

SAFETY DATA SHEET

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

1.1. Product identifier

Product name: SURGICAL DRESSING

Product code: ART-11630.

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:.

info@pd-dental.com https://pd-dental.com

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

Association/Organisation: .

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS compliant.

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

Eye irritation, Category 2A (Eye Irrit. 2A, H319).

Skin sensitisation, Category 1 (Skin Sens. 1, H317).

This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

2.2. Label elements

GHS compliant.

Hazard pictograms:



GHS07

Signal Word : WARNING

Product identifiers:

CAS 94-09-7 BENZOCAINE

Hazard statements:

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.

Precautionary statements - Prevention:

P261 Avoid breathing vapours.

P264 Wash hands thoroughly after handling.

P280 Wear protective gloves according to the hygienic rules in force in dental

surgeries.

Precautionary statements - Response:

P302 + P352 IF ON SKIN: Wash with plenty of water

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P337 + P313 If eye irritation persists: Get medical advice/attention.

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

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

Composition:

Identification	Classification GHS	Note	%
CAS: 90-05-1	GHS07		$10 \le x \% < 25$
EC: 604-031-00-6	Wng		
	Acute Tox. 4, H302		
GAIACOL	Acute Tox. 5, H313		
	Skin Irrit. 2, H315		
	Eye Irrit. 2, H319		
CAS: 94-09-7	GHS07		$2.5 \le x \% < 10$
EC: 202-303-5	Wng		
	Skin Irrit. 2, H315		
BENZOCAINE	Skin Sens. 1, H317		
CAS: 2216-51-5	GHS07		$2.5 \le x \% < 10$
EC: 218-690-9	Wng		
REACH: 01-2119458866-21-xxxx	Skin Irrit. 2, H315		
MENTHOL			
CAS: 552-22-7	GHS07, GHS09		$1 \le x \% < 2.5$
EC: 209-007-5	Wng		
	Acute Tox. 4, H302		
IODURE DE THYMOL / THYMOL IODIDE	Aquatic Chronic 2, H411		
CAS: 119-36-8	GHS08, GHS07	[ii]	$1 \le x \% < 2.5$
_	Wng		
SALICYLATE DE MÉTHYLE / METHYLIS	Acute Tox. 4, H302		
SALICYLAS	Skin Irrit. 2, H315		
	Eye Irrit. 2, H319		
	STOT SE 3, H335		
	Repr. 2, H361		

Information on ingredients:

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

[ii] Carcinogenic, mutagenic or reprotoxic (CMR) substance.

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.

In the event of splashes or contact with eyes:

Wash thoroughly with fresh, 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.

If the contaminated aera is widespread and/or there is damage to the skin, a doctor must be consulted or the patient transferred to hospital.

Wash the skin thoroughly with soap and fresh water.

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 and consult a doctor.

Seek medical attention immediately, 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

Suitable methods of extinction

In the event of a fire, use:

- water
- carbon dioxide (CO2)
- powder

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)
- gas / irritant vapours
- halogenic compounds

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 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 any contact with the skin and eyes.

6.2. Environmental precautions

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Retrieve the product by mechanical means.

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.

Avoid any contact with skin and eyes.

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

Fire prevention:

Prevent access by unauthorised personnel.

Recommended equipment and procedures:

For personal protection, see section 8.

Avoid skin and eye contact with this mixture.

Packages which have been opened must be reclosed carefully.

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

Keep the well closed bottle.

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

No data available.

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.

- 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

No data available.

Physical state

Physical state: Paste.

Colour

Colour: Brownish

Odour

Odour threshold : Not stated.
Odour Characteristic

Melting point

Melting point/melting range: Not relevant.

Freezing point

Freezing point / Freezing range : Not stated. **Boiling point or initial boiling point and boiling range**

Boiling point/boiling range: Not relevant.

Flammability

Flammability (solid, gas): Not stated.

Lower and upper explosion limit

Explosive properties, lower explosivity limit (%) Not stated.:

Explosive properties, upper explosivity limit (%) Not stated.

: 1

Flash point

Flash point interval: Not relevant.

Auto-ignition temperature

Self-ignition temperature: Not relevant.

Decomposition temperature

Decomposition point/decomposition range: Not relevant.

pН

pH (aqueous solution): Not stated. pH: Not relevant.

Kinematic viscosity

Viscosity: Not stated.

Solubility

Water solubility: Insoluble. Fat solubility: Not stated.

Partition coefficient n-octanol/water (log value)

Partition coefficient: n-octanol/water: Not stated.

Vapour pressure

Vapour pressure (50°C): Not relevant.

