

BACTYNEA PE 500 ML - LB920260

SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2015/830)

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

1.1. Product identifier

Product name : BACTYNEA PE 500 ML
Product code : LB920260.

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

Cleaning disinfectant for medical devices
Professional use

1.3. Details of the supplier of the safety data sheet

Registered company name : ORAPI.
Address : PARC INDUSTRIEL DE LA PLAINE DE L'AIN - 225 ALLEE DES CEDRES.01150.SAINT-VULBAS.FRANCE.
Telephone : 33-(0)4-74-40-20-20. Fax : 33-(0)4-74-40-20-21.
fds@orapi.com

1.4. Emergency telephone number : 33-(0)1-45-42-59-59.

Association/Organisation : INRS .

Other emergency numbers

Emergency Action: In the event of a medical enquiry involving this product, please contact your doctor or local hospital accident and emergency department.

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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

Hazardous to the aquatic environment - Chronic hazard, Category 3 (Aquatic Chronic 3, H412).
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 a health hazard with the exception of possible occupational exposure thresholds (see paragraphs 3 and 8).

2.2. Label elements

Detergent mixture (see section 15).

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

Hazard statements :

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements - General :

P102 Keep out of reach of children.

Precautionary statements - Prevention :

P273 Avoid release to the environment.

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.

P312 Call a POISON CENTER or doctor if you feel unwell.

Precautionary statements - Disposal :

P501 Dispose of contents and container in accordance with local regulations.

Other information :

Do not reuse the packaging.

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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SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Composition :

Identification	(EC) 1272/2008	Note	%
INDEX: 612_131_006B CAS: 7173-51-5 CHLORURE DE DIDECYLDIMETHYLAMMONIUM	GHS07, GHS05, GHS09 Dgr Acute Tox. 4, H302 Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Chronic 2, H411 Aquatic Acute 1, H400 M Acute = 10		0 <= x % < 2.5
INDEX: 68424_81B CAS: 68424-85-1 EC: 270-325-2 COMPOSE DE L ION AMMONIUM QUATERNAIRE, BENZYLALKYL EN C12-16 DIMETHYLES CHLORURES	GHS07, GHS05, GHS09 Dgr Met. Corr. 1, H290 Acute Tox. 4, H302 Skin Corr. 1B, H314 Aquatic Acute 1, H400 M Acute = 10 Aquatic Chronic 1, H410 M Chronic = 1		0 <= x % < 2.5

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 exposure by inhalation :

Bring to the fresh air.

In the event of splashes or contact with eyes :

Rinse with clean water for 10 min.

In the event of splashes or contact with skin :

Wash immediately with soap and water. Take off all contaminated clothing.

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

Suitable methods of extinction

Foam, CO2, powder

Unsuitable methods of extinction

Water jets

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)

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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 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.

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.

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.

Storage

Keep out of reach of children.

Keep the container away from heat, bad weather, dampness and freezing.

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

No data available.

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 in accordance with standard EN166.

- Hand protection

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

- Body protection

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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

General information :

Physical state : Fluid liquid.
Odor: odorless
Colour: colorless

Important health, safety and environmental information

pH : 7.60 .
Neutral.
Boiling point/boiling range : Not relevant.
Flash point interval : Not relevant.
Vapour pressure (50°C) : Between 175 kPa and 300 kPa inclusive.
Density : = 1
Water solubility : Soluble.
Melting point/melting range : Not specified.
Self-ignition temperature : Not relevant.
Decomposition point/decomposition range : Not specified.

9.2. Other information

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 :
- heat
- frost

10.5. Incompatible materials

Keep away from :
- acids
- oxidising agents

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

No data available.

11.1.1. Substances

Acute toxicity :

COMPOSE DE L ION AMMONIUM QUATERNAIRE, BENZYLALKYL EN C12-16 DIMETHYLES CHLORURES (CAS: 68424-85-1)
Oral route : LD50 = 795 mg/kg
Species : Rat

11.1.2. Mixture

No toxicological data available for the mixture.

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SECTION 12 : ECOLOGICAL INFORMATION

Harmful to aquatic life with long lasting effects.

The product must not be allowed to run into drains or waterways.

12.1. Toxicity

12.1.1. Substances

COMPOSE DE L ION AMMONIUM QUATERNAIRE, BENZYLALKYL EN C12-16 DIMETHYLES CHLORURES (CAS: 68424-85-1)

Fish toxicity : LC50 = 0.085 mg/l
Factor M = 10
Species : Oncorhynchus mykiss
Duration of exposure : 96 h
OECD Guideline 203 (Fish, Acute Toxicity Test)

Crustacean toxicity : EC50 = 0.016 mg/l
Species : Daphnia magna
Duration of exposure : 48 h

NOEC = 0.025 mg/l
Species : Daphnia magna
OECD Guideline 211 (Daphnia magna Reproduction Test)

Algae toxicity : ECr50 = 0.025 mg/l
Species : Selenastrum capricornutum
Duration of exposure : 72 h
OECD Guideline 201 (Alga, Growth Inhibition Test)

EC10 mg/l
Factor M = 1
Species : Selenastrum capricornutum
Duration of exposure : 72 h
OECD Guideline 201 (Alga, Growth Inhibition Test)

CHLORURE DE DIDECYLDIMETHYLAMMONIUM (CAS: 7173-51-5)

Fish toxicity : 0.01 < LC50 <= 0.1 mg/l
Factor M = 10
Duration of exposure : 96 h

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

12.2.1. Substances

COMPOSE DE L ION AMMONIUM QUATERNAIRE, BENZYLALKYL EN C12-16 DIMETHYLES CHLORURES (CAS: 68424-85-1)

Biodegradability : Rapidly degradable.

CHLORURE DE DIDECYLDIMETHYLAMMONIUM (CAS: 7173-51-5)

Biodegradability : Rapidly degradable.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

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12.6. 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, preferably 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

-

14.5. Environmental hazards

-

14.6. Special precautions for user

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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. 487/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 758/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 944/2013.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 605/2014.
- EU Regulation No. 1272/2008 amended by EU Regulation No. 1297/2014.

- Container information:

No data available.

- Particular provisions :

No data available.

- Labelling for detergents (EC Regulation No. 648/2004,907/2006) :

- less than 5 % : cationic surfactants
- disinfectants

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 :

H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

Abbreviations :

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.

WGK : Wassergefährdungsklasse (Water Hazard Class).

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.