

Product Name: Zinc Oxide Eugenol Quick Set Cement, Polymer Reinforced

Date Issued: 15/09/23 Date Revised: 31/01/24

Revision No: 1 Pages: 6

SECTION 1: Identification of the substance/preparation and of the company/undertaking

1.1- Product Identification

Product Name : Zinc Oxide Eugenol Quick Set Cement Polymer Reinforced

Product Code : RZE

Product Description : Powder for dental temporary filling material

Packing Available : 15 g powder & 10 ml Liquid

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

Relevant identified uses : Powder and Liquid for dental temporary filling material. Used by dental

professional only. For dental use only.

1.3- Details of the supplier of the safety data sheet

Manufacturer : Prime Dental Products Pvt Ltd.

Address : Plot No. A-148, Road No. 24, MIDC, Wagle Industrial Estate, Thane (West)-

400604, Maharashtra, India

Email : info@prime-dental.in
Web : www.prime-dental.in

1.4- Emergency contact details

Telephone : +919272235922 / +919272235925

SECTION 2: Composition/information on ingredients

2.1- Mixture

Component	C.A.S.	EINECS	Classification*	Weight%	LD50
Zinc Oxide	1314-13-2	NA	R50/53	40-90%	Ingestion (Rat): >5,000 mg/kg.

^{*}For wording of the listed 'R' phrases and 'H' statements see section 16

SECTION 3: Identification of Hazards

3.1- Hazard Description : Not Applicable

3.2- Information concerning to particular hazards to man and environment: This product is not classed as flammable. Refer to the recommendations regarding the other products present Possibility of serious lesions to the eyes. Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

SECTION 4: First aid measures

4.1- Description of first aid measures

Contact with skin: Wash with soap and water. Get medical attention if irritation develops or persists. **Contact with eyes**: Flush eyes with plenty of water. Get medical attention, if irritation persists. **Ingestion**: Give water. DO NOT induce vomiting. Consult a physician if ingested in large amounts.

Inhalation: Not applicable

SECTION 5: Fire-Fighting Measures

5.1- Recommended extinguishers: Water, CO2, foam, or chemical powders, depending on the materials involved in the fire.

5.2- Extinguishers not to be used: None in particular.

5.3- Risks arising from combustion: Avoid inhaling the fumes.

5.4- Protective equipment: Wear self-contained respiratory protective device.

SECTION 6: Accidental Release Measures



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6.1 Measures for personal safety: None in particular

6.2 Measures for environmental protection: Do not allow product to reach sewage system or any water

courses.

6.3 Measures for cleaning/collecting: Pick up mechanically

SECTION 7: Handling and Storage

7.1-Handling product: Is intended for dental use only.

7.2- Information for safe handling: No special measures required. Observe normal care for working with chemicals.

7.3- Information about fire and explosion protection: No special measures required.

7.4- Storage requirements to be met by storerooms and receptacles: Store only in the original receptacle.

7.5- Information about storage in one common storage facility: Not required.

7.6- Further information about storage conditions: Protect from heat and direct sunlight.

SECTION 8: Exposure Controls/Personal Protection

8.1- Additional information about design of technical facilities: No further data; see section 7.

8.2- Ingredients with limit values that require monitoring at the workplace:

Zinc Oxide -

OSHA- TWA (as Fume): 5

ACGIH- TWA (respirable): 2mg/m³, STEL (respirable): 10mg/m³

8.3- Personal protective equipment:

a. Respiratory protection : Not required.

b. Protection of hands : The glove material has to be impermeable and resistant to the product/ the

substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

c. Eye protection : Safety glasses

d. Body protection : Protective work clothing

SECTION 9: Physical and Chemical Properties

9.1- Physical Properties:

Form : Powder

Color : White to yellowish white

Odour : None

9.2- Chemical Properties:

Melting point/Melting range : Undetermined Boiling point/Boiling range : Undetermined Ignition temperature : Undetermined : Undetermined : Undetermined : Undetermined : Undetermined : Undetermined

Self-igniting : Product is not self-igniting.

Danger of explosion : Product does not present an explosion hazard.

Density : Undetermined Solubility in / Miscibility with Water : Undetermined

SECTION 10: Stability and Reactivity

10.1- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

10.2- Dangerous reactions: No dangerous reactions known

10.3 Dangerous decomposition products: No dangerous decomposition products known



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SECTION 11: Stability and Reactivity

11.1- Acute toxicity

Zinc Oxide LD50: Ingestion (Rat): >5,000 mg/kg.

11.2- Primary irritant effect : Nil

11.3- On the skin
11.4- On the eye
11.5- Sensitization
: May cause skin irritation
: May cause irritating effect.
: No sensitizing effects known.

SECTION 12: Ecological Information

12.1- Environmental data: Can be toxic to aquatic environment.

Zinc Oxide LC50 - Oncorhynchus mykiss (rainbow trout) - 1.1 mg/l - 96.0 (Zinc oxide)

SECTION 13: Disposal Consideration

13.1- Product Recommendation: Must not be disposed together with household garbage. Do not allow product to reach sewage system.

13.2- Uncleaned Packaging Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport Information

14.1- Air (ICAO/IATA)

Primary Hazard Class/Division : No classification

14.2- Road (RID/ADR)

Primary Hazard Class/Division : No classification

14.3- Vessel (IMO/IMDG/RID/ADR)

Primary Hazard Class/Division : No classification

SECTION 15: Regulatory Information

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

General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2- Chemical safety assessment: See Section 11

SECTION 16: Additional Information

16.1- 'R' phrases and 'H' statement:

R22: Harmful if swallowed

R41: Risk of serious damage to eyes

R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

16.2- Prepared by: Tanay Thakkar

16.3- Manufacturer Disclaimer: For Dental Use Only, Use as directed.

