

Product Name: RC SEAL PLUS

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

1.1- Product Identification

Product Name : RC Seal Plus Base
Product Description : Epoxy bonded root canal sealant
Packing Available : 10ml (12g Base + 3.5g Catalyst)

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

Relevant identified uses : Epoxy bonded root canal sealant. 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
Epoxy Resin	25036-25-3	NA	H315,317, 319, 411	30-55%	Not known

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

SECTION 3: Identification of Hazards

3.1- Hazard Description : Epoxy Resin- H315, 317, 319, 411

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

H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H411 Toxic to aquatic life with long lasting effects.

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: Depending on the materials involved in the fire.

5.2- Extinguishers not to be used: Water with full jet

5.3- Risks arising from combustion: Formation of toxic gases is possible during heating or in case of fire.

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

SECTION 6: Accidental Release Measures

6.1 Measures for personal safety: Wear protective clothing

Product Name: RC SEAL PLUS

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

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 : Paste

Color : Yellow

Odour : None

9.2- Chemical Properties:

Melting point/Melting range : Undetermined

Boiling point/Boiling range : Undetermined

Ignition temperature : Undetermined

Flash point : >200°C

Self-igniting : Product is not self-igniting.

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

Density : 1.1-1.4 g/cm³

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. Strong oxidants, acids, bases.

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: Not known

11.2- Primary irritant effect : Nil

11.3- On the skin : May cause skin irritation

Product Name: RC SEAL PLUS

- 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.

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:

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H411 Toxic to aquatic life with long lasting effects.

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 SEAL PLUS

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

1.1- Product Identification

Product Name : RC Seal Plus Catalyst
Product Description : Epoxy bonded root canal sealant
Packing Available : 10ml (12g Base + 3.5g Catalyst)

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

Relevant identified uses : Epoxy bonded root canal sealant. 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)-
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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
N-(2-Hydroxyethyl)ethylenediamine	111-41-1	NA	H317, H314, H335, H360Df	5-25%	Oral (Rat): 3.000 mg/kg

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

SECTION 3: Identification of Hazards

3.1- Hazard Description : H314, H317, H335, H360Df

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

H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation
H360Df Toxic May damage the unborn child. Suspected of damaging fertility.

SECTION 4: First aid measures

4.1- Description of first aid measures

Contact with skin: Wash with soap and water. Get medical attention.
Contact with eyes: Flush eyes with plenty of water. Get medical attention.
Ingestion: Give water. DO NOT induce vomiting. Consult a physician.
Inhalation: Supply fresh air. Get medical attention, if irritation persists.

SECTION 5: Fire-Fighting Measures

5.1- Recommended extinguishers: CO₂, Water Foam Carbon dioxide (CO₂) Dry powder

5.2- Extinguishers not to be used: No extinguishing agent limits.

5.3- Risks arising from combustion:

Carbon oxides
Nitrogen oxides (NO_x)
Combustible.
Fire may cause evolution of:
nitrogen oxides
Vapours are heavier than air and may spread along floors.

Product Name: RC SEAL PLUS

Forms explosive mixtures with air on intense heating.
Development of hazardous combustion gases or vapours possible in the event of fire.

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

SECTION 6: Accidental Release Measures

6.2 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.

6.3 Measures for cleaning/collecting: Take up carefully with liquid-absorbent material. Dispose of properly. Clean up affected area.

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 : Paste

Color : White

Odour : None

9.2- Chemical Properties:

Melting point/Melting range : No Data Available

Boiling point/Boiling range : 237-243°C

Ignition temperature : No Data Available

Flash point : 144°C

Self-igniting : No Data Available.

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

Density : Undetermined

Solubility in / Miscibility with Water : No Data Available

SECTION 10: Stability and Reactivity

Product Name: RC SEAL PLUS

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

SECTION 11: Stability and Reactivity

11.1- Acute toxicity:

LD50 Oral (Rat): 3.000 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.

11.5- Sensitization : No sensitizing effects known.

SECTION 12: Ecological Information

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

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:

Refer Section 3.

16.2- Prepared by: Tanay Thakkar

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

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