



SAFETY DATA SHEETS

In accordance with CE Regulation 1907/2006 modified
by UE regulation no. 453/2010

LIQUID CALBENIUM®

Version : A
03/03/2014

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

1.1 Identification of the substance/ mixture

Name of the substance/preparation: **LIQUID CALBENIUM®**

Class **IIb** product according to the European directive 2007/47/CE about medical devices

1.2 Identified relevant use and non-recommended use of the substance or the mixture

Recommended use

CALBENIUM is used for dentistry. **It must be imperatively diluted (concentration of 2%) before use.**

1.3 Information about the supplier of the safety data sheet

Name of the company: **AIREL**
Address: 917, rue Marcel Paul – ZA des Grands Godets
Postal code and city: 94500 Champigny sur Marne
Country: FRANCE
Telephone: + 33.148.822.222
Fax: + 33.148.824.613
Email: raq@airrel.com

1.4 Emergency telephone number

AIREL Standard No.: +33 148 822 222 (during business hours)

Contact in case of an emergency:

ORFILA Server of INRS (24x7) = Tel: +33 1 45 42 59 59

Poisons centre: 24-hour hotline = Tel: +33 140 370 404

Poisons unit closer to the company: F. VIDAL Hospital = Tel: +33 140 054 848

Emergency service – Number in the European Union = 112

2. HAZARDS IDENTIFICATION

Effects on the environment: Very toxic for aquatic organisms.

Classification: Toxic to the environment

2.3 Other risks

No other information available currently.



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3. COMPOSITION / INFORMATION ABOUT THE CONSTITUENTS

Product	EC Number	CAS Number	Symbols for pure raw material	H and R phrases for pure raw material	Concentration
Bronidox	250-001-7	30007-47-7	Xi and N	38, 50/53	0.39%
Myristalkonium Chloride	205-352-0	139-08-2	C and N	34, 21-22, 50	0.6%
Ethyl Alcohol	200-578-6	64-17-5	F	11	3.18%
Dissolvine*- EDTA	205-358-3	139-33-3	Not classified	Not classified	6.9%

*: For substances with an exposure limit value, refer to section 8.

4. FIRST AID

4.1 Description of first aid

In the event of contact with skin:

Remove all contaminated clothes and shoes. Clean with water and soap, rinse thoroughly with water.
In case of persistent irritation, consult a doctor.

In the event of contact with eyes:

Rinse immediately with water for at least 15 minutes. In case of persistent irritation, consult an ophthalmologist.

If swallowed:

Rinse immediately and thoroughly with water and consult a specialist if required

If inhaled:

Fresh air and rest. Consult a specialist if required.

4.2 Main symptoms and effects, acute and delayed

No problem known at present. No additional data available.

4.3 Indications regarding the possible immediate medical care and special treatments required

No problem known at present. No additional data available.



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5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Appropriate extinguishing media:

None. The product is non-flammable.

Inappropriate extinguishing media:

None.

5.2 Specific hazards resulting from the substance or the mixture

None.

5.3 Instructions for fire-fighters

None.

6. MEASURES TO BE TAKEN IN CASE OF ACCIDENTAL DISCHARGE

6.1 Personal precautions, safety equipment and emergency procedures

Wear eye/face protection in order to prevent the discharge from splashing into the eyes.

6.2 Precautions for environmental protection

Avoid discharge into drains or water points.

Contain and absorb with absorbent inert material (sand, sawdust ...).

Sweep and shovel the solid product into a suitable container.

6.3 Containment and cleaning methods and equipment

Clean the floor with water and detergent.

Collect wash water into a suitable container.

6.4 Reference to other sections

For personal protective equipment, refer to section 8.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

None.

7.2 Conditions for safe storage, including the possible precautions

Store at room temperature.

7.3 Specific final use

No specific information available.



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8. EXPOSURE CONTROL / PERSONAL PROTECTION

8.1 Control parameters

CAS Number	Products	Average exposure value (mg/m ³)
205-352-0	Myristalkonium chloride	4
200-548-6	Ethyl alcohol	1900
139-33-3	Dissolvine – EDTA	5

8.2 Exposure control

Respiratory protection: none

Hand protection: wear latex gloves.

