

Product Name: RC FILL I

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

1.1- Product Identification

Product Name : RC Fill I Liquid
Product Code : RFL
Product Description : ZnOE bonded root canal sealant
Packing Available : 10ml

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

Relevant identified uses : ZnOE bonded root canal sealant. Used by dental professional only. For dental use only.

1.3- Details of the supplier of the safety data sheet

Manufacture : 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
Eugenol	97-53-0	202-589-1	H317, 319	<75%	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.

Product Name: RC FILL I

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:

Melting point/Melting range : Undetermined

Boiling point/Boiling range : Undetermined

Ignition temperature : Undetermined

Flash point : Undetermined

Self-igniting : Product is not self-igniting.

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

Density : <1.2 g/cm³

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. Avoid strong oxidizing agents.

10.2- Dangerous reactions: No dangerous reactions known

10.3 Dangerous decomposition products: Carbon oxides

SECTION 11: Stability and Reactivity

11.1- Acute toxicity:

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

11.2- Primary irritant effect : Nil

11.3- On the skin : May cause skin irritation

11.4- On the eye : May cause irritating effect.

Product Name: RC FILL I

11.5- Sensitization : 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 data available

14.2- Road (RID/ADR)

Primary Hazard Class/Division : No data available

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

Primary Hazard Class/Division : No data available

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.

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.

Product Name: RC FILL I

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

1.1- Product Identification

Product Name : RC Fill I Powder
Product Description : ZnOE bonded root canal sealant
Packing Available : 15g + 5g Accelerator

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

Relevant identified uses : ZnOE bonded root canal sealant. Used by dental professional only. For dental use only.

1.3- Details of the supplier of the safety data sheet

Manufacture : Prime Dental Products Pvt Ltd.
Address : Plot No. A-148, Road No. 24, MIDC, Wagle Industrial Estate, Thane
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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	R22, R41, R50/53	<75	Ingestion (Rat): >5,000 mg/kg.
Iodoform	75-47-8	NA	R22, R41, R50/53	<45	Oral (Rat): 335 mg/kg

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

SECTION 3: Identification of Hazards

3.1- Hazard Description : R22, R41, R50/53

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.

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.

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 or milk. DO NOT induce vomiting. Consult a physician if ingested in large amounts.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

SECTION 5: Fire-Fighting Measures

5.1- Recommended extinguishers: 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.

Product Name: RC FILL I

SECTION 6: Accidental Release Measures

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:

Small spill: Clean up spills immediately, observing precautions in Protective Equipment section.

Large spill: Collect in tightly closed containers.

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

Iodoform

OSHA- PEL; TWA: 0.6mm, TWA: 10mg/m³

8.3- Personal protective equipment:

a. Respiratory protection : Well ventilated room.

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 : Yellowish

Odour : No data available

9.2- Chemical Properties:

Melting point/Melting range : Undetermined

Boiling point/Boiling range : Undetermined

Ignition temperature : Undetermined

Flash point : 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 : Nil

SECTION 10: Stability and Reactivity

10.1- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications. Avoid strong acids and metals.

Product Name: RC FILL I

10.2- Dangerous reactions: No dangerous reactions known

10.3 Dangerous decomposition products: No dangerous decomposition products known

SECTION 11: Stability and Reactivity

11.1- Acute toxicity

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

Iodoform LD50: Oral (Rat): 335 mg/kg

11.2- Primary irritant effect : Nil

11.3- On the skin : May cause skin irritation

11.4- On the eye : May cause irritating effect.

11.5- Sensitization : 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; 96h

Iodoform LC50 - Pimephales promelas - 2.92 mg/L; 96h

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 data available

14.2- Road (RID/ADR)

Primary Hazard Class/Division : No data available

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

Primary Hazard Class/Division : No data available

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.

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