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 : CALBENIUM LIQUIDE NEUTRE

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

Use in Odontology. It must imperatively be diluted to 2%.

1.3. Details of the supplier of the safety data sheet

Registered company name : AIREL.

Address : 917, rue Marcel Paul - Z.A. des Grands Godets.94500.Champigny-sur-Marne.France.

Telephone : 01 48 82 22 22. Fax : 01 48 82 46 13.

Email : office@airel.com

http://www.airel.com

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

Association/Organisation : INRS / ORFILA http://www.centres-antipoison.net.

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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

May produce an allergic reaction (EUH208).

Hazardous to the aquatic environment - Acute hazard, Category 1 (Aquatic Acute 1, H400).

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.

2.2. Label elements

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

Hazard pictograms :

GHS09

Signal Word :

WARNING

Additional labeling :

EUH208	Contains BENZENESULFONAMIDE, N-CHLORO-4-METHYL-, SODIUM SALT, HYDRATE (1:1:3). May produce an allergic reaction.

Hazard statements :

H410	Very toxic to aquatic life with long lasting effects.

Precautionary statements - Prevention :

P273	Avoid release to the environment.

Precautionary statements - Response :

P391	Collect spillage.

Precautionary statements - Disposal :

P501	Dispose of contents/container at a disposal facility in accordance with local regulations.

2.3. Other hazards

The mixture does not contain substances classified as ‘Substances of Very High Concern' (SVHC) >= 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: 139-33-3 EC: 205-358-3 REACH: 01-2119486775-20 DISODIUM DIHYDROGEN ETHYLENEDIAMINETETRAACETATE	GHS07, GHS08 Wng Acute Tox. 4, H332 STOT RE 2, H373		2.5 <= x % < 10
CAS: 57-09-0 EC: 200-311-3 REACH: 01-2119989160-35 CETRIMONIUM BROMIDE	GHS07, GHS05, GHS09, GHS08 Dgr Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H335 STOT RE 2, H373 Aquatic Acute 1, H400 M Acute = 100		0 <= x % < 1
CAS: 7080-50-4 EC: 204-854-7 BENZENESULFONAMIDE, N-CHLORO-4-METHYL-, SODIUM SALT, HYDRATE (1:1:3)	GHS07, GHS05, GHS08 Dgr Acute Tox. 4, H302 Skin Corr. 1B, H314 Resp. Sens. 1, H334 EUH:031		0 <= x % < 1
CAS: 30007-47-7 EC: 250-001-7 5-BROMO-5-NITRO-1,3-DIOXANNE	GHS07, GHS05, GHS09 Dgr Acute Tox. 4, H302 Skin Corr. 1B, H314 Aquatic Acute 1, H400 M Acute = 1 Aquatic Chronic 1, H410 M Chronic = 1		0 <= x % < 1

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

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 :

In the event of an allergic reaction, seek medical attention.

In the event of splashes or contact with eyes :

Wash thoroughly with soft, clean water for 15 minutes holding the eyelids open.

If there is any redness, pain or visual impairment, consult an ophthalmologist.

In the event of splashes or contact with skin :

In the event of an allergic reaction, seek medical attention.

Remove contaminated clothing and wash the skin thoroughly with soap and water or a recognised cleaner.

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

No data available.

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 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.

Remove and wash contaminated clothing before re-using.

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

No data available.

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

DISODIUM DIHYDROGEN ETHYLENEDIAMINETETRAACETATE (CAS: 139-33-3)

Final use:	**Workers.**
Exposure method:	Inhalation.
Potential health effects:	Short term local effects.
DNEL :	3 mg of substance/m3
Exposure method:	Inhalation.
Potential health effects:	Long term local effects.
DNEL :	1.5 mg of substance/m3

Final use:	**Consumers.**
Exposure method:	Ingestion.
Potential health effects:	Long term systemic effects.
DNEL :	25 mg/kg body weight/day
Exposure method:	Inhalation.
Potential health effects:	Short term local effects.
DNEL :	1.2 mg of substance/m3
Exposure method:	Inhalation.
Potential health effects:	Long term local effects.
DNEL :	0.6 mg of substance/m3

