



SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 453/2010)

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

1.1. Product identifier

Product name : ASEPTOL SA

Product code : 282000

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

Cleaning and disinfection of suction circuits and medical devices in dental sector.

1.3. Details of the supplier of the safety data sheet

Registered company name : SEPTODONT.

Address : 58, rue du Pont de Créteil.94107.SAINT-MAUR-DES-FOSSES Cedex.FRANCE.

Telephone : +33 (0)1 49 76 70 00. Fax : +33 (0)1 48 85 54 01.

e:mail : msds@septodont.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 directives 67/548/EEC, 1999/45/EC and their amendments.

Skin irritation (Xi, R 38).

Serious eye damage (Xi, R 41).

Aquatic environmental hazard, chronic toxicity: toxic (N, R 51/53).

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).

This mixture being intended for professional use only, the labelling for contents under detergent regulation does not appear on the label but is resumed in section 15

In compliance with directives 67/548/EEC, 1999/45/EC and their amendments.

Hazard symbols :



Irritant



Dangerous for the environment

Risk phrase :

R 51/53

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R 38

Irritating to skin.

R 41

Risk of serious damage to eyes.

Safety phrase :

S 26

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 36/39

Wear suitable protective clothing and eye/face protection.

S 45

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S 61

Avoid release of undiluted product to the environment. Refer to special instructions/Safety data sheets.

S 37

Wear suitable gloves.

S 2

Keep out of the reach of children.

Contains POLYHEXAMETHYLENE BIGUANIDE HYDROCHLORIDE

2.3. Other hazards

No other hazard identified in the current state of knowledge.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Title for H, EUH and R indications: see § 16.

3.1. Substances

Not applicable

3.2. Mixtures**Composition :**

Identification	(EC) 1272/2008	67/548/EEC	Note	%
CAS: 138698-36-9 EC: 270-331-5 N-DECYL-N-ISONOYL-N, N-DIMETHYLAMMONIUM CHLORIDE	GHS07, GHS05, GHS09 Dgr Acute Tox. 4, H302 Skin Corr. 1B, H314 Aquatic Acute 1, H400	C,N C;R34 Xn;R22 N;R50		2.5 <= x % < 10
CAS: 37971-36-1 EC: 253-733-5 REACH: 01-2119436643-39 2- PHOSPHONOBUTANE-1,2, 4- TRICARBOXYLIC ACID	GHS05 Wng Met. Corr. 1, H290 Eye Irrit. 2, H319	Xi Xi;R36		0 <= x % < 2.5

Information on ingredients :

CAS: 64-17-5 EC: 200-578-6	ETHANOL
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Other data :

CAS 64-17-5 ETHANOL < 0.5%

CAS 27083-27-8 POLYHEXAMETHYLENE BIGUANIDE HYDROCHLORIDE | Concentration >= 0.00% and <2.50%. Symbol: GHS05, GHS09, Dgr, Xi N H: 302-315-317-318-335-410 R: 37/38-43-50/53-41-22

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 :**

Move the person away from the place of exposure and take him/her outside.

In the event of splashes or contact with eyes :

If applicable, remove contact lenses.

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

Additional treatment to be provided immediately in an eye clinic or by an ophthalmologist. Show this container or label.

Continue rinsing until medical advice is obtained.

In the event of splashes or contact with skin :

Remove all contaminated or stained clothing immediately. Do not use them again until they have been decontaminated.

Rinse immediately and thoroughly with water.

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 :

Rinse out the mouth, do not induce vomiting, keep the person calm and take him/her to a clinic or a doctor's. Show the container or label.

4.2. Most important symptoms and effects, both acute and delayed

Cf. § 11

4.3. Indication of any immediate medical attention and special treatment needed

Refer to the recommendation of the doctor.

SECTION 5 : FIREFIGHTING MEASURES**5.1. Extinguishing media****Suitable methods of extinction**

Any extinguishing agents are authorized: foam, sand, carbon dioxide, water, powder.

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.

5.3. Advice for firefighters

Use autonomous insulating breathing apparatus and a full protective suit.

