

**BEPRO CLEANER TE****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 / 19500204

**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&amp;H Sterilization Srl. Via Bolgara 2. 24060 Brusaporto (BG) - 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

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/...

**BEPRO CLEANER TE****2.3. Other hazards**

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC)  $\geq 0.1\%$  published by the European Chemicals Agency (ECHA) under article 59 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  $\geq 0.1\%$  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 $\leq$ 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 $\leq$ x % < 10
CAS: 532-32-1 EC: 208-534-8 SODIUM BENZOATE	GHS07 Wng Eye Irrit. 2, H319		0 $\leq$ 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 $\leq$ 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

**Information on ingredients :**

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

**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**

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**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 (CO<sub>2</sub>)

**5.3. Advice for firefighters**

No data available.

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**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**

Clean preferably with a detergent, do not use solvents.

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.

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**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.

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**SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION****8.1. Control parameters**

No data available.

**Predicted no effect concentration (PNEC):**

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

Environmental compartment:

Soil.

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

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**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.

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**Lower and upper explosion limit**

Explosive properties, lower explosivity limit (%) Not stated.

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Explosive properties, upper explosivity limit (%) Not stated.

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**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 : &gt; 1

**Relative vapour density**

Vapour density : Not stated.

**Particle characteristics**

The mixture does not contain nanoforms.

**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.

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**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 (CO<sub>2</sub>)

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**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****Endocrine disrupting properties**

The mixture does not contain any substance evaluated as an endocrine disruptor with effects on human health.

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**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)

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Octanol/water partition coefficient :

log K<sub>ow</sub> = -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**

The mixture does not contain any substance evaluated as an endocrine disruptor with environmental effects.

**12.7. Other adverse effects**

No data available.

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**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.

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**SECTION 14 : TRANSPORT INFORMATION**

Exempt from transport classification and labelling.

**14.1. UN number or ID number**

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**14.2. UN proper shipping name**

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**14.3. Transport hazard class(es)**

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**14.4. Packing group**

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**14.5. Environmental hazards**

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**14.6. Special precautions for user**

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**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. 2023/707.

- EU Regulation No. 1272/2008 amended by EU Regulation No. 2024/197. (ATP 21)

**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.

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**Particular provisions :**

No data available.

**15.2. Chemical safety assessment**

No data available.

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**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 :**

H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

**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.