SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2020/878)

SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : BEPRO CLEANER TE

Product code : 19500200.

1.2. Relevant identified uses of the substance or mixture and uses advised against

Neutral trienzymatic detergent for the automated processing of surgical and dental instruments.

1.3. Details of the supplier of the safety data sheet

Registered company name : FRANKLAB.

Address : 3 avenue des Frênes.78180.MONTIGNY LE BRETONNEUX.FRANCE.

Telephone : +33 1 39 44 93 40. Fax : +33 1 39 44 93 41.

contact@sterifrance.com

www.sterifrance.com

Downstream user / importer / distributor : W&H Sterilization Srl. Via Bolgara 2. 24060 Brusaporto (GB) - Italy

Phone : +39 035 66 63 000 E-mail : office.sterilization@wh.com Internet : www.wh.com

Email address of the entity responsible for the safety data sheet: contact@sterifrance.com

1.4. Emergency telephone number : +33 1 40 44 30 00.

Association/Organisation : INRS Paris.

Complete list of poison center available at : https://www.eapcct.org/index.php?page=links

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Serious eye damage, Category 1 (Eye Dam. 1, H318).

This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

2.2. Label elements

Detergent mixture (see section 15).

In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard pictograms :

GHS05

Signal Word :

DANGER

Product identifiers :

EC 259-217-6 D-GLUCOSIDE D'HEXYLE

Additional labeling :

Hazard statements :

H318	Causes serious eye damage.

Precautionary statements - Prevention :

P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/ ...

Precautionary statements - Response :

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/doctor/...

2.3. Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) >= 0.1% published by the European CHemicals Agency (ECHA) under article 57 of REACH: http://echa.europa.eu/fr/candidate-list-table

The mixture fulfils neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

The mixture does not contain substances> = 0.1% with endocrine disrupting properties in accordance with the criteria of the Delegated Regulation (EU) 2017/2100 of the Commission or Regulation (EU) 2018/605 of the Commission.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Composition :

Identification	Classification (EC) 1272/2008	Note	%
CAS: 26468-86-0 2-ETHYLHEXANOL ETHOXYLE	GHS07 Wng Eye Irrit. 2, H319		2.5 <= x % < 10
CAS: 54549-24-5 EC: 259-217-6 REACH: 01-2119492545-29 D-GLUCOSIDE D'HEXYLE	GHS05 Dgr Eye Dam. 1, H318		2.5 <= x % < 10
CAS: 532-32-1 EC: 208-534-8 SODIUM BENZOATE	GHS07 Wng Eye Irrit. 2, H319		0 <= x % < 2.5
CAS: 5949-29-1 REACH: 01-2119457026-42-xxxx ACIDE CITRIQUE, MONOHYDRATE	GHS07 Wng Eye Irrit. 2, H319 STOT SE 3, H335		0 <= x % < 2.5
CAS: 9014-01-1 EC: 232-752-2 REACH: 01-2119480434-38 SUBTILISIN	GHS07, GHS05, GHS09, GHS08 Dgr Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Resp. Sens. 1, H334 STOT SE 3, H335 Aquatic Chronic 2, H411 Aquatic Acute 1, H400 M Acute = 1	[1]	0 <= x % < 2.5
CAS: 1310-73-2 EC: 215-185-5 REACH: 01-2119457892-27-xxxx SODIUM HYDROXIDE	GHS05 Dgr Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318	[1]	0 <= x % < 2.5

Specific concentration limits:

Identification	Specific concentration limits	ATE
CAS: 532-32-1 EC: 208-534-8 SODIUM BENZOATE		oral: ATE = 3450 mg/kg BW
CAS: 5949-29-1 REACH: 01-2119457026-42-xxxx ACIDE CITRIQUE, MONOHYDRATE		oral: ATE = 5400 mg/kg BW
CAS: 1310-73-2 EC: 215-185-5 REACH: 01-2119457892-27-xxxx SODIUM HYDROXIDE	Skin Corr. 1A: H314 C>= 5% Skin Corr. 1B: H314 2% <= C < 5% Skin Irrit. 2: H315 0.5% <= C < 2% Eye Dam. 1: H318 C>= 2% Eye Irrit. 2: H319 0.5% <= C < 2%	

Information on ingredients :

(Full text of H-phrases: see section 16)

[1] Substance for which maximum workplace exposure limits are available.

SECTION 4 : FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

4.1. description of first aid measures

In the event of splashes or contact with eyes :

Wash thoroughly with fresh, clean water for 15 minutes holding the eyelids open.

Regardless of the initial state, refer the patient to an ophthalmologist and show him the label.

