

# Roydent Dental Products

## Safety Data Sheet

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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](mailto: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
<b>Note to Physicians (Treatment, Testing, and Monitoring):</b> Treat Symptomatically	

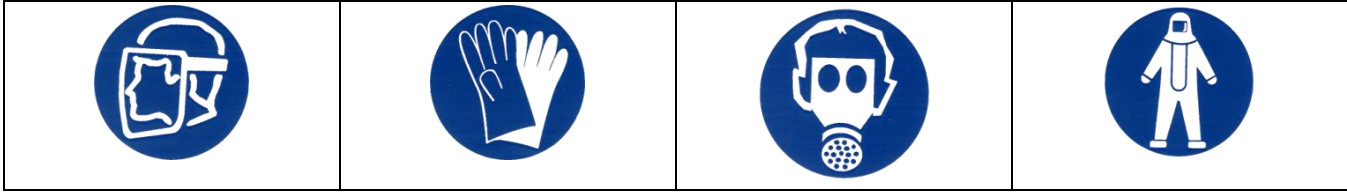
## 5. FIRE-FIGHTING MEASURES

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

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

## 10. STABILITY AND REACTIVITY

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

## 11. TOXICOLOGICAL INFORMATION

<b>Signs and Symptoms of Overexposure:</b> May be irritating to eyes or skin on contact							
<b>Emergency Overview:</b> 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)
<b>Eye:</b>	Irritation	Single	Mild	None	None	NA	NA
<b>Skin:</b>	Irritation	Single	Mild	None	None	NA	NA
<b>Inhalation:</b>	None	NA	NA	NA	NA	NA	NA
<b>Ingestion:</b>	None	None	None	None	None	Oralrat 2000mg/kg	NA
<b>Other:</b>	None known	NA	NA	NA	NA	NA	NA
<b>Medical Conditions Aggravated by Exposure:</b> None Known							
<b>Carcinogenicity:</b> No ingredient listed as a carcinogen							
<b>Other-Clinical experience:</b> 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

<b>Toxicity:</b> No Ecological toxicity or damage/impact anticipated when handled as indicated.
<b>Persistence and Degradability:</b> None Determined
<b>Bio-accumulative Potential:</b> None Determined
<b>Mobility in Soil:</b> 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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<b>Immediate Hazard:</b>	NA	<b>Pressure Hazard:</b>	NA
<b>Delayed Hazard:</b>	NA	<b>Reactivity Hazard:</b>	NA
<b>Fire Hazard:</b>	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)