Predicted no effect concentration (PNEC):

DISODIUM DIHYDROGEN ETHYLENEDIAMINETETRAACETATE (CAS: 139-33-3)

Environmental compartment:	Soil.
PNEC :	0.72 mg/kg
Environmental compartment:	Fresh water.
PNEC :	2.2 mg/l
Environmental compartment:	Sea water.
PNEC :	0.22 mg/l
Environmental compartment:	Intermittent waste water.
PNEC :	1.2 mg/l
Environmental compartment:	Waste water treatment plant.
PNEC :	43 mg/l

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

Pictogram(s) indicating the obligation of wearing personal protective equipment (PPE) :

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

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.

Type of gloves recommended :

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

Recommended properties :

- Impervious gloves in accordance with standard EN374

- 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

General information :

Physical state :	Fluid liquid.
Odour:	Odourless.
Colour:	Blue.

Important health, safety and environmental information

pH :	Not stated. Neutral.
Flash point interval :	Not relevant.
Vapour pressure (50°C) :	Not relevant.
Density :	> 1
Water solubility :	Dilutable.

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 :

- frost

10.5. Incompatible materials

Keep away from :

- 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 :

5-BROMO-5-NITRO-1,3-DIOXANNE (CAS: 30007-47-7)

Oral route :	LD50 = 455 mg/kg Species : Rat

BENZENESULFONAMIDE, N-CHLORO-4-METHYL-, SODIUM SALT, HYDRATE (1:1:3) (CAS: 7080-50-4)

Oral route :	LD50 = 1000 mg/kg Species : Rat
Inhalation route (n/a) :	LC50 > 0.275 mg/l

CETRIMONIUM BROMIDE (CAS: 57-09-0)

Oral route :	LD50 = 465 mg/kg Species : Rat
Dermal route :	LD50 = 2150 mg/kg

Species : Rabbit

Inhalation route (n/a) : LC50 = 1.8 mg/m3
Species : Mouse

DISODIUM DIHYDROGEN ETHYLENEDIAMINETETRAACETATE (CAS: 139-33-3)
Oral route : 2000 < LD50 <= 5000 mg/kg
Species : Rat
OECD Guideline 401 (Acute Oral Toxicity)

11.1.2. Mixture

Respiratory or skin sensitisation :

Contains at least one sensitising substance. May cause an allergic reaction.

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

CAS 64-17-5 : IARC Group 1 : The agent is carcinogenic 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

5-BROMO-5-NITRO-1,3-DIOXANNE (CAS: 30007-47-7)
Fish toxicity : LC50 = 0.5 mg/l
Factor M = 1
Species : Leuciscus idus
Duration of exposure : 96 h

Crustacean toxicity : EC50 = 2.4 mg/l
Species : Daphnia magna
Duration of exposure : 48 h

DISODIUM DIHYDROGEN ETHYLENEDIAMINETETRAACETATE (CAS: 139-33-3)
Fish toxicity : LC50 > 100 mg/l
Species : Lepomis macrochirus
Duration of exposure : 96 h

Crustacean toxicity : EC50 > 100 mg/l
Species : Daphnia magna
Duration of exposure : 48 h

Algae toxicity : ECr50 > 100 mg/l
Species : Scenedesmus subspicatus
Duration of exposure : 72 h

BENZENESULFONAMIDE, N-CHLORO-4-METHYL-, SODIUM SALT, HYDRATE (1:1:3) (CAS: 7080-50-4)
Fish toxicity : LC50 = 31 mg/l
Species : Poecilia reticulata
Duration of exposure : 96 h

Crustacean toxicity : EC50 = 4.5 mg/l
Species : Daphnia magna
Duration of exposure : 48 h

Algae toxicity : ECr50 = 80 mg/l
Species : Chlorella pyrenoidosa
Duration of exposure : 72 h

NOEC = 1.1 mg/l

CETRIMONIUM BROMIDE (CAS: 57-09-0)