In the event of swallowing :

Seek medical attention, showing the label.

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

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5 : FIREFIGHTING MEASURES

Non-flammable.

5.1. Extinguishing media

5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

In the event of a fire, the following may be formed :

- carbon monoxide (CO)
- carbon dioxide (CO2)

5.3. Advice for firefighters

No data available.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

For non first aid worker

Avoid any contact with the skin and eyes.

For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

6.2. Environmental precautions

Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal.

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

In the event of soiling with the ground, and after recovering the product by sponging it with an inert and non-combustible absorbent material, wash the soiled surface with plenty of water.

6.4. Reference to other sections

No data available.

SECTION 7 : HANDLING AND STORAGE

Requirements relating to storage premises apply to all facilities where the mixture is handled.

7.1. Precautions for safe handling

Always wash hands after handling.

Remove and wash contaminated clothing before re-using.

Emergency showers and eye wash stations will be required in facilities where the mixture is handled constantly.

Fire prevention :

Prevent access by unauthorised personnel.

Recommended equipment and procedures :

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Avoid eye contact with this mixture at all times.

Prohibited equipment and procedures :

No smoking, eating or drinking in areas where the mixture is used.

7.2. Conditions for safe storage, including any incompatibilities

No data available.

Packaging

Always keep in packaging made of an identical material to the original.

7.3. Specific end use(s)

No data available.

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Occupational exposure limits :

- France (INRS - Outils 65 / 2021-1849, 2021-1763, decree of 09/12/2021) :

CAS	VME-ppm :	VME-mg/m3 :	VLE-ppm :	VLE-mg/m3 :	Notes :	TMP No :
1310-73-2	-	2	-	-	-	-

- UK / WEL (Workplace exposure limits, EH40/2005, Fourth Edition 2020) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
9014-01-1	0.00004 mg/m³			Sen	
1310-73-2		2 mg/m³			

Predicted no effect concentration (PNEC):

ACIDE CITRIQUE, MONOHYDRATE (CAS: 5949-29-1)

Environmental compartment:	Soil.
PNEC :	33.1 mg/kg
Environmental compartment:	Fresh water.
PNEC :	0.44 mg/l
Environmental compartment:	Sea water.
PNEC :	0.044 mg/l
Environmental compartment:	Fresh water sediment.
PNEC :	3.46 mg/kg
Environmental compartment:	Marine sediment.
PNEC :	34.6 mg/kg
Environmental compartment:	Waste water treatment plant.
PNEC :	1000 mg/l

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

- Eye / face protection

Avoid contact with eyes.

Use eye protectors designed to protect against liquid splashes

Before handling, wear safety goggles with protective sides accordance with standard EN166.

In the event of high danger, protect the face with a face shield.

Prescription glasses are not considered as protection.

Individuals wearing contact lenses should wear prescription glasses during work where they may be exposed to irritant vapours.

Provide eyewash stations in facilities where the product is handled constantly.

- Hand protection

Wear suitable protective gloves in the event of prolonged or repeated skin contact.

Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN ISO 374-1.

Gloves must be selected according to the application and duration of use at the workstation.

Protective gloves need to be selected according to their suitability for the workstation in question : other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of dexterity required.

- Body protection

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	
Physical state :	Fluid liquid.
Colour	
Unspecified	
Odour	
Odour threshold :	Not stated.
Freezing point	
Freezing point / Freezing range :	Not stated.
Boiling point or initial boiling point and boiling range	
Boiling point/boiling range :	Not relevant.
Flammability	
Flammability (solid, gas) :	Not stated.
Lower and upper explosion limit	
Explosive properties, lower explosivity limit (%) :	Not stated.
Explosive properties, upper explosivity limit (%) :	Not stated.
Flash point	
Flash point interval :	Not relevant.
Auto-ignition temperature	
Self-ignition temperature :	Not relevant.
Decomposition temperature	
Decomposition point/decomposition range :	Not relevant.
pH	
pH (aqueous solution) :	Not stated.
pH :	Not stated. Neutral.
Kinematic viscosity	
Viscosity :	Not stated.
Solubility	
Water solubility :	Soluble.
Fat solubility :	Not stated.
Partition coefficient n-octanol/water (log value)	
Partition coefficient: n-octanol/water :	Not stated.
Vapour pressure	
Vapour pressure (50°C) :	Below 110 kPa (1.10 bar).
Density and/or relative density	
Density :	> 1
Relative vapour density	
Vapour density :	Not stated.

9.2. Other information

No data available.

9.2.1. Information with regard to physical hazard classes

No data available.

9.2.2. Other safety characteristics

No data available.

