

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

1.1- Product Identification

Product Name : RC Help
Product Code : RHS
Product Description : EDTA Gel in water soluble base
Packing Available : 3g syringe and 20g syringe

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

Relevant identified uses : Endodontic chelator and file lubricant. 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
EDTA	60-00-4	200-573-9	Xi; R 36/38	2-20	Oral Rat : 4500 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

The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

3.3- Classification system

The classification is according to the latest editions of the EU-lists and extended by company and literature data.

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 uncomfortable

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

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- 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 : Paste/Gel

Color : Whitish

Odour : Odourless

9.2- Chemical Properties:

Melting point/Melting range : Undetermined

Boiling point/Boiling range : Undetermined

Ignition temperature : Undetermined

Flash point : Not applicable

Self-igniting : Product is not self-igniting.

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

Density : Not determined

Solubility in / Miscibility with Water : Soluble

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

SECTION 11: Stability and Reactivity

11.1- Acute toxicity : Nil

11.2- Primary irritant effect : Nil

11.3- On the skin : May cause skin irritation

11.4- On the eye : May cause irritating effect.

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11.5- Sensitization : No sensitizing effects known.

SECTION 12: Ecological Information

12.1- Environmental data: No data available. Contact Env. Dept.

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:

Xi- Irritant

R36 & R38- Irritating to eyes and skin

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.