SECTION 6 : ACCIDENTAL RELEASE MEASURES**6.1. Personal precautions, protective equipment and emergency procedures**

Consult the safety measures listed under headings 7 and 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.

Do not get rid in natural spaces (waterways, ground and vegetations...)

6.3. Methods and material for containment and cleaning up

Absorb any spilled product with absorbent non-combustible materials, and sweep away or remove with a shovel. Put any waste in drums for disposal. Do not mix with any other waste. Wash the contaminated surface thoroughly with water.

Do not collect the product for re-use.

Do not get rid in natural spaces.

6.4. Reference to other sections

Disposal considerations: see section 13.

SECTION 7 : HANDLING AND STORAGE**7.1. Precautions for safe handling**

Product for external use - do not swallow.

Avoid all contact with skin, eyes and clothes.

Handle in accordance with user instructions on label

Recommended equipment and procedures :

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Avoid eye contact with this mixture at all times.

Eye bath and water point nearby.

7.2. Conditions for safe storage, including any incompatibilities

Keep the container tightly closed

Store ONLY in the original package.

Store between + 5 °C and + 35 °C in a dry, well ventilated place

Do not use after the expiry date mentioned on the packaging.

Keep out of the reach of children

7.3. Specific end use(s)

For professional use only

See paragraph 1, label and technical file for product indication

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

The information in this chapter refers to the product specifically described in this document. If the product is handled and/or exposed simultaneously with other chemical agents, these must be taken into consideration when choosing personal safety equipment.

8.1. Control parameters**Occupational exposure limits :**

- Switzerland (SUVA 2009) :

CAS	VME-mg/m ³ :	VME-ppm :	VLE-mg/m ³ :	VLE-ppm :	Temps :	RSB :
64-17-5	960	500	1920	1000	4x15	-

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

CAS	VME :	VME :	Excess	Notes
64-17-5	500 ml/m ³	960 mg/m ³	2(II)	DFG. Y

Slovakia (Regulation No. 300/2007) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
64-17-5	500 ppm	960 mg/m3	II..1		

Czech Republic (Regulation No. 361/2007) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
64-17-5	1000 mg/m3	3000 mg/m3	-	-	-

- Spain (Instituto Nacional de Seguridad e Higiene en el Trabajo (INSHT), Mayo 2010) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
64-17-5	1000 ppm	-	-	-	-

- Poland (2009) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
64-17-5	1900 mg/m3	-	-	-	-

- Belgium (Order of 19/05/2009, 2010) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
64-17-5	1000 ppm	-	-	-	-

- France (INRS - ED984 :2008) :

CAS	VME-ppm :	VME-mg/m3 :	VLE-ppm :	VLE-mg/m3 :	Notes :	TMP No :
64-17-5	1000	1900	5000	9500	-	84

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

Prescription glasses are not considered as protection.

Avoid all contact with skin or eyes.

Make safety goggles with side protection available to the personnel.

Provide eye washes in workshops.

If necessary, the nearest water supply

- Hand protection

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.

When handling this product, wear suitable gloves.

Nitrile, latex or vinyl gloves.

Gloves must be replaced immediately if they show signs of wear and tear.

- Body protection

Avoid skin contact.

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.

- Respiratory protection

Not applicable in normal conditions of use.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES**9.1. Information on basic physical and chemical properties****General information :**

Physical state :	fluid liquid.
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Important health, safety and environmental information

pH :	Not stated.
	strongly acidic.
Boiling point/boiling range :	not specified.
Flash point interval :	not relevant.
Vapour pressure :	not relevant.
Density :	+/- 1,01
Water solubility :	Soluble.
Melting point/melting range :	not specified.
Self-ignition temperature :	not specified.
Decomposition point/decomposition range :	not specified.

9.2. Other information

pH pure product: < 2.

The strong acid property is linked to the formulation natural pH - it does not correspond to the presence of strong acid compound in the preparation.

Odour :	Weak
Colour:	red

SECTION 10 : STABILITY AND REACTIVITY**10.1. Reactivity**

No hazardous reaction if the instructions/indications for storage and handling are respected.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

Cf. § 10.1 and 10.2

10.4. Conditions to avoid

Do not mix with other products.