Density and/or relative density

Density: 0.9

Relative vapour density

Vapour density: Not stated.

9.2. Other information

No data available.

9.2.1. Information with regard to physical hazard classes

No data available.

9.2.2. Other safety characteristics

No data available.

Miscibility

Miscibility: Ethanol

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

10.5. Incompatible materials

Keep away from:

- strong oxidising agents

10.6. Hazardous decomposition products

The thermal decomposition may release/form:

- carbon monoxide (CO)
- carbon dioxide (CO2)
- gas / irritant vapours
- halogenic compounds

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

11.1.1. Substances

a) Acute toxicity:

SALICYLATE DE MÉTHYLE / METHYLIS SALICYLAS (CAS: 119-36-8)

Oral route: LD50 = 887 mg/kg body weight

Species: Rabbit

Dermal route: LD50 > 5000 mg/kg body weight

Species: Rabbit

BENZOCAINE (CAS: 94-09-7)

Oral route : LD50 = 3.042 mg/kg body weight

Species: Rat

GAIACOL (CAS: 90-05-1)

Oral route : LD50 = 725 mg/kg body weight

Species: Rat

Dermal route: LD50 = 4600 mg/kg body weight

Species: Rabbit

b) Skin corrosion/skin irritation:

GAIACOL (CAS: 90-05-1)

Species: Rabbit

OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

Species: Rabbit

OECD Guideline 404 (Acute Dermal Irritation / Corrosion)

c) Serious damage to eyes/eye irritation:

SALICYLATE DE MÉTHYLE / METHYLIS SALICYLAS (CAS: 119-36-8)

Causes serious eye irritation.

Corneal haze: 1 <= Average score < 2 and effects totally reversible within 21 days of observation

d) Respiratory or skin sensitisation:

No data available.

e) Germ cell mutagenicity:

No data available.

f) Carcinogenicity:

No data available.

g) Reproductive toxicant:

No data available.

h) Specific target organ systemic toxicity - single exposure :

No data available.

i) Specific target organ systemic toxicity - repeated exposure :

No data available.

j) Aspiration hazard:

No data available.

11.1.2. Mixture

11.1.2.1 Information on hazard classes

a) Acute toxicity:

Oral route : No data available.

No data available.

Dermal route:

b) Skin corrosion/skin irritation:

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.

c) Serious damage to eyes/eye irritation:

May have reversible effects on the eyes, such as eye irritation which is totally reversible by the end of observation at 21 days.

d) Respiratory or skin sensitisation:

May cause an allergic reaction by skin contact.

e) Germ cell mutagenicity:

No data available.

f) Carcinogenicity:

No data available.

g) Reproductive toxicant :

No data available.

$\label{eq:control_problem} \textbf{h) Specific target organ systemic toxicity-single exposure:}$

No data available.

i) Specific target organ systemic toxicity - repeated exposure :

No data available.

$j) \ A spiration \ hazard:$

No data available.

11.1.2.2 Other information

11.2. Information on other hazards

SECTION 12 : ECOLOGICAL INFORMATION

12.1. Toxicity

12.1.2. Mixtures

No aquatic toxicity data available for the substances.

12.2. Persistence and degradability

No data available.

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. Endocrine disrupting properties

No data available.

12.7. Other adverse effects

No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

The appropriate waste management of the mixture and/or its container must be determined in accordance with local regulations.

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, 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

Exempt from transport classification and labelling.

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards

14.6. Special precautions for user

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

SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

The following regulations have been used:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), review no. 8 (2019)

Container information:

No data available.

Particular provisions:

No data available.

Substances that deplete the ozone layer (EC Regulation No. 1005/2009, Montreal Protocol):

The mixture does not contain any substance posing a risk to the ozone layer.

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.
H313	May be harmful in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H360	May damage fertility or the unborn child .
H411	Toxic to aquatic life with long lasting effects.

Abbreviations and acronyms:

LD50: The dose of a test substance resulting in 50% lethality in a given time period.

REACH: Registration, Evaluation, Authorization and Restriction of Chemical Substances.

CMR: Carcinogenic, mutagenic or reprotoxic.

ADR: European agreement concerning the international carriage of dangerous goods by Road.

GHS07 : Exclamation mark

IATA: International Air Transport Association.
IMDG: International Maritime Dangerous Goods.
ICAO: International Civil Aviation Organisation
PBT: Persistent, bioaccumulable and toxic.

RID: Regulations concerning the International carriage of Dangerous goods by rail.

vPvB: Very persistent, very bioaccumulable.