



SAFETY DATA SHEET

Complies with the european regulation EC 1272/2008
Dental use

PROVISIONAL RESTORATIVE MATERIAL

Publication date: 06/07/2015
Review date: 03/07/2015
Revision number: 5

SECTION 1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION AND THE COMPANY

1.1 Product identification

Name of the product: MATERIAL RESTAURADOR PROVISIONAL PROCLINIC

Description of the product: Provisional cement zinc oxide eugenol for professional dental use

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

Main identification of use: Restoration/ dental temporary cementation.

1.3 Details of the supplier of the safety data sheet

Manufacturer:

J.RIPOLL S.L.
C/RIO TIETAR Nº20
POLIGONO EL NOGAL
ALGETE (MADRID)
SPAIN

Distributor:

PROCLINIC SA
PASEO ZONA FRANCA 111

08038 BARCELONA

SPAIN

Email:

proclinic@proclinic.es

Tel. de emergencia: +34 932649666

1.4 Emergency number

Emergency number: +34 932649666

SECTION 2. HAZAR IDENTIFICATION

2.1 Classification of the substance or mixture

Warning word: Danger

Clasification according to the regulation **CE N°1272/2008**

Acute aquatic 1 H400

Chronic Aquatic. 1 H410

Eye irritation 2. H319

Skin sensitization 1B H317

2.2 Label elements

Clasification according to the regulation **CE N°1272/2008**

(CPL) Danger pictograms:



Signal word: Attention.



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Danger phrases:

H317 May cause an allergic skin reaction

H319 Causes eye irritation

H400 Very toxic to aquatic organisms.

H410 Very toxic to aquatic organisms, with lasting harmful effects.

Prudence tips

P210 Keep away from heat sources, open flame sparks or hot surfaces. No Smoking..

P273 Avoid release to the environment.

P280 Wear gloves / clothing / glasses / protective mask.

P302 + 352 In case of skin contact, wash with plenty of water and soap

P305+P351+P338: In case of contact with eyes; Rinse carefully with water for several minutes. Remove contact lenses, if worn and easy. Continue rinsing.

P337+P313 If eye irritation persists: Consult a doctor.

P333+P313 In case of skin irritation or rash. Consult a doctor.

2.3 Other dangers

General recommendations: No hay information available.

SECTION 3. COMPOSITION/INFORMATION OF THE COMPONENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Powder component

Chemical name	CAS	EINECS	Clasification according to 67/548/EC	Clasification according to (EC) No 1272/2008 CLP
Zinc oxide	1314-13-2	215-222-5	R 50/53	Acute aquatic 1 Chronic aquatic 1
PMMA	9011-14-7	-	-	-
Zinc Acetate 2-hydrate	5970-45-6	209-170-2	R22, R36, R50/53	Acute oral toxicity 4 Eye irritation 2 Acute aquatic 1

Liquid component

Chemical name	CAS	EINECS	Clasification according to 67/548/EC	Clasification according to (EC) No 1272/2008 CLP
Eugenol	9753-0	202-589-1	-	Skin sensitivity 1B Eye irritation 2
Acetic acid	64-19-7	200-580-7	R10, R35	Flammable liquid 3 Cutaneous corrosion 1A



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SECTION 4. FIRST AID

4.1 First aid description

Eye contact: Immediately flush eyes with plenty of water, also under the eyelid, for at least 15 minutes. Examine the eyes and be treated by medical personnel. If the patient wears contact lenses, remove them if it is easy.

Skin contact: Take off immediately all contaminated clothing. In case of skin contact, wash immediately with plenty of soap and water. Seek medical attention if irritation occurs or persists. If the product causes burns or freezing, the clothes should not be removed because it could worsen the injury if it is attached to the skin. In the case of blistering of the skin, they should never burst as it would increase the risk of infection.

Ingestion: Drink plenty of water. Avoid vomiting Request medical attention infection.

Inhalation: Move the affected person outdoors. In case of suffocation proceed immediately to artificial respiration or oxygen. Seek immediate medical attention.

4.2 Main symptoms and effects, both acute and delayed

Signs and effects of eye irritation may include a burning sensation, redness, inflammation and / or blurred vision. Acute and delayed effects are those indicated in sections 2 and 11.

4.3 Indication of all medical attention and special treatments to be given immediately.

Not relevant.

SECTION 5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Extinguishing media: Non-flammable product under normal conditions of storage, handling and use. In case of inflammation as a result of mishandling, storage or misuse, preferably use polyvalent powder extinguishers (ABC powder). It is not recommended to use jet water as an extinguishing agent.

Unsuitable extinguishing media: NEVER PUT WATER TO JET.

5.2 Special hazards arising from the substance or mixture

As consequence of combustion or thermal decomposition, reaction by-products are generated that can be highly toxic and, consequently, can present a high health risk.

5.3 Recommendations for firefighters

Depending on the magnitude of the fire, the use of full protective clothing and self-contained breathing apparatus may be necessary. Remove any source of ignition. Avoid the spillage of products used in extinguishing the fire in the aquatic environment.



