

Name : ENDOSEPTONE - ART.11350



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 : ENDOSEPTONE

Product code : ART.11350.

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

For dental professional use only.

1.3. Details of the supplier of the safety data sheet

Registered company name : PRODUITS DENTAIRES SA.

Address : Rue des Bosquets 18 .1800 .Vevey .Switzerland.

Telephone : +41 21 921 26 31. Fax : +41 21 921 39 79.

info@pdsa.ch

http://www.pdsa.ch

1.4. Emergency telephone number : +41 21 921 26 31.

Association/Organisation : .

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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

Acute oral toxicity, Category 4 (Acute Tox. 4, H302).

Acute inhalation toxicity, Category 4 (Acute Tox. 4, H332).

Skin irritation, Category 2 (Skin Irrit. 2, H315).

Serious eye damage, Category 1 (Eye Dam. 1, H318).

Specific target organ toxicity (single exposure), Category 2 (STOT SE 2, H371).

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.

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

Acute oral toxicity: harmful (Xn, R 22).

Acute cutaneous toxicity: harmful (Xn, R 21).

Acute inhalation toxicity: harmful (Xn, R 20).

Irreversible non-lethal effects after a single oral exposure: harmful (Xn, R 68/22).

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

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

Hazard pictograms :



GHS07



GHS05



GHS09



GHS08

Signal Word :

DANGER

Product identifiers :

EC 200-945-0

604-008-00-0

CAMPHOR L(XN68)=10% X

4-CHLOROPHENOL

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EC 201-944-8 THYMOL

Hazard statements :

H302 + H332 Harmful if swallowed or if inhaled.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H371 May cause damage to organs (if swallowed).
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements - Prevention :

P260 Avoid breathing vapours.
P264 Wash hands thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves according to the hygienic rules in force in dental surgeries.

Precautionary statements - Response :

P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P330 Rinse mouth.
P332 + P313 If skin irritation occurs: Get medical advice/attention.
P391 Collect spillage.

Precautionary statements - Disposal :

P501 Dispose of contents/container according to the hygienic rules in force in dental surgeries and according to the legislation in force.

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 satisfies 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	67/548/EEC	Note	%
CAS: 76-22-2 EC: 200-945-0 CAMPHOR L(XN68)=10% X INDEX: 604-008-00-0 CAS: 106-48-9 EC: 203-402-6 4-CHLOROPHENOL	GHS08, GHS02, GHS07 Wng Acute Tox. 4, H332 STOT SE 2, H371	Xn,F Xn;R68/22-R20 F;R11	[1]	50 <= x % < 100
CAS: 89-83-8 EC: 201-944-8 THYMOL	GHS07, GHS05, GHS09 Dgr Acute Tox. 4, H302 Skin Corr. 1B, H314 Aquatic Chronic 2, H411	C,N C;R34 Xn;R22 N;R51/53		2.5 <= 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 :

In the event of massive inhalation, remove the person exposed to fresh air. Keep warm and at rest.

Do not proceed with mouth-to-mouth or mouth-to-nose resuscitation. Use the appropriate equipment.

In the event of splashes or contact with eyes :

Wash thoroughly with soft, 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 :

Wash the skin thoroughly with soap and fresh water.

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

Be careful with product which can remain between the skin and the clothes, the watch, the jewels.

In the event of swallowing :

Do not give the patient anything orally.

In the event of swallowing, if the quantity is small (no more than one mouthful), rinse the mouth with water, administer activated medical charcoal and consult a doctor.

If swallowed accidentally, call a doctor to ascertain whether observation and hospital care will be necessary. Show the label.

Rinse the mouth with water.

Do not induce vomiting.

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

Irritation, corrosion, cough, breathing difficulties, dizziness, migraine.

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

In the event of a fire, use :

- sprayed water or water mist
- powder
- carbon dioxide (CO₂)
- stable foams in alcohols

Unsuitable methods of extinction

In the event of a fire, do not use :

- water jet

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)
- hydrochloric gas

5.3. Advice for firefighters

Wear self-contained breathing apparatus.

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 inhaling the vapors.

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).

Avoid inhaling the vapors.

Avoid any contact with the skin and eyes.

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

Respect storage precautions mentioned on the packaging or in the instructions for use.

7.1. Precautions for safe handling

Always wash hands after handling.

The persons who have medical histories of cutaneous reactions must use this product with all the required precautions.

Avoid any contact with skin and eyes.

Fire prevention :

Prevent access by unauthorised personnel.

Recommended equipment and procedures :

For personal protection, see section 8.

Packages which have been opened must be reclosed carefully and stored in an upright position.

7.2. Conditions for safe storage, including any incompatibilities

Keep in the original container, respect the storage temperatures mentioned on the container, the leaflet and the box.

Storage

Respect storage precautions mentioned on the packaging or in the instructions for use.

Packaging

Always conserve in the original packaging.

7.3. Specific end use(s)

Consult instructions for use enclosed.

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 :
76-22-2	2 ppm	3 ppm	-	-	-

- France (INRS - ED984 :2008) :

CAS	VME-ppm :	VME-mg/m3 :	VLE-ppm :	VLE-mg/m3 :	Notes :	TMP No :
76-22-2	2	12	-	-	-	-

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

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CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
76-22-2	2 ppm	3 ppm	-	-	-

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

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



- Eye / face protection

Avoid contact with eyes.

