

Roydent Dental Products

Safety Data Sheet

Date Issued: 08/11/2014

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Date Revised:

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1. PRODUCT IDENTIFICATION

Trade Name (as labeled): ENDO-Cleanse
Chemical Name/Classification: EDTA 17% Solution
Product Identifier (Part/Item Number): IF-2176
U.N. Number: Non-hazardous material / Not regulated
U.N. Dangerous Goods Classification: NA
Recommended Use: For preparing root canals for obturation
Restrictions on Use: Pulpdent products are for use by dental professionals only
Distributed by: **Roydent Dental Products**
Distributors Address: **608 Rolling Hills Dr., Johnson City, TN 37604**
Distributors Telephone Number: **800-992-7767 (Product Information)**
Emergency Contact Telephone Number: **Chemtrec (800) -262-8200**
Email address: Chemtrec@chemtrec.com

2. HAZARD(S) IDENTIFICATION

Hazard/Danger Classification:

Health	Environmental	Physical
R 36/38,	None known	None known

Associated Hazards:

Hazard Statements	Precautionary Statements
H319, H315	P305/P351/P338, P302/P352



Include as applicable

EU Classification: IIA Medical Device under the MDD 93/42/EEC

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EU Risk (R) and Safety (S) Phrases: R36, R38

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Ethylenediaminetetraacetic acid	60-00-4	EDTA	R36, R38	17%

Refer to Section 16 for the full text of the GHS and H phrases and EU Classifications and R Phrases.

4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	Wash with copious amounts of water
Skin	Wash with water
Inhalation	No harm anticipated in liquid form
Ingestion	Serve large amounts of fluids, 2-3 cups (milk or water). Contact physician.
Most important symptoms of exposure	Irritation
Other	Contact Physician if conditions persist
Note to Physicians (Treatment, Testing, and Monitoring): Treat Symptomatically	

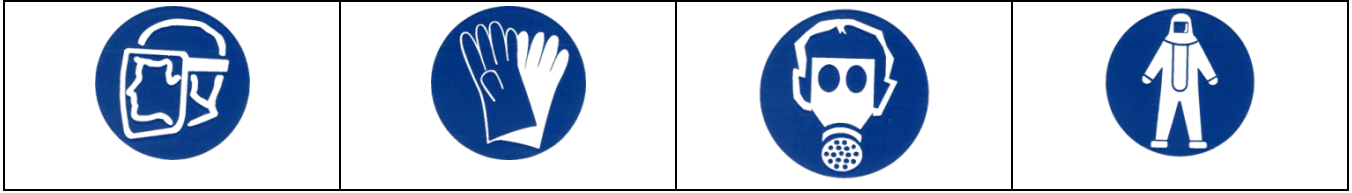
5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media:	Water contact acceptable
Fire Fighting Procedures:	None
Specific Hazards Arising from the Chemical:	None specific
Precautions for Fire Fighters:	None specific

Recommended Protective Equipment for Fire Fighters:

EYES/FACE	SKIN	RESPIRATORY	THERMAL
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6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Avoid contact with skin, eyes, and mucous membranes

Environmental Precautions: Dispose in accordance with local, state, and federal 11.1 regulations.

Methods and Materials for Containment and Clean-up: Wash spills to sewage

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	SKIN
	

7. HANDLING AND STORAGE

Precautions for Safe Handling: For intraoral use only by trained dental professionals. Follow good hygiene practices. Do not smoke, eat or drink while using.

Conditions for Safe Storage: Keep container closed. Store product in original container at cool room temperature (< 25°C). Shelf life for unopened product is two years from date of manufacture, provided proper storage.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits: No special equipment required

Biological Exposure Limits: None




Appropriate Engineering Controls: None

Individual Protection Measures (PPE)
Specific Eye/face Protection: Safety glasses

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Specific Skin Protection: Good personal hygiene, lab coat and gloves. Wash hands after use.
Specific Respiratory Protection: Not required
Specific Thermal Hazards: None

