

BACTINYL ASPIRATION CHIRURGICALE - LB920300

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 : BACTINYL ASPIRATION CHIRURGICALE
Product code : LB920300.

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.

Skin corrosion, Category 1B (Skin Corr. 1B, H314).
Serious eye damage, Category 1 (Eye Dam. 1, H318).
Hazardous to the aquatic environment - Acute hazard, Category 1 (Aquatic Acute 1, H400).
Hazardous to the aquatic environment - Chronic hazard, Category 2 (Aquatic Chronic 2, H411).
This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

2.2. Label elements

Detergent mixture (see section 15).

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

Hazard pictograms :



GHS05

GHS09

Signal Word :

DANGER

Product identifiers :

CAS 7173-51-5 CHLORURE DE DIDECYLDIMETHYLAMMONIUM

Hazard statements :

H314 Causes severe skin burns and eye damage.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements - Prevention :

P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statements - Response :

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

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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/container as hazardous waste.

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.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Composition :

| Identification | (EC) 1272/2008 | Note | % |
|---|--|------|---------------------|
| 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 | | 10 \leq x % < 25 |
| CAS: 68424-85-1 EC: 270-325-2 COMPOSE DE L ION AMMONIUM QUATERNAIRE, BENZYLALKYL EN C12-16 DIMETHYLES CHLORURES | GHS07, GHS05, GHS09 Dgr Acute Tox. 4, H302 Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Acute 1, H400 M Acute = 10 Aquatic Chronic 1, H410 M Chronic = 1 | | 10 \leq x % < 25 |
| INDEX: 603-117-00-0 CAS: 67-63-0 EC: 200-661-7 REACH: 01-2119457558-25 PROPAN-2-OL | GHS02, GHS07 Dgr Flam. Liq. 2, H225 Eye Irrit. 2, H319 STOT SE 3, H336 | [1] | 2.5 \leq x % < 10 |
| CAS: 69011-36-5 EC: 931-138-8 REACH: 01-2119976362-32 ISOTRIDECANOL, ETHOXYLATED | GHS07, GHS05 Dgr Acute Tox. 4, H302 Eye Dam. 1, H318 | | 2.5 \leq x % < 10 |

Information on ingredients :

[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 exposure by inhalation :

Bring to the fresh air.
If necessary call a doctor.

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.

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In contact with skin, rinse with water for at least 15 minutes. Consult a doctor.

In the event of swallowing :

Do not give the patient anything orally.
Seek medical attention immediately, showing the label.
Rinse the mouth with water

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)

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 acidic decontaminant.

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.

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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 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

Occupational exposure limits :

- ACGIH TLV (American Conference of Governmental Industrial Hygienists, Threshold Limit Values, 2010) :

| CAS | TWA : | STEL : | Ceiling : | Definition : | Criteria : |
|---------|---------|---------|-----------|--------------|------------|
| 67-63-0 | 200 ppm | 400 ppm | | A4; BEI | |

- Germany - AGW (BAuA - TRGS 900, 21/06/2010) :

| CAS | VME : | VME : | Excess | Notes |
|---------|-------|----------------------|--------|-------|
| 67-63-0 | | 200 ppm 500 mg/m3 | | 2(II) |

- France (INRS - ED984 :2012) :

| CAS | VME-ppm : | VME-mg/m3 : | VLE-ppm : | VLE-mg/m3 : | Notes : | TMP No : |
|---------|-----------|-------------|-----------|-------------|---------|----------|
| 67-63-0 | - | - | 400 | 980 | - | 84 |

- UK / WEL (Workplace exposure limits, EH40/2005, 2007) :

| CAS | TWA : | STEL : | Ceiling : | Definition : | Criteria : |
|---------|----------------------|-----------------------|-----------|--------------|------------|
| 67-63-0 | 400 ppm 999 mg/m3 | 500 ppm 1250 mg/m3 | | | |

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

PROPAN-2-OL (CAS: 67-63-0)

Final use:

Exposure method:
Potential health effects:
DNEL :

Workers.

Dermal contact.
Long term systemic effects.
888 mg/kg body weight/day

Exposure method:
Potential health effects:
DNEL :

Inhalation.
Long term systemic effects.
500 mg of substance/m3

Final use:

Exposure method:
Potential health effects:
DNEL :

Consumers.

Ingestion.
Long term systemic effects.
26 mg/kg body weight/day

Exposure method:
Potential health effects:
DNEL :

Dermal contact.
Long term systemic effects.
319 mg/kg body weight/day

Exposure method:
Potential health effects:
DNEL :

Inhalation.
Long term systemic effects.
89 mg of substance/m3

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Predicted no effect concentration (PNEC):

PROPAN-2-OL (CAS: 67-63-0)

| | |
|--------------------------------------|---|
| Environmental compartment: PNEC : | Soil. 28 mg/kg |
| Environmental compartment: PNEC : | Fresh water. 140.9 mg/l |
| Environmental compartment: PNEC : | Sea water. 140.9 mg/l |
| Environmental compartment: PNEC : | Intermittent waste water. 140.9 mg/l |
| Environmental compartment: PNEC : | Fresh water sediment. 552 mg/kg |
| Environmental compartment: PNEC : | Marine sediment. 552 mg/kg |
| Environmental compartment: PNEC : | Waste water treatment plant. 2251 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

Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN374.

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.

Recommended properties :

- Impervious gloves in accordance with standard EN374

- 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 to prevent skin contact.

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

Wear suitable protective clothing and, in particular, an apron and boots. These items of clothing shall be maintained 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.