Fish toxicity :	LC50 = 0.2 mg/l Factor M = 1 Species : Danio rerio Duration of exposure : 96 h
Crustacean toxicity :	EC50 = 0.026 mg/l Species : Daphnia magna Duration of exposure : 48 h
	NOEC = 0.023 mg/l Duration of exposure : 21 days OECD Guideline 211 (Daphnia magna Reproduction Test)
Algae toxicity :	ECr50 = 0.00411 mg/l Species : Pseudokirchnerella subcapitata Duration of exposure : 72 h

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

12.2.1. Substances

5-BROMO-5-NITRO-1,3-DIOXANNE (CAS: 30007-47-7)
Biodegradability : Non-rapidly degradable.

BENZENESULFONAMIDE, N-CHLORO-4-METHYL-, SODIUM SALT, HYDRATE (1:1:3) (CAS: 7080-50-4)
Biodegradability : Rapidly degradable.

CETRIMONIUM BROMIDE (CAS: 57-09-0)
Biodegradability : Rapidly degradable.

DISODIUM DIHYDROGEN ETHYLENEDIAMINETETRAACETATE (CAS: 139-33-3)
Biodegradability : Rapidly degradable.

12.3. Bioaccumulative potential

12.3.1. Substances

BENZENESULFONAMIDE, N-CHLORO-4-METHYL-, SODIUM SALT, HYDRATE (1:1:3) (CAS: 7080-50-4)
Octanol/water partition coefficient : log Koe = -1.3

CETRIMONIUM BROMIDE (CAS: 57-09-0)
Octanol/water partition coefficient : log Koe = 3.18

DISODIUM DIHYDROGEN ETHYLENEDIAMINETETRAACETATE (CAS: 139-33-3)
Octanol/water partition coefficient : log Koe = -4.3

Bioaccumulation : BCF = 1.8
Species : Lepomis macrochirus (Fish)

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

German regulations concerning the classification of hazards for water (WGK, AwSV vom 18/04/2017, KBws) :

WGK 2 : Hazardous for water.

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

3082

14.2. UN proper shipping name

UN3082=ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

(cetrimonium bromide, 5-bromo-5-nitro-1,3-dioxanne)

14.3. Transport hazard class(es)

- Classification :

9

14.4. Packing group

III

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
	9	M6	III	9	90	5 L	274 335 375 601	E1	3	-

Not subject to this regulation if Q <= 5 l / 5 kg (ADR 3.3.1 - DS 375)

IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ
	9	-	III	5 L	F-A,S-F	274 335 969	E1

Not subject to this regulation if Q <= 5 l / 5 kg (IMDG 3.3.1 - 2.10.2.7)

IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ
	9	-	III	964	450 L	964	450 L	A97 A158 A197	E1
	9	-	III	Y964	30 kg G	-	-	A97 A158 A197	E1

Not subject to this regulation if Q <= 5 l / 5 kg (IATA 4.4.4 - DS A197)

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. 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. 2018/669 (ATP 11)

- Container information:

No data available.

- Particular provisions :

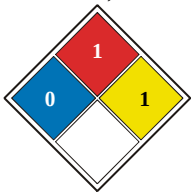
No data available.

- German regulations concerning the classification of hazards for water (WGK, AwSV vom 18/04/2017, KBws) :

WGK 2 : Hazardous for water.

- Standardised American system for the identification of hazards presented by the product in view of emergency procedures (NFPA 704) :

NFPA 704, Labelling: Health=0 Inflammability=1 Instability/Reactivity=1 Specific Risk=none



- Swiss ordinance on the incentive tax on volatile organic compounds :

64-17-5 éthanol, seulement s'il s'agit d'alcools impropres à la consommation (art. 31 de la loi fédérale sur l'alcool)

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 :

H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H332	Harmful if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H373	May cause damage to organs through prolonged or repeated exposure .
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
EUH031	Contact with acids liberates toxic gas.

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 : Wassergefahrdungsklasse (Water Hazard Class).

GHS09 : Environment

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.