Recommended Personal Protective Equipment

EYES/FACE	SKIN
	 

Environmental Exposure Controls: Follow all government regulations

General Hygiene Considerations and Work Practices: N/A

Protective Measures During Repair and Maintenance of Contaminated Equipment: N/A

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear liquid	Explosive limits:	N/A
Odor:	N/A	Vapor pressure:	Not determined
Odor threshold:	N/A	Vapor density:	Not determined
pH:	6.8 to 7.4	Relative density:	Not determined
Melting/freezing point:	N/A	Solubility:	Soluble in Water
Initial boiling point and range:	212oF / 100°C	Partition coefficient: n-octanol/water:	Not determined
Flash point:	Nonflammable	Auto-ignition temperature:	Not determined
Evaporation rate:	Not Determined	Decomposition temperature:	Not determined
Flammability:	N/A	Viscosity:	N/A
Explosive Properties:	N/A	Oxidizing Properties:	N/A

10. STABILITY AND REACTIVITY

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Reactivity: Contact with strong alkalis and alkaline metals.
Chemical Stability: Stable
Possibility of Hazardous Reactions: Not reactive
Conditions to Avoid: Contact with strong alkalis and alkaline metals
Incompatible materials: Alkaline metals (sodium, potassium, magnesium) isocyanides, strong alkalis, and all materials incompatible with water.
Hazardous Decomposition Products: Nitrogen oxides, carbon monoxide, carbon dioxide, ammonia and/or derivatives.

11. TOXICOLOGICAL INFORMATION

Signs and Symptoms of Overexposure: May be irritating to eyes or skin on contact							
Emergency Overview: None Known							
Likely Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)	LD50 Testing Data (as applicable)	LC50 Testing Data (as applicable)
Eye:	Irritation	Single	Mild	None	None	NA	NA
Skin:	Irritation	Single	Mild	None	None	NA	NA
Inhalation:	None	NA	NA	NA	NA	NA	NA
Ingestion:	None	None	None	None	None	Oralrat 2000mg/kg	NA
Other:	None known	NA	NA	NA	NA	NA	NA
Medical Conditions Aggravated by Exposure: None Known							
Carcinogenicity: No ingredient listed as a carcinogen							
Other-Clinical experience: EDTA 17% Solution has been on the market in the US and internationally for more than 15 years. Using EDTA 17% Solution as part of root canal treatment is a well-established (20+ years), industry-accepted endodontic practice. EDTA is considered to be safe and effective treatment in the hands of a dental professional.							

12. ECOLOGICAL INFORMATION

Toxicity: No Ecological toxicity or damage/impact anticipated when handled as indicated.
Persistence and Degradability: None Determined
Bio-accumulative Potential: None Determined
Mobility in Soil: None Determined

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Other Adverse Effects: None Determined

Results of PBT/vPvB Assessment: None Determined

13. DISPOSAL CONSIDERATIONS

Regulations: Follow all local and national government regulations

Properties (Physical/Chemical) Affecting Disposal: Liquid

Waste Treatment Recommendations: Dispose in accordance with local, state, and federal regulations. Dilute and dispose in sewer.

14. TRANSPORT INFORMATION

UN Identification Number: Non Hazardous/Not Regulated

UN Proper Shipping Name: Not Regulated

Transport hazard class(es): Not Regulated

Packing Group: Not Regulated

Special precautions for user: Non Hazardous/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

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): None

Toxic Substances Control Act (TSCA): None

Clean Water Act (CWA): None

Clean Air Act (CAA): None

Superfund Amendments and Reauthorization Act (SARA) Title III Information: None

SARA Section 311/312 (40 CFR 370) Hazard Categories: None

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Immediate Hazard:	NA	Pressure Hazard:	NA
Delayed Hazard:	NA	Reactivity Hazard:	NA
Fire Hazard:	NA		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None	NA	NA

State Regulations

California: This product contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm:

Components	C.A.S. #	WT %
None	NA	NA

International Regulations

Canadian Environmental Protection Act: Not Regulated

Canadian Workplace Hazardous Materials Information System (WHMIS): NA

European Inventory of Existing Chemicals (EINECS): Not listed

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3:

List of relevant R phrases - R 36/38 Irritating to eyes and skin

Hazardous statement- H 319 Causes serious eye irritation. Category 2. H 315 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, and continue rinsing.

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

Restrictions on use: Pulpdent products are for use by dental professionals only

Date of SDS Preparation/Revision: 08/11/2014

Data Sources: Supplier

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).
National Institute for Occupational Safety (NIOSH)
US Occupational Safety and Health Administration (OSHA)