

4-FIRST AID MEASURES

General Information	EDTA, 17% solution is non-hazardous. EDTA powder may cause mild, mechanical eye irritation or mild skin irritation. Powder may present as a nuisance dust. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.
Inhalation	Move person to fresh air. If effects occur, seek medical attention.
Skin Contact	Wash skin thoroughly with soap and water.
Eye Contact	Keep eyelids apart, flush with running water for 15+ minutes. Remove contact lenses after several minutes. Consult an ophthalmologist for persistent irritation
Ingestion	Large amounts: contact Poison Control Center or physician. Induce vomiting only on medical advice.
Precautions for first responders	Wear safety glasses and gloves. If a large amount of EDTA powder is present, wear a dust mask.
Information for physicians Symptoms	Mild irritation/redness in eyes or on skin after contact. Sneezing or coughing after inhalation of powder.
Hazards	EDTA powder may cause mild, mechanical eye irritation, mild skin irritation and sneezing or coughing on inhalation.
Treatment	Same as above under First Aid.

5-FIRE-FIGHTING MEASURES

Suitable Extinguishing Media	Whatever is appropriate for surrounding fire
Extinguishing media to avoid	Decision should be based on surrounding fire.
Specific exposure hazards in a fire	None
Special Protective Equipment for Fire-Fighters	Usual protective equipment is sufficient.

6-ACCIDENTAL RELEASE MEASURES

Personal Precautions	·Wear safety glasses, gloves, and lab coat.
Environmental Precautions	·Follow all government regulations.
Methods for Cleaning Up	Liquid: Absorb or wipe up spill with paper towels or disposable cloths. Collect for disposal in covered container. Wash area with soap and water. Collect powder spill without dispersing into air. Place material in covered container. Wash area of spill with soap and water.

7-HANDLING AND STORAGE

Handling	<i>For intraoral use only</i> by trained dental professionals. Follow good hygiene practices. Do not smoke, eat or drink while using.
Storage	Keep container closed. Store product in original container at cool room temperature (< 25OC). Shelf life for unopened product is three years from date of manufacture, provided proper storage.
Specific uses	Dental chelating agent used to debride root canals.

8-EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limit values	PEL: Not established. TLV: Not established.
Exposure controls	
Occupational exposure controls	No special equipment required.

Respiratory protection	None required under normal conditions of use of EDTA, 17% solution.
Hand protection	No special requirements under normal conditions of use.
Eye protection	Safety glasses
Skin protection	Good personal hygiene, lab coat and gloves. Wash hands after use.
Other controls	Emergency eye wash fountain close by.

Environmental exposure controls Follow all government regulations.

9-PHYSICAL AND CHEMICAL PROPERTIES

Characteristics	
Appearance /Color / Physical state	Clear, colorless liquid
Odor	None
Important health, safety and environmental information	
pH	6.8 to 7.4
Boiling point	212°F / 100°C
Flash point	Not applicable
Flammability (solid, gas)	Not applicable
Explosive properties	Not applicable
Oxidizing properties	Not applicable
Vapor pressure	Not applicable
Specific gravity	1.000
Solubility in water	Soluble
Partition coefficient	Not determined
Viscosity	Not determined
Vapor density	Not determined
Evaporation rate	Not determined

10-STABILITY AND REACTIVITY

Conditions to avoid	None known
Materials to avoid	Strong oxidizing agents
Hazardous decomposition products	Carbon monoxide, carbon dioxide, nitrogen oxides
Further information	Stable material

11-TOXICOLOGICAL INFORMATION

Acute toxicity	Not toxic. Oral rat LD50: 2000mg/kg
Irritation and corrosiveness	May be irritating to eyes or skin on contact.
Sensitization	Not applicable
Sub-acute, sub-chronic and prolonged toxicity	None known
Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known
Empirical data	Not available
Clinical experience	Using EDTA as part of root canal treatment is a well-established (20+ years), industry-accepted, safe/effective endodontic practice.

12-ECOLOGICAL INFORMATION

Ecotoxicity	Not toxic. Follow all government regulations.
-------------	---

13-DISPOSAL CONSIDERATIONS

Regulations	Follow all local and national government regulations.
-------------	---

14-TRANSPORT INFORMATION

Restrictions	Non-hazardous material / Not regulated.
--------------	---

15-REGULATORY INFORMATION

EU	Class IIa medical device under the MDD 93/42/EEC.
US FDA	Class II medical device
Health Canada	Class II medical device

16-OTHER INFORMATION

List of relevant R phrases	R36, Irritating to eyes. R38, Irritating to skin.
Hazard Statements	H319: Causes serious eye irritation. Category 2. H315: Causes skin irritation. Category 2.
Precautionary Statements	P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P302+P352: If on skin, wash with plenty of soap and water.
Restrictions on use	C-Root products are for use by dental professionals only.
Further information	The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as a warranty or representation for which C-Root Corporation bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.
Sources of key data	National Institute for Occupational Safety (NIOSH) US Occupational Safety and Health Administration (OSHA) Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH). Guidance on the compilation of safety data sheets. Version 1.1; December 2011. European Chemicals Agency
Information which has been added, deleted or revised.	This Safety Data Sheet has been revised to meet the requirements of the GHS SDS format and Regulations (EC) No. 1272/2008 (CLP) and (EC) No. 1907/2006 (REACH). Specifically, Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified.

SAFETY DATA SHEET

Date Issued:2022.12.06 Rev B/0

Beijing C-Root Dental Medical Devices Co., LTD.

C-Root EDTA Gel

1-IDENTIFICATION

Product Identifier	Trade Name	Product Identifier Number (REF)
C-Root EDTA Gel		0.2 g,0.5 g,2.0 g,3.0 g,6.0g,10g

Product Use	C-Root EDTA Gel
Restrictions on Use	For dental use only.
Supplier	Beijing C-Root Dental Medical Devices Co., LTD. Room 301, Building 10, Yard 12, Middle Juyuan Road, Mapo Town, Shunyi District, Beijing, China Tel:+8610 010-56467681
Emergency Contact	Tel:+861018601299788

2-HAZARDS IDENTIFICATION

Classification

Classification according to Regulation	Hazard Class	Signal Word	Hazard Category	Hazard Statement
(EC) No. 1272/2008 [CLP]	Eye irritation	Warning	2	H319
Unincorporated powder only	Skin irritation	Warning	2	
Classification per Directive 67/548/EEC	Irritant (Xi) (powder only);R36/38 (Section 16 for full text of risk phrases)			

GHS Label Elements

Hazard Pictograms

Signal Word: **Warning****Restricted to use by dental professional only****Hazard Statements:**

Unincorporated powder only

H319: Causes serious eye irritation. Category 2.

H315: Causes skin irritation. Category 2.

Precautionary Statements:

P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P302+P352: If on skin, wash with plenty of soap and water.

3-COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization of the preparation 17% aqueous solution of ethylenediaminetetraacetic acid

Hazardous Ingredients

CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1272/2008 (CLP).
60-00-4	Ethylenediaminetetraacetic acid	17%	<i>Unincorporated powder only</i> Irritant (Xi) / R36/38	<i>Unincorporated powder only</i> Eye irritation; Category 2 Skin irritation; Category