The information and recommendations are taken from sources (raw material MSDS(s) and manufacturer's knowledge) believed to be accurate; however, Prime Dental Products Pvt Ltd, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.



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SECTION 1: Identification of the substance/preparation and of the company/undertaking

1.1- Product Identification

Product Name : Zinc Oxide Eugenol Quick Set Cement Polymer Reinforced

Product Code : RZE

Product Description : Liquid for dental temporary filling material

Packing Available : 15 g powder & 10 ml Liquid

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

Relevant identified uses : Powder and Liquid for dental temporary filling material. Used by dental

professional only. For dental use only.

1.3- Details of the supplier of the safety data sheet

Manufacturer : Prime Dental Products Pvt Ltd.

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1.4- Emergency contact details

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SECTION 2: Composition/information on ingredients

2.1- Mixture

Component	C.A.S.	EINECS	Classification*	Weight%	<u>LD50</u>
Eugenol	97-53-0	202-589-1	H317, 319	40-900	Oral (Rat) - >2000 mg/kg

^{*}For wording of the listed 'R' phrases and 'H' statements see section 16

SECTION 3: Identification of Hazards

3.1- Hazard Description: Eugenol- H317, 319

3.2- Information concerning to particular hazards to man and environment:

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

SECTION 4: First aid measures

4.1- Description of first aid measures

Contact with skin: Wash with soap and water. Get medical attention if irritation develops or persists. **Contact with eyes**: Flush eyes with plenty of water. Get medical attention, if irritation persists. **Ingestion**: Give water. DO NOT induce vomiting. Consult a physician if ingested in large amounts.

Inhalation: Supply fresh air. Get medical attention, if irritation persists.

SECTION 5: Fire-Fighting Measures

5.1- Recommended extinguishers: CO2, dry chemicals, water spray or alcohol resistant foam.

5.2- Extinguishers not to be used: Not known

5.3- Risks arising from combustion: Release of carbon oxides

5.4- Protective equipment: Wear self-contained respiratory protective device.

SECTION 6: Accidental Release Measures

6.1 Measures for personal safety: Wear protective clothing

6.2 Measures for environmental protection: Do not allow product to reach sewage system or any water courses.



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6.3 Measures for cleaning/collecting: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Ensure adequate ventilation.

SECTION 7: Handling and Storage

- **7.1-Handling product:** Is intended for dental use only.
- **7.2- Information for safe handling:** No special measures required. Observe normal care for working with chemicals.
- 7.3- Information about fire and explosion protection: No special measures required.
- 7.4- Storage requirements to be met by storerooms and receptacles: Store only in the original receptacle.
- 7.5- Information about storage in one common storage facility: Not required.
- 7.6- Further information about storage conditions: Protect from heat and direct sunlight.

SECTION 8: Exposure Controls/Personal Protection

- 8.1- Additional information about design of technical facilities: No further data; see section 7.
- 8.2- Ingredients with limit values that require monitoring at the workplace: No known
- 8.3- Personal protective equipment:
- **a. Respiratory protection** : Not required if room is well ventilated
- **b. Protection of hands** : The glove material has to be impermeable and resistant to the product/ the

substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

c. Eye protection : Safety glasses

d. Body protection : Protective work clothing

SECTION 9: Physical and Chemical Properties

9.1- Physical Properties:

Form: Liquid

Color : Clear to yellowish Odour : No data available

9.2- Chemical Properties:

For Eugenol

Melting point/Melting range : -12°C Boiling point/Boiling range : 254°C

 $\begin{array}{ll} \mbox{Ignition temperature} & : \mbox{Undetermined} \\ \mbox{Flash point} & : \mbox{112}^{0}\mbox{C} - \mbox{closed cup} \\ \end{array}$

Self-igniting : Product is not self-igniting.

Danger of explosion : Product does not present an explosion hazard.

 $\begin{array}{ll} \mbox{Density} & : < 1.1 \ \mbox{g/cm}^3 \\ \mbox{Solubility in / Miscibility with Water} & : \mbox{Undetermined} \end{array}$

SECTION 10: Stability and Reactivity

10.1- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications. Avoid strong oxidizing agents.

10.2- Dangerous reactions: No dangerous reactions known10.3 Dangerous decomposition products: Carbon oxides

SECTION 11: Stability and Reactivity

11.1- Acute toxicity:

Eugenol LD50 Oral (Rat): >2,000 mg/kg



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11.2- Primary irritant effect : Nil

11.3- On the skin
11.4- On the eye
11.5- Sensitization
May cause skin irritation
May cause irritating effect.
No sensitizing effects known.

SECTION 12: Ecological Information

12.1- Environmental data: Can be toxic to aquatic environment.

LC50 - Danio rerio (zebra fish): 13 mg/l - 96 h (Eugenol)

SECTION 13: Disposal Consideration

13.1- Product Recommendation: Must not be disposed together with household garbage. Do not allow product to reach sewage system.

13.2- Uncleaned Packaging Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport Information

14.1- Air (ICAO/IATA)

Primary Hazard Class/Division : No classification

14.2- Road (RID/ADR)

Primary Hazard Class/Division: No classification

14.3- Vessel (IMO/IMDG/RID/ADR)

Primary Hazard Class/Division : No classification

SECTION 15: Regulatory Information

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

General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2- Chemical safety assessment : See Section 11

SECTION 16: Additional Information

16.1- 'R' phrases and 'H' statement:

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

16.2- Prepared by: Tanay Thakkar

16.3- Manufacturer Disclaimer: For Dental Use Only, Use as directed.

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