10.5. Incompatible materials

Strong bases.

10.6. Hazardous decomposition products

At high temperatures, dangerous decomposition products may be produced, such as fumes, carbon dioxide and carbon monoxide, nitrogen oxide.

SECTION 11 : TOXICOLOGICAL INFORMATION**11.1. Information on toxicological effects**

The classification of this preparation with regard to health risks for corrosive and irritating effects to skin is based on a specific toxicological expertise.

11.1.1. Substances

Not specified

11.1.2. Mixture**Acute toxicity :**

Inhalation may lead to irritation of the respiratory tracts.

Ingestion may lead to irritation of the digestive system, abdominal pain, headaches and nausea.

Acute toxicity estimate (ATE)* :

Oral ATE : > 2000 mg/kg

* according to the method of calculation describe in the CLP regulation (Classification, Labelling, Packaging) Part 3 Chapter 3.1 based on the data of the different components present in the product.

Skin corrosion/skin irritation :

Dermal irritation/corrosion test in the rabbit (OECD 404):

The preparation, tested as such, appears to be irritating to skin.

Skin irritation: itching, light to moderate local redness, burning sensation...

Serious damage to eyes/eye irritation :

Serious eyes damage.

Burns, characterized by discomfort or pain, excessive blinking, lacrimation and redness, swelling of the conjunctiva.

Other information

Skin sensitisation in the guinea-pig - maximisation test (OECD 406):

The preparation is not classified among the chemicals which may cause sensitisation by skin contact.

SECTION 12 : ECOLOGICAL INFORMATION

Following information is based on data from the compounds.

Avoid any product release into waterways.

12.1. Toxicity**12.1.1. Substances**

Not specified

12.1.2. Mixtures

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

(according to the conventional method of calculation included in the directive 99/45/CE)

12.2. Persistence and degradability

The surfactant(s) contained in this preparation complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents.

Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.

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.

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.

The packages must not be reused.

Do not pour into waterways.

13.1. Waste treatment methods**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.

Soiled packaging :

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

Codes of wastes (Decision 2001/573/EC, Directive 2006/12/EEC, Directive 94/31/EEC on hazardous waste) :

18 01 06 * chemicals consisting of or containing dangerous substances

For information :

The waste code is given for indicative purposes.

The waste code must be determined by the user, according to the application of the product.

18 = Wastes from human or animal health care and/or related research (except kitchen and restaurant wastes not arising from immediate health care)

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 2011 - IMDG 2010 - ICAO/IATA 2012).

14.1. UN number

3082

14.2. UN proper shipping name

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

N.O.S : (POLYHEXAMETHYLENE BIGUANIDE HYDROCHLORIDE)

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	274 335 601	E1	3	E
IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ			
	9	-	III	5 L	F-A,S-F	274 335	E1			
IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ	
	9	-	III	964	450 L	964	450 L	A97 A158	E1	
	9	-	III	Y964	30 kg G	-	-	A97 A158	E1	

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable

SECTION 15 : REGULATORY INFORMATION**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****- Particular provisions :**

No data available.

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

- less than 5 % : phosphonates
- 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.

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.

It is recommended that the information contained in this safety data sheet is provided to the users, if necessary in an appropriate form.

This information relates to the specifically designated product and may not be valid in combination with any other product. The product must not be used for applications other than those specified in heading 1 without having first obtained written handling instructions.

UPDATES SINCE PREVIOUS VERSION

New format in accordance with rule 453/2010 (EU).

- § 3
- § 11

Title for H, EUH and R indications mentioned in section 3 :

H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
R 22	Harmful if swallowed.
R 34	Causes burns.
R 36	Irritating to eyes.
R 50	Very toxic to aquatic organisms.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H335 May cause respiratory irritation.

H410 Very toxic to aquatic life with long lasting effects.

R 37/38 Irritating to respiratory system and skin.

R 41 Risk of serious damage to eyes.

R 43 May cause sensitisation by skin contact.

R 50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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.