

BEPRO CLEANER TE - GHS**SAFETY DATA SHEET****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 : 40 Rue du chemin vert.78610.LE PERRY EN YVELINES.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 (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

Local Sponsor: W&H Australasia Pty Ltd

10 Konando Tce Edwardstown SA 5039

Tel: +61 1300 613 988

Website: www.wh.com

Email: support.aus@wh.com

ABN: 33 108 399 800

1.4. Emergency telephone number : 131 126.

Association/Organisation : NSW Poisons Information Centre

Complete list of poison center available at : <https://www.poisonsinfo.nsw.gov.au/>

SECTION 2 : HAZARDS IDENTIFICATION**2.1. Classification of the substance or mixture****GHS compliant.**

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**GHS compliant.**

Hazard pictograms :



GHS05

Signal Word :

DANGER

Product identifiers :

CAS 54549-24-5 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/...

2.3. Other hazards

BEPRO CLEANER TE - GHS

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Composition :

Identification	Classification GHS	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: 164462-16-2 EC: 423-270-5 REACH: 01-0000016977-53-0000 ALANINE,N,N-BIS(CARBOXYMETHYL)-,SE L DE TRISODIUM	GHS05 Wng Met. Corr. 1, H290 Aquatic Acute 3, H402		2.5 <= x % < 10
CAS: 532-32-1 EC: 208-534-8 SODIUM BENZOATE	GHS07 Wng Acute Tox. 5, H303 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	[i]	0 <= x % < 2.5
INDEX: 011-002-00-6 CAS: 1310-73-2 EC: 215-185-5 REACH: 01-2119457892-27-xxxx SODIUM HYDROXIDE	GHS05 Dgr Skin Corr. 1A, H314	[i]	0 <= x % < 2.5

Information on ingredients :

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

[i] 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.

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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

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.

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.

BEPRO CLEANER TE - GHS

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

- ACGIH TLV (American Conference of Governmental Industrial Hygienists, Threshold Limit Values) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
1310-73-2 SODIUM HYDROXIDE			2 mg/m ³	2	

- UK :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
9014-01-1 SUBTILISIN	0.00004 mg/m ³				
1310-73-2 SODIUM HYDROXIDE		2 mg/m ³			

- Australia :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
1310-73-2 SODIUM HYDROXIDE			2 mg/m ³	2	

Derived no effect level (DNEL) or derived minimum effect level (DMEL):

SUBTILISIN (CAS: 9014-01-1)

Final use:

Exposure method:
Potential health effects:
DMEL :

Workers.

Inhalation.
Long term local effects.
0.000060 mg of substance/m³

Predicted no effect concentration (PNEC):

SUBTILISIN (CAS: 9014-01-1)

Environmental compartment: Fresh water.
PNEC : 0.06 µg/l

Environmental compartment: Sea water.
PNEC : 0.006 µg/l

Environmental compartment: Waste water treatment plant.
PNEC : 65000 µg/l

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.

BEPRO CLEANER TE - GHS

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 ISO 16321.

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**

No data available.

Physical state

Physical state : Fluid liquid.

Colour

Unspecified

Odour

Odour threshold : Not stated.

Melting point

Melting point/melting range : Not relevant.

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.

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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 toxicological effects****11.1.1. Substances****a) Acute toxicity :**

SUBTILISIN (CAS: 9014-01-1)

Oral route :

LD50 = 1800 mg/kg body weight
OECD Guideline 401 (Acute Oral Toxicity)

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

Oral route :

LD50 = 5400 mg/kg body weight
Species : Mouse
OECD Guideline 401 (Acute Oral Toxicity)

Dermal route :

LD50 > 2000 mg/kg body weight
Species : Rat
OECD Guideline 402 (Acute Dermal Toxicity)

SODIUM BENZOATE (CAS: 532-32-1)

Oral route :

LD50 = 3450 mg/kg body weight

ALANINE,N,N-BIS(CARBOXYMETHYL)-,SEL DE TRISODIUM (CAS: 164462-16-2)

Oral route :

LD50 > 2000 mg/kg body weight
Species : Rat (recommended by the CLP)

BEPRO CLEANER TE - GHS

Other guideline

Dermal route : LD50 > 2000 mg/kg body weight
Species : Rat (recommended by the CLP)
OECD Guideline 402 (Acute Dermal Toxicity)

Inhalation route (n/a) : LC50 > 5 mg/l
Species : Rat (recommended by the CLP)

b) Skin corrosion/skin irritation :

No data available.

c) Serious damage to eyes/eye irritation :

No data available.

d) Respiratory or skin sensitisation :

ALANINE,N,N-BIS(CARBOXYMETHYL)-,SEL DE TRISODIUM (CAS: 164462-16-2)
Guinea Pig Maximisation Test (GMPT) : Non-sensitiser.
OECD Guideline 406 (Skin Sensitisation)

e) 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

ALANINE,N,N-BIS(CARBOXYMETHYL)-,SEL DE TRISODIUM (CAS: 164462-16-2)
No mutagenic effect.