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SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information :

Physical state : Fluid liquid.
Odour: mild
N/A

Important health, safety and environmental information

pH : Not stated.
Slightly basic.
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

10.5. Incompatible materials

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

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

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 :

ISOTRIDECANOL, ETHOXYLATED (CAS: 69011-36-5)

Oral route : 300 < LD50 <= 2000 mg/kg
Species : Rat

Dermal route : LD50 > 2000 mg/kg
Species : Rabbit

Skin corrosion/skin irritation :

ISOTRIDECANOL, ETHOXYLATED (CAS: 69011-36-5)

Irritation : No observed effect.
Average score < 1.5

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Serious damage to eyes/eye irritation :

ISOTRIDEKANOL, ETHOXYLATED (CAS: 69011-36-5)

Causes serious eye damage.

Corneal haze : Average score ≥ 3
Species : Rabbit

Respiratory or skin sensitisation :

ISOTRIDEKANOL, ETHOXYLATED (CAS: 69011-36-5)

Guinea Pig Maximisation Test (GMPT) : Non-sensitiser.

Germ cell mutagenicity :

ISOTRIDEKANOL, ETHOXYLATED (CAS: 69011-36-5)

No mutagenic effect.

Carcinogenicity :

ISOTRIDEKANOL, ETHOXYLATED (CAS: 69011-36-5)

Carcinogenicity Test : Negative.
No carcinogenic effect.

Reproductive toxicant :

ISOTRIDEKANOL, ETHOXYLATED (CAS: 69011-36-5)

No toxic effect for reproduction

11.1.2. Mixture

Acute toxicity :

Oral route : No observed effect.
LD50 > 5000 mg/kg

Monograph(s) from the IARC (International Agency for Research on Cancer) :

CAS 67-63-0 : IARC Group 3 : The agent is not classifiable as to its carcinogenicity to humans.

SECTION 12 : ECOLOGICAL INFORMATION

Very toxic 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

ISOTRIDEKANOL, ETHOXYLATED (CAS: 69011-36-5)

Fish toxicity : LC50 > 1 mg/l
Species : Cyprinus carpio
Duration of exposure : 96 h
OECD Guideline 203 (Fish, Acute Toxicity Test)

Crustacean toxicity : EC50 > 1 mg/l
Species : Daphnia magna
Duration of exposure : 48 h
OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)

NOEC = 2.6 mg/l
Species : Daphnia magna
Duration of exposure : 21 days
OECD Guideline 211 (Daphnia magna Reproduction Test)

Algae toxicity : ECr50 > 1 mg/l
Species : Desmodesmus subspicatus
Duration of exposure : 72 h
OECD Guideline 201 (Alga, Growth Inhibition Test)

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

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| | |
|---|---|
| Fish toxicity : | LC50 = 0.85 mg/l Factor M = 1 Species : Oncorhynchus mykiss Duration of exposure : 96 h OECD Guideline 203 (Fish, Acute Toxicity Test) |
| Crustacean toxicity : | EC50 = 0.016 mg/l Factor M = 10 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 = 0.02 mg/l Factor M = 10 Species : Scenedesmus 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

ISOTRIDEKANOL, ETHOXYLATED (CAS: 69011-36-5)

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

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

12.3.1. Substances

ISOTRIDEKANOL, ETHOXYLATED (CAS: 69011-36-5)

Octanol/water partition coefficient : log K_{ow} > 5000

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

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2017 - IMDG 2016 - ICAO/IATA 2017).

14.1. UN number

3267

14.2. UN proper shipping name

UN3267=CORROSIVE LIQUID, BASIC, ORGANIC, N.O.S.

(chlorure de didecylidimethylammonium, compose de 1 ion ammonium quaternaire, benzylalkyl en c12-16 dimethyles chlorures)

14.3. Transport hazard class(es)

- Classification :



8

14.4. Packing group

II

14.5. Environmental hazards

- Environmentally hazardous material :



14.6. Special precautions for user

| ADR/RID | Class | Code | Pack gr. | Label | Ident. | LQ | Provis. | EQ | Cat. | Tunnel |
|---------|-------|------|----------|-------|--------|-----|---------|----|------|--------|
| | 8 | C7 | II | 8 | 80 | 1 L | 274 | E2 | 2 | E |

| IMDG | Class | 2°Label | Pack gr. | LQ | EMS | Provis. | EQ |
|------|-------|---------|----------|-----|---------|---------|----|
| | 8 | - | II | 1 L | F-A,S-B | 274 | E2 |

| IATA | Class | 2°Label | Pack gr. | Passager | Passager | Cargo | Cargo | note | EQ |
|------|-------|---------|----------|----------|----------|-------|-------|------------|----|
| | 8 | - | II | 851 | 1 L | 855 | 30 L | A3 A803 | E2 |
| | 8 | - | II | Y840 | 0.5 L | - | - | A3 A803 | E2 |

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.

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

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. 2016/1179. (ATP 9)

- Container information:

No data available.

- Particular provisions :

No data available.

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

- less than 5 % : nonionic surfactants

- disinfectants

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 :

| | |
|------|---|
| H225 | Highly flammable liquid and vapour. |
| H302 | Harmful if swallowed. |
| H314 | Causes severe skin burns and eye damage. |
| H318 | Causes serious eye damage. |
| H319 | Causes serious eye irritation. |
| H336 | May cause drowsiness or dizziness. |
| 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 :

DNEL : Derived No-Effect Level

PNEC : Predicted No-Effect Concentration

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).

GHS05 : Corrosion

GHS09 : Environment

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.