SECTION 10 : STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Avoid :

- frost

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

The thermal decomposition may release/form :

- carbon monoxide (CO)
- carbon dioxide (CO2)

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

May have irreversible effects on the eyes, such as tissue damage in the eye, or serious physical decay of sight, which is not fully reversible by the end of observation at 21 days.

Serious eye damage is typified by the destruction of cornea, persistent corneal opacity and iritis.

11.1.1. Substances

Acute toxicity :

ACIDE CITRIQUE, MONOHYDRATE (CAS: 5949-29-1)

Oral route :	LD50 = 5400 mg/kg bodyweight/day Species : Mouse OECD Guideline 401 (Acute Oral Toxicity)
Dermal route :	LD50 > 2000 mg/kg bodyweight/day Species : Rat OECD Guideline 402 (Acute Dermal Toxicity)

SODIUM BENZOATE (CAS: 532-32-1)

Oral route :	LD50 = 3450 mg/kg bodyweight/day

Germ cell mutagenicity :

ACIDE CITRIQUE, MONOHYDRATE (CAS: 5949-29-1)

Mutagenesis (in vivo) :	Negative. OECD Guideline 475 (Mammalian Bone Marrow Chromosome Aberration Test)
Mutagenesis (in vitro) :	Negative. Species : Others

11.1.2. Mixture

No toxicological data available for the mixture.

11.2. Information on other hazards

SECTION 12 : ECOLOGICAL INFORMATION

12.1. Toxicity

12.1.1. Substances

ACIDE CITRIQUE, MONOHYDRATE (CAS: 5949-29-1)

Fish toxicity :	LC50 = 440 mg/l Species : Leuciscus idus melanotus

Duration of exposure : 48 h
OECD Guideline 203 (Fish, Acute Toxicity Test)

Crustacean toxicity : EC50 = 1535 mg/l
Species : Daphnia magna
Duration of exposure : 24 h

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

12.2.1. Substances

ACIDE CITRIQUE, MONOHYDRATE (CAS: 5949-29-1)
Biodegradability : Rapidly degradable.

12.3. Bioaccumulative potential

12.3.1. Substances

ACIDE CITRIQUE, MONOHYDRATE (CAS: 5949-29-1)
Octanol/water partition coefficient : log Koe = -0.2

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Endocrine disrupting properties

No data available.

12.7. Other adverse effects

No data available.

SECTION 13 : DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1. Waste treatment methods

Do not pour into drains or waterways.

Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging :

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

SECTION 14 : TRANSPORT INFORMATION

Exempt from transport classification and labelling.

14.1. UN number or ID number

-

14.2. UN proper shipping name

-

14.3. Transport hazard class(es)

-

14.4. Packing group

-

14.5. Environmental hazards

-

14.6. Special precautions for user

-

14.7. Maritime transport in bulk according to IMO instruments

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SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Classification and labelling information included in section 2:

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 2022/692 (ATP 18)

Container information:

No data available.

Restrictions applied under Title VIII of Regulation (EC) No. 1907/2006 (REACH):

The mixture does not contain any substance restricted under Annex XVII of Regulation (EC) No. 1907/2006 (REACH): https://echa.europa.eu/substances-restricted-under-reach.

Explosives precursors :

The mixture does not contain any substance subject to Regulation (EU) 2019/1148 on the marketing and use of explosives precursors.

Particular provisions :

No data available.

15.2. Chemical safety assessment

No data available.

SECTION 16 : OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

Wording of the phrases mentioned in section 3 :

H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.

Abbreviations and acronyms :

LD50 : The dose of a test substance resulting in 50% lethality in a given time period.

LC50 : The concentration of a test substance resulting in 50% lethality in a given period.

EC50 : The effective concentration of substance that causes 50% of the maximum response.

REACH : Registration, Evaluation, Authorization and Restriction of Chemical Substances.

ATE : Acute Toxicity Estimate

BW : Body Weight

PNEC : Predicted No-Effect Concentration

STEL : Short-term exposure limit

TWA : Time Weighted Averages

TMP : French Occupational Illness table

TLV : Threshold Limit Value (exposure)

AEV : Average Exposure Value.

ADR : European agreement concerning the international carriage of dangerous goods by Road.

IMDG : International Maritime Dangerous Goods.

IATA : International Air Transport Association.

ICAO : International Civil Aviation Organisation

RID : Regulations concerning the International carriage of Dangerous goods by rail.

GHS05 : Corrosion
PBT: Persistent, bioaccumulable and toxic.
vPvB : Very persistent, very bioaccumulable.
SVHC : Substances of very high concern.