f) Carcinogenicity :

ALANINE,N,N-BIS(CARBOXYMETHYL)-,SEL DE TRISODIUM (CAS: 164462-16-2)
Carcinogenicity Test : Negative.
No carcinogenic effect.

g) Reproductive toxicant :

ALANINE,N,N-BIS(CARBOXYMETHYL)-,SEL DE TRISODIUM (CAS: 164462-16-2)
No toxic effect for reproduction

h) Specific target organ systemic toxicity - single exposure :

No data available.

i) Specific target organ systemic toxicity - repeated exposure :

No data available.

j) Aspiration hazard :

No data available.

11.1.2. Mixture**11.1.2.1 Information on hazard classes****a) Acute toxicity :**

Oral route : No data available.

Dermal route : No data available.

b) Skin corrosion/skin irritation :

No data available.

c) Serious damage to eyes/eye irritation :

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.

BEPRO CLEANER TE - GHS**d) Respiratory or skin sensitisation :**

No data available.

e) Germ cell mutagenicity :

No data available.

f) Carcinogenicity :

No data available.

g) Reproductive toxicant :

No data available.

h) Specific target organ systemic toxicity - single exposure :

No data available.

i) Specific target organ systemic toxicity - repeated exposure :

No data available.

j) Aspiration hazard :

No data available.

11.1.2.2 Other information**11.2. Information on other hazards****SECTION 12 : ECOLOGICAL INFORMATION****12.1. Toxicity****12.1.1. Substances**

SUBTILISIN (CAS: 9014-01-1)

Fish toxicity :

LC50 = 8.2 mg/l

Duration of exposure : 96 h

Crustacean toxicity :

EC50 = 0.586 mg/l

Duration of exposure : 48 h

OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

Algae toxicity :

ECr50 = 0.830 mg/l

Duration of exposure : 72 h

OECD Guideline 201 (Alga, Growth Inhibition Test)

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

ALANINE,N,N-BIS(CARBOXYMETHYL)-,SEL DE TRISODIUM (CAS: 164462-16-2)

Fish toxicity :

LC50 > 100 mg/l

Species : *Brachydanio rerio*

Duration of exposure : 96 h

OECD Guideline 203 (Fish, Acute Toxicity Test)

Crustacean toxicity :

EC50 > 100 mg/l

Species : *Daphnia magna*

Duration of exposure : 48 h

OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

Aquatic plant toxicity :

ECr50 > 100 mg/l

Species : Others

Duration of exposure : 72 h

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Other guideline

12.1.2. Mixtures

No aquatic toxicity data available for the substances.

12.2. Persistence and degradability**12.2.1. Substances**

SUBTILISIN (CAS: 9014-01-1)

Biodegradability : Rapidly degradable.

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

Biodegradability : Rapidly degradable.

ALANINE,N,N-BIS(CARBOXYMETHYL)-,SEL DE TRISODIUM (CAS: 164462-16-2)

Biodegradability : no degradability data is available, the substance is considered as not degrading quickly.

12.3. Bioaccumulative potential**12.3.1. Substances**

SUBTILISIN (CAS: 9014-01-1)

Octanol/water partition coefficient : $\log K_{ow} < 0$

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

Octanol/water partition coefficient : $\log K_{ow} = -0.2$ **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

The appropriate waste management of the mixture and/or its container must be determined in accordance with local regulations.

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

-

14.2. UN proper shipping name

-

14.3. Transport hazard class(es)

-

14.4. Packing group

-

BEPRO CLEANER TE - GHS**14.5. Environmental hazards**

-

14.6. Special precautions for user

-

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

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SECTION 15 : REGULATORY INFORMATION**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

The following regulations have been used:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), review no. 8 (2019)

Container information:

No data available.

Particular provisions :

No data available.

Substances that deplete the ozone layer (EC Regulation No. 1005/2009, Montreal Protocol) :

The mixture does not contain any substance posing a risk to the ozone layer.

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.
H303	May be 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.
H402	Harmful 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.

ECr50 : The effective concentration of substance that causes 50% reduction in growth rate.

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

DMEL : Derived Minimal Effect Level

PNEC : Predicted No-Effect Concentration

STEL : Short-term exposure limit

TWA : Moyenne pondérée dans le temps

TLV : Threshold Limit Value (exposure)

AEV : Average Exposure Value.

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

GHS05 : Corrosion

IATA : International Air Transport Association.

IMDG : International Maritime Dangerous Goods.

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ICAO : International Civil Aviation Organisation

PBT: Persistent, bioaccumulable and toxic.

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

vPvB : Very persistent, very bioaccumulable.