

Name : ROSEN ROOT-CANAL CEMENT POWDER SILVER FREE - ART.10245



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 : ROSEN ROOT-CANAL CEMENT POWDER SILVER FREE

Product code : ART.10245.

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

To mix with ROSEN ROOT-CANAL CEMENT LIQUID.

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.

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

Hazardous to the aquatic environment - Chronic hazard, Category 1 (Aquatic Chronic 1, H410).

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 a health hazard with the exception of possible occupational exposure thresholds (see paragraphs 3 and 8).

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

Aquatic environmental hazard, chronic toxicity: very toxic (N, R 50/53).

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 a health hazard with the exception of possible occupational exposure thresholds (see paragraphs 3 and 8).

2.2. Label elements

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

Hazard pictograms :



GHS09

Signal Word :

WARNING

Hazard statements :

H410

Very toxic to aquatic life with long lasting effects.

Precautionary statements - Prevention :

P273

Avoid release to the environment.

P280

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

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Precautionary statements - Response :

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

In use, may form flammable/explosive dust-air mixture.

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	%
INDEX: 030-013-00-7 CAS: 1314-13-2 EC: 215-222-5 ZINC OXIDE	GHS09 Wng Aquatic Acute 1, H400 M Acute = 1 Aquatic Chronic 1, H410 M Chronic = 1	N N;R50/53	[1]	25 \leq x % < 50
CAS: 552-22-7 EC: 209-007-5 IODURE DE THYMOL	GHS07 Wng Acute Tox. 4, H302	Xn Xn;R22		2.5 \leq 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.

If the person is unconscious, place in recovery position. Notify a doctor in all events, to ascertain whether observation and supportive hospital care will be necessary.

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 :

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 an allergic reaction, seek medical attention.

In the event of swallowing :

Do not induce vomiting.

Rinse the mouth with water and then drink a lot of water. Seek medical attention.

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

Breathing system irritation.

Severe eyes irritation.

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)
- metallic oxide smokes
- 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 generating dusts.

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 generating dusts.

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 (sweeping/vacuuming) : do not generate dust.

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 away from direct light.

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 :
1314-13-2	2 mg/m ³	10 mg/m ³	-	-	R

- France (INRS - ED984 :2008) :

CAS	VME-ppm :	VME-mg/m ³ :	VLE-ppm :	VLE-mg/m ³ :	Notes :	TMP No :
1314-13-2	-	5	-	-	-	-

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

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

- Respiratory protection

Avoid breathing dust.

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

Physical state :	Powder or dust.
Colour:	beige
Odour:	characteristic

Important health, safety and environmental information

pH :	Not relevant.
Boiling point/boiling range :	Not relevant.
Flash point interval :	Not relevant.
Vapour pressure (50°C) :	Not relevant.
Density :	1.04
Water solubility :	Insoluble.
Melting point/melting range :	Not relevant.

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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 :

- formation of dusts
- exposure to light

10.5. Incompatible materials

Keep away from :

- acids
- alkalis

10.6. Hazardous decomposition products

The thermal decomposition may release/form :

- carbon monoxide (CO)
 - carbon dioxide (CO₂)
 - metallic oxide smokes
 - halogenic compounds
-

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

No data available.

11.1.1. Substances

Carcinogenicity :

IODURE DE THYMOL (CAS: 552-22-7)

Carcinogenicity Test : Negative.

No carcinogenic effect.

11.1.2. Mixture

No toxicological data available for the mixture.

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

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

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. 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.

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 5KG, UN N° 3077 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:

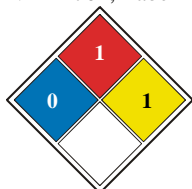
The mixture is contained in packaging that does not exceed 125 ml.

- 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=0 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 :



Dangerous for the environment

Risk phrase :

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

Safety phrase :

S 61 Avoid release to the environment. Refer to special instructions/Safety data sheets.

S 22 Do not breathe dust.

S 57 Use appropriate container to avoid environmental contamination.

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

H302 Harmful if swallowed.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

R 22 Harmful if swallowed.

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.

GHS09 : Environment