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SECTION 6. MEASURES IN CASE OF ACCIDENTAL SPILLAGE

6.1 Personal precautions, protective equipment and emergency procedures

Do not inhale the dust. Do not inhale vapors. Avoid contact with skin, eyes and clothing.
Special protective equipment: Do not inhale the vapors. Use a respirator when the operations performed involve a potential exposure to product vapor

6.2 Environmental precaution

Water spill: Do not allow the product to enter the sewer pipe or drainage systems that connect to waterways

6.3 Methods and material for containment and cleaning

Small spillage: Clean up spills immediately following the precautions contained in the protective equipment section

Large spill: Absorb with an inert and absorbent material, or failing sand or dry soil, then wash the area with water.

6.4 Reference to other sections

Reference to other sections: Personal protective equipment, see section 8.

SECTION 7. MANIPULATION AND STORAGE

7.1 Precautions for sale handling

Ensure good ventilation and air renewal in the premises.

7.2 Conditions for safe storage, including any incompatibilities

Shelf life: Keep container tightly closed. To maintain product quality, do not store in heat or direct sunlight or sources of ignition. Keep in a dry, cool and well ventilated place.

7.3 Specific end uses

Specific end uses: Provisional zinc-eugenol oxide cement for professional dental use.

SECTION 8. EXPOSURE CONTROLS PERSONAL PROTECTION

8.1 Control parameters

Control parameters: Ensure good ventilation and air renewal of the premises.
VLA-ED: 10 mg / m³

8.2 Exposure controls

Face / eye protection: Wear eye protection

Skin protection: Wear suitable protective clothing and gloves

Respiratory system protection: Good ventilation would be sufficient to keep airborne particle levels under control. In case of dust formation, wear breathing equipment with P filter.

Hygiene measures: Wash hands before breaks and immediately after handling the substance.



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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state: Powder-Liquid
Color: White powder - yellowish liquid.
Smell: Characteristic smell.
Water solubility: Insoluble.
Soluble in diluted acids.
Density (20/4): 5.61

9.2 Additional Information

No data available

SECTION 10. STABILITY AND REACTIVITY

10.1 Reactivity:

Reactivity: Stable

10.2 Chemical stability

Chemical stability: Stable when stored and handled under recommendations.

10.3 Possibility of dangerous reactions

Hazardous polymerization: None

10.4 Conditions to avoid

Conditions to avoid: High temperatures.

10.5 Incompatible materials

Incompatible materials: Hydrogen peroxide (hydrogen peroxide). Magnesium. Water.

10.6 Hazardous decomposition products

Hazardous decomposition products: It does not decompose if stored under normal conditions.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

There are no relevant data on the toxicity of the product. May cause mild skin and eye irritation.
Ingestion of large quantities: Irritations in mucous membranes, gastro-intestinal disorders.
By inhalation of vapors: fever.

SECTION 12. ECOLOGICAL INFORMATION

12.1 Toxicity

Very toxic to fish. Do not let groundwater, water streams or sewage infiltrate. It is also toxic to fish and plankton in water bodies. Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.



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12.2 Persistence and degradability

Persistence and degradability: Undetermined.

12.3 Bioaccumulative potential

Bioaccumulative potential: Undetermined.

12.4 Ground movility

Ground movility: Undetermined.

12.5 PBT and mPmB assessment results.

PBT and mPmB assessment results: Undetermined.

12.6 Other adverse effects

Environmental data: Undetermined

SECTION 13. RELATIVE CONSIDERATIONS TO ELIMINATION

13.1 Waste treatment methods

Disposal method: Eliminate in compliance with government regulations, the autonomous and local community.

SECTION 14. INFORMATION RELATED TO TRANSPORTATION

14.1 ONU number

ONU number: Not applicable

14.2 United Nations official transportation designation

United Nations official transportation designation: Not applicable

14.3 Hazard clases for transportation

Primary hazard class/division: Not applicable

14.4 Packing group

Packing group: Not applicable

14.5 Environmental hazards

Marine pollutant #1: Not applicable

14.6 Special precautions for users

Not applicable

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Transport in bulk: Not applicable



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SECTION 15. REGULATORY INFORMATION

15.1 Regulatory information on safety, health and environment specific to the substance or mixture.

RoHS: See Directive on medical devices 93/42 / ECC. Type IIa medical device.

15.2 Chemical safety assessment

Chemical safety assessment: See sección 11

SECTION 16. OTHER INFORMATION

Any chemical product can be handled safely if its physicochemical and toxicological properties are known and the appropriate technical means and organizational measures and appropriate personal protective equipment are used.

The information offered in this safety data sheet is based on our current knowledge. However, the data provided and the recommendations made do not imply a guarantee. It is the responsibility of the user to determine the conditions for safe use of this product.

This safety data sheet has been prepared based on regulation 453/2010 of the commission of May 20, 2010 for the elaboration of Safety Data Sheets by which Regulation (EC) No. 1907/2006 of the European Parliament and of the council is modified , concerning the registration, evaluation, authorization and restriction of chemical substances and preparations (REACH).

Prepared by: José Ignacio Ripoll.

General information: NA=Not applicable

Manufacturer's disclaimer:

FOR DENTAL USE ONLY: Use as directed. The information and recommendations come from sources (the safety data sheets of the raw materials and the manufacturer's knowledge) that are considered accurate; However, J.Ripoll S.L .. does not guarantee the accuracy of this information or the adequacy of the recommendations, and does not assume any responsibility for any damage arising. The user should review these recommendations, in the specific context of the intended use, and determine if they are appropriate.