Eye protection: wear protection glasses.

Protection of the skin and body: none.

Specific hygiene measures:

Do not eat, drink or smoke during use.

Remove immediately contaminated clothes.

After work and during break, wash hands and face.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Important information about the physical and chemical properties

<i>Appearance</i>	:	Liquid
<i>Colour</i>	:	Blue or green
<i>Odour</i>	:	None or mint
<i>Boiling temperature</i>	:	Undetermined
<i>pH value</i>	:	5 ± 0,2
<i>Flash point</i>	:	Undetermined
<i>Density at 20°C</i>	:	1.01
<i>Solubility in water</i>	:	Completely soluble in water

9.2 Additional information

No specific information available.



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10. STABILITY AND REACTIVITY

10.1 Reactivity

No reactivity known at present.

10.2 Chemical stability

If stored and used as per the prescriptions and in its original packaging, the product is stable for 2 years from the manufacturing date.

10.3 Possibility of chemical reaction

No possible reaction known at present.

10.4 Conditions to be avoided

Store away from heat and incandescent sources.

10.5 Incompatible materials

No specific information available.

10.6 Hazardous decomposition products

No specific information available.

11. TOXICOLOGICAL INFORMATION

Information about toxicological effects

Bronidox	30007-47-7	Acute toxicity LD50 oral	LD50 > 2000 mg/kg
Ethyl Alcohol	64-17-5	Acute toxicity LC50 by inhalation, rat	LC50 > 2000 mg/kg
		Acute toxicity LD50 by contact with skin, rat	LD50 > 2000 mg/kg
Dissolvine	139-33-3	Acute toxicity LD50 oral, rat	LD50 > 2000 mg/kg

Main pathological effects known or observed:

Eyes: no available data up to date when used according to instructions
Skin: no available data up to date when used according to instructions
Accidental swallowing: no available data up to date when used according to instructions



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12. ECOLOGICAL INFORMATION

12.1 Toxicity

Bronidox (30007-47-7)	LC50 fish : >1-<=10 mg/L EC0 bacteria : >1-10 mg/L
Ethyl Alcohol (64-17-5)	LC50 fish (24h): 11400 mg/L LC50 algae (24h): 5000 mg/L
Dissolvine (139-08-2)	LC50 fish (96h): 320 mg/L LC50 Pseudomonas putida (8h): 56 mg/L
Myristalkonium Chloride (139-08-2)	LC50 fish (96h): 0.31 mg/L LC50 daphnia (48h): 0.02 mg/L

12.2 Persistence and degradability: No data available at present.

12.3 Bioaccumulation potential: No data available at present.

12.4 Mobility in soil: No data available at present.

12.5 Results of PBT and vPvB evaluations: No data available at present.

12.6 Other harmful effects: No data available at present.

13. DISPOSAL CONSIDERATIONS

Waste and residues:

- Incineration in an approved center.

Packaging:

- Disposal according to local regulations.

14. TRANSPORT INFORMATION

Cans/bottles should be transported in an upright position.

This product is not subjected to the international regulation on the transport of harmful goods
(ADR/RID/ADNR/IATA/IMDG)

15. REGULATORY INFORMATION

15.1 Regulations/legislation related to the substance or the mixture as regards safety, health and environment

At present, our suppliers have not provided any information about this point.

15.2 Assessment of chemical safety

At present, our suppliers have not provided any information about this point.



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16. ADDITIONAL INFORMATION

Complete version of the R and S phrases

R50/53	Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment.
R50	Very toxic to aquatic organisms
R34	Causes burns
R11	Highly flammable
R38	Irritating to skin
R21/22	Harmful in contact with skin and if swallowed

Special instructions:

Also refer to the technical usage instructions.
For all the additional information, contact the nearest supplier.

Sources for preparing the safety data sheet:

REACH ordinance, INRS, safety data sheets from suppliers, etc.

List of changes to the safety data sheet:

Creation: 03/03/2014

The information provided here is based on our current state of knowledge.
It describes the safety measures to be taken as regards the product in question.
It does not represent a guarantee about the product properties.
Users are requested to take into account the risks that might arise if
this product is used for purposes other than those intended.