Individuals wearing contact lenses should wear prescription glasses during work where they may be exposed to irritant vapours.

- Hand protection

Wear gloves according to the hygienic rules in force in dental surgeries.

- Body protection

Avoid skin contact.

After contact with the product, all parts of the body that have been soiled must be washed.

- Respiratory protection

Avoid breathing vapours.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information :

Physical state :	Fluid liquid.
Colour:	yellowish.
Odour:	camphorated.

Important health, safety and environmental information

pH :	5.00 . Neutral.
Boiling point/boiling range :	Not relevant.
Flash point interval :	Not relevant.
Vapour pressure (50°C) :	Not relevant.
Density :	1.022
Miscibility :	Ethanol
Water solubility :	Insoluble.
Viscosity :	15.8 Method for determining the viscosity : DIN 51562-1 (Viscometry - Measurement of kinematic viscosity by means of the Ubbelohde viscometer - Part 1: Viscometer specification and measurement procedure).
Melting point/melting range :	Not relevant.
Self-ignition temperature :	Not relevant.
Decomposition point/decomposition range :	Not relevant.

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.

Do not use if the expiry date is exceeded.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Avoid :

- heat
- exposure to light

10.5. Incompatible materials

Keep away from :

- strong oxidising agents
- strong reducing agents
- chlorinated solvents

10.6. Hazardous decomposition products

The thermal decomposition may release/form :

- carbon monoxide (CO)
- carbon dioxide (CO₂)
- hydrochloric gas

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Harmful if swallowed.

Harmful by inhalation.

May cause irreversible damage to the skin; namely inflammation of the skin or the formation of erythema and eschar or oedema following exposure up to four hours.

May have irreversible effects on the eyes, such as tissue damage in the eye, or serious physical decay of sight, which is not fully reversible by the end of observation at 21 days.

Serious eye damage is typified by the destruction of cornea, persistent corneal opacity and iritis.

May cause damage to organs.

11.1.1. Substances

Acute toxicity :

THYMOL (CAS: 89-83-8)

Oral route :

LD50 = 980 mg/kg

Species : Rat (recommended by the CLP)

Dermal route :

LD50 > 2000 mg/kg

Species : Rat (recommended by the CLP)

CAMPHOR L(XN68)=10% X (CAS: 76-22-2)

Oral route :

LD50 = 4900 mg/kg

Inhalation route :

LC50 = 1.5 mg/l

Skin corrosion/skin irritation :

THYMOL (CAS: 89-83-8)

Species : Rabbit (recommended by the CLP)

OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

Serious damage to eyes/eye irritation :

THYMOL (CAS: 89-83-8)

Species : Rabbit (recommended by the CLP)

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OECD Guideline 405 (Acute Eye Irritation / Corrosion)

Species : Rabbit (recommended by the CLP)
OECD Guideline 405 (Acute Eye Irritation / Corrosion)

Species : Rabbit (recommended by the CLP)
OECD Guideline 405 (Acute Eye Irritation / Corrosion)

Germ cell mutagenicity :

THYMOL (CAS: 89-83-8)
Ames test (in vitro) :

Negative.

11.1.2. Mixture

No toxicological data available for the mixture.

SECTION 12 : ECOLOGICAL INFORMATION

Toxic to aquatic life with long lasting effects.

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

12.1. Toxicity

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

12.2.1. Substances

THYMOL (CAS: 89-83-8)
Biodegradability :

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

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.

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.

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SECTION 14 : TRANSPORT INFORMATION

Exempt from transport classification and labelling.

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2013 - IMDG 2012 - ICAO/IATA 2014).

As per Special Provision A197, this product is not considered as hazardous for transport. In case of bulk transport of more than 5L, UN N° 3082 is applicable.

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:

- Directive 67/548/EEC and its adaptations
- Directive 1999/45/EC and its adaptations

- Container information:

The mixture is contained in packaging that does not exceed 125 ml.

- Particular provisions :

No data available.

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

NFPA 704, Labelling: Health=3 Inflammability=1 Instability/Reactivity=1 Specific Risk=none



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.

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

Hazard symbols :



Harmful



Dangerous for the environment

Contains :

604-008-00-0
EC 200-945-0

4-CHLOROPHENOL
CAMPBOR L(XN68)=10% X

Risk phrase :

R 51/53

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

R 20/21/22

Harmful by inhalation, in contact with skin and if swallowed.

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R 68/22	Harmful: possible risk of irreversible effects if swallowed.
Safety phrase :	
S 36/37	Wear suitable protective clothing and gloves.
S 61	Avoid release to the environment. Refer to special instructions/Safety data sheets.
S 60	This material and its container must be disposed of as hazardous waste.
S 9	Keep container in a well-ventilated place.
S 57	Use appropriate container to avoid environmental contamination.

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

H228	Flammable solid.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H332	Harmful if inhaled.
H371	May cause damage to organs .
H411	Toxic to aquatic life with long lasting effects.
R 11	Highly flammable.
R 20	Harmful by inhalation.
R 20/21/22	Harmful by inhalation, in contact with skin and if swallowed.
R 22	Harmful if swallowed.
R 34	Causes burns.
R 51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R 68/22	Harmful: possible risk of irreversible effects if swallowed.

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.
GHS05 : Corrosion
GHS07 : Exclamation mark
GHS08 : Health hazard
GHS09 : Environment