: 1.0

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 Pre-Cleaning Kit
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

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

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin Irrit. 2 H315
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 (GHS-US) :



GHS07

Signal word (GHS-US) : Warning
Hazard statements (GHS-US) : H315 - Causes skin 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.

Revital-Ox™ Bedside Concentrate Pre-Cleaning Kit

Safety Data Sheet

According to amending Regulation (EC) No. 1907/2006 (REACH)

P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313 - If skin irritation occurs: Get medical attention.
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

Name	Product identifier	%	GHS-US classification
Subtilisins (proteolytic enzymes)	(CAS No) 9014-01-1 (EC No) 232-752-2	0.1 – 1.0	Skin Irrit. 2, H315 Eye Dam. 1, H318 Resp. Sens. 1, H334 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
1-Octanamine, N,N-dimethyl-, N-oxide	(CAS No) 2605-78-9 (EC No) 607-854-9	1 – 3	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

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".

Revital-Ox™ Bedside Concentrate Pre-Cleaning Kit

Safety Data Sheet

According to amending Regulation (EC) No. 1907/2006 (REACH)

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

Subtilisins (proteolytic enzymes) (9014-01-1)		
United Kingdom	WEL TWA (mg/m³)	0.00004 mg/m³
United Kingdom	WEL STEL (mg/m³)	0.00012 mg/m³ (calculated)
USA - ACGIH	ACGIH Ceiling (mg/m³)	0.00006 mg/m³
USA - NIOSH	NIOSH REL (STEL) (mg/m³)	0.00006 mg/m³

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 goggles 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 respiratory equipment.

Other information : Do not eat, drink or smoke during use.

Revital-Ox™ Bedside Concentrate Pre-Cleaning Kit

Safety Data Sheet

According to amending Regulation (EC) No. 1907/2006 (REACH)

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

(a) Physical state	:	Liquid
(b) Colour	:	Straw, clear to slight haze
(c) Odour	:	Mild chemical
(d) Melting point/ Freezing point	:	No data available
(e) Boiling point	:	No data available
(f) Flammability (solid, gas)	:	No data available
(g) Lower and upper explosion limit	:	No data available
(h) Flash point	:	No data available
(i) Auto-ignition temperature	:	No data available
(j) Decomposition temperature	:	No data available
(k) pH	:	7.4 – 8.0
(l) Kinematic viscosity	:	No data available
(m) Solubility	:	Water: Completely soluble
(n) Partition coefficient n-octanol/water (log value)	:	No data available
(o) Vapour pressure	:	No data available
(p) Density	:	Approx 1.05 g/ml Specific Gravity
(q) Relative vapour density at 20 °C	:	No data available
(r) Particle Character	:	No data available
Relative evaporation rate (butyl acetate=1)	:	No data available
Relative density	:	No data available
Log Pow	:	No data available
Log Kow	:	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.

9.2.1. Information with regard to physical hazard classes

No additional information available.

9.2.2. Other safety characteristics

No additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available.

10.2. Chemical stability

Stable under normal conditions.

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 hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity	:	Not classified
Based on available data, the classification criteria are not met.		

Revital-Ox™ Bedside Concentrate Pre-Cleaning Kit

Safety Data Sheet

According to amending Regulation (EC) No. 1907/2006 (REACH)

Revital-Ox™ Bedside Concentrate Pre-Cleaning Kit	
LD50 oral rat	Not established
LD50 dermal rat	Not established

Subtilisins (proteolytic enzymes) (9014-01-1)	
LD50 oral rat	3700 mg/kg
ATE CLP (oral)	3700.000 mg/kg body weight

Skin corrosion/irritation	: Causes skin irritation
Serious eye damage/irritation	: Mildly irritating pH: 7.4 – 8.0
Respiratory or skin sensitisation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
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.

11.2.1 Endocrine disrupting properties

No additional information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Readily biodegradable. (OECD 301B method). 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.
-------------------	---

12.2. Persistence and degradability

Revital-Ox™ Bedside Concentrate Pre-Cleaning Kit	
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% TCO ₂ 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 Pre-Cleaning Kit	
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. Endocrine disrupting properties

Avoid release to the environment

12.7. Other adverse effects

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.
--------------------------------	---

Revital-Ox™ Bedside Concentrate Pre-Cleaning Kit

Safety Data Sheet

According to amending Regulation (EC) No. 1907/2006 (REACH)

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 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

No additional information available.

14.6.2. Transport by sea

No additional information available.

14.6.3. Air transport

No additional information available.

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 > 0.1 % / SCL.

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	: 06/06/2023
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- 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
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

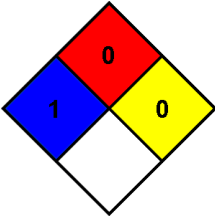
Revital-Ox™ Bedside Concentrate Pre-Cleaning Kit

Safety Data Sheet

According to amending Regulation (EC) No. 1907/2006 (REACH)

H315	Causes skin irritation
H334	May be harmful if inhaled
H335	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H318	Causes serious eye damage
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 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.