

BEPRO NEUTRALIZER C - 19500202



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 NEUTRALIZER C

Product code : 19500202.

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

Neutralizing agent 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.

Skin corrosion, Category 1 (Skin Corr. 1, H314).

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

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

Hazard pictograms :



GHS05

Signal Word :

DANGER

Additional labeling :

Hazard statements :

H314

Causes severe skin burns and eye damage.

Precautionary statements - Prevention :

P280

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

Precautionary statements - Response :

P303 + P361 + P353

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

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) $\geq$ 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.

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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: 64-19-7 EC: 200-580-7 ACETIC ACID	GHS05, GHS02 Dgr Flam. Liq. 3, H226 Skin Corr. 1A, H314 Eye Dam. 1, H318	[1]	10 <= x % < 25
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

Specific concentration limits:

Identification	Specific concentration limits	ATE
CAS: 64-19-7 EC: 200-580-7 ACETIC ACID	Skin Corr. 1A: H314 C>= 90% Skin Corr. 1B: H314 25% <= C < 90% Skin Irrit. 2: H315 10% <= C < 25% Eye Dam. 1: H318 C>= 25% Eye Irrit. 2: H319 10% <= C < 25%	oral: ATE = 3350 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)

[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 splashes or contact with skin :

Remove any soiled or splashed clothing immediately.

Watch out for any remaining product between skin and clothing, watches, shoes, etc.

If the contaminated area is widespread and/or there is damage to the skin, a doctor must be consulted or the patient transferred to hospital.

In the event of swallowing :

Do not give the patient anything orally.

Seek medical attention immediately, 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)

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- 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

Neutralise with an alkaline decontaminant, such as an aqueous solution of sodium carbonate or similar.

If the ground is contaminated, once the product has been recovered by sponging with an inert and non-combustible absorbent material, wash the contaminated area in plenty of water.

Clean preferably with a detergent, do not use solvents.

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.

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 :**

- European Union (2022/431, 2019/1831, 2017/2398, 2017/164, 2009/161, 2006/15/CE, 2000/39/CE, 98/24/CE) :

CAS	VME-mg/m ³ :	VME-ppm :	VLE-mg/m ³ :	VLE-ppm :	Notes :
64-19-7	25	10	50	20	-

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

CAS	VME-ppm :	VME-mg/m ³ :	VLE-ppm :	VLE-mg/m ³ :	Notes :	TMP No :
64-19-7	10	25	20	50	-	-

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

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CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
64-19-7	10 ppm 25 mg/m ³	20 ppm 50 mg/m ³			

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

ACETIC ACID (CAS: 64-19-7)

Final use:

Exposure method:
Potential health effects:
DNEL :

Workers.

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

Exposure method:
Potential health effects:
DNEL :

Inhalation.
Short term local effects.
25 mg of substance/m3

Final use:

Exposure method:
Potential health effects:
DNEL :

Consumers.

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

Exposure method:
Potential health effects:
DNEL :

Inhalation.
Short term local effects.
25 mg of substance/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

ACETIC ACID (CAS: 64-19-7)

Environmental compartment: Soil.
PNEC : 0.47 mg/kg

Environmental compartment: Fresh water.
PNEC : 3.058 mg/l

Environmental compartment: Sea water.
PNEC : 0.306 mg/l

Environmental compartment: Intermittent waste water.
PNEC : 30.58 mg/l

Environmental compartment: Fresh water sediment.
PNEC : 11.36 mg/kg

Environmental compartment: Marine sediment.

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PNEC :	1.136 mg/kg
Environmental compartment:	Waste water treatment plant.
PNEC :	85 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.

Type of gloves recommended :

- Natural latex
- Nitrile rubber (butadiene-acrylonitrile copolymer rubber (NBR))
- PVC (polyvinyl chloride)
- Butyl Rubber (Isobutylene-isoprene copolymer)

- Body protection

Avoid skin contact.

Wear suitable protective clothing.

Suitable type of protective clothing :

In the event of substantial spatter, wear liquid-tight protective clothing against chemical risks (type 3) in accordance with EN14605/A1 to prevent skin contact.

In the event of a risk of splashing, wear protective clothing against chemical risks (type 6) in accordance with EN13034/A1 to prevent skin contact.

Wear suitable protective clothing, in particular overalls and boots. These items must be kept in good condition and cleaned after use.

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.

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**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 : 1.90 .
Strongly acidic.

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)

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**SECTION 11 : TOXICOLOGICAL INFORMATION****11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

May cause irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following exposure for up to three minutes.

Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discolouration due to blanching of the skin, complete areas of alopecia, and scars.

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)

ACETIC ACID (CAS: 64-19-7)

Oral route : LD50 = 3350 mg/kg bodyweight/day
Species : Rat

Inhalation route (Dusts/mist) : LC50 > 40 mg/l
Species : Rat

Skin corrosion/skin irritation :

ACETIC ACID (CAS: 64-19-7)

OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

Serious damage to eyes/eye irritation :

ACETIC ACID (CAS: 64-19-7)

OECD Guideline 405 (Acute Eye Irritation / Corrosion)

OECD Guideline 405 (Acute Eye Irritation / Corrosion)

OECD Guideline 405 (Acute Eye Irritation / Corrosion)

OECD Guideline 405 (Acute Eye Irritation / Corrosion)

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

ACETIC ACID (CAS: 64-19-7)

Mutagenesis (in vivo) : Negative.
OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test)

Mutagenesis (in vitro) : Negative.
Species : Mammalian Cell Line
OECD Guideline 476 (In vitro Mammalian Cell Gene Mutation Test)

11.1.2. Mixture**Skin corrosion/skin irritation :**

The 'corrosive' classification is based on the low/high pH which has been confirmed by tests.

11.2. Information on other hazards

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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.

ACETIC ACID (CAS: 64-19-7)

Biodegradability :

Rapidly degradable.

12.3. Bioaccumulative potential**12.3.1. Substances**

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

Octanol/water partition coefficient :

log K_{ow} = -0.2

ACETIC ACID (CAS: 64-19-7)

Octanol/water partition coefficient :

log K_{ow} = -0.17

Bioaccumulation :

BCF = 3

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.

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SECTION 14 : TRANSPORT INFORMATION

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2023 - IMDG 2020 [40-20] - ICAO/IATA 2023 [64]).

14.1. UN number or ID number

2790

14.2. UN proper shipping name

UN2790=ACETIC ACID SOLUTION, more than 10% and less than 50% acid, by mass

14.3. Transport hazard class(es)

- Classification :



8

14.4. Packing group

III

14.5. Environmental hazards

-

14.6. Special precautions for user

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	8	C3	III	8	80	5 L	597 647	E1	3	E

IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ	Stowage Handling	Segregation
	8	-	III	5 L	F-A. S-B	-	E1	Category A	SGG1 SG36 SG49

IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ
	8	-	III	852	5 L	856	60 L	A803	E1
	8	-	III	Y841	1 L	-	-	A803	E1

For limited quantities, see part 2.7 of the OACI/IATA and chapter 3.4 of the ADR and IMDG.

For excepted quantities, see part 2.6 of the OACI/IATA and chapter 3.5 of the ADR and IMDG.

14.7. Maritime transport in bulk according to IMO instruments

No data available.

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.

BEPRO NEUTRALIZER C - 19500202**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 :

H226	Flammable liquid and vapour.
H314	Causes severe skin burns and eye damage.
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
DNEL : Derived No-Effect Level
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.