

ROYDENT Dental Products

Safety Data Sheet

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1. PRODUCT IDENTIFICATION

Trade Name (as labeled): C.L. – Canal Lubricant
Chemical Name/Classification: EDTA Gel 17% Solution
Product Identifier (Part/Item Number): 101, 103
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: For use by Dental Professionals only
Distributed by: Roydent Dental Products
Distributors Address: 608 Rolling Hills Dr., Johnson City, TN 37604
Distributors Telephone Number: 1-800-992-7767 (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, S 26, S 28B, S45	None known	S2

Associated Hazards:

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

ROYDENT Dental Products



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

EU Risk (R) and Safety (S) Phrases: R 36/38, S2, S26, S28B, S45

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 %
Glycine,,N,N'-1,2-ethanediylbis[N-(carboxymethyl	60-00-4 200-449-4	EDTA	R 36/38	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 fog, alcohol foam, CO2 , dry chemical
Fire Fighting Procedures:	None
Specific Hazards Arising from the Chemical:	None specific

ROYDENT Dental Products

Precautions for Fire Fighters:		None specific	
Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			



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: Avoid contact with skin, mucous membranes, and eyes.

Conditions for Safe Storage: Store at temperatures not exceeding 75°F (24°C).

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits: No special equipment required

ROYDENT Dental Products

Biological Exposure Limits: None	
Appropriate Engineering Controls: None	
Individual Protection Measures (PPE) Specific Eye/face Protection: Goggles recommended if splashing of liquid is possible. Specific Skin Protection: Plastic gloves recommended if prolonged exposure is likely 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: None	
Protective Measures During Repair and Maintenance of Contaminated Equipment: None required	

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear liquid/Gel	Explosive limits:	Not Applicable
Odor:	None	Vapor pressure:	ca 760 mm Hg @ 98° C
Odor threshold:	Not Applicable	Vapor density:	Lower than air
pH:	Neutral	Relative density:	Not Determined
Melting/freezing point:	Not Applicable	Solubility:	Soluble in Water
Initial boiling point and range:	ca 101° 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:	No	Viscosity:	Not Applicable

ROYDENT Dental Products

Explosive Properties:	Not Applicable	Oxidizing Properties:	None
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10. STABILITY AND REACTIVITY

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: Irritation

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

12. ECOLOGICAL INFORMATION

Toxicity: No Ecological toxicity or damage/impact anticipated when handled as indicated.

Persistence and Degradability: None Determined

ROYDENT Dental Products

Bio-accumulative Potential: None Determined

Mobility in Soil: None Determined

Other Adverse Effects: None Determined

Results of PBT/vPvB Assessment: None Determined

13. DISPOSAL CONSIDERATIONS

Regulations: Dispose in accordance with local, state, and federal regulations. Dilute and dispose in sewer.

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

U.S. Federal Regulations

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

ROYDENT Dental Products

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

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

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:

R 36/38 Irritating to eyes and skin

S 2 Keep out of the reach of children.

S 26 In case of contact with eyes rinse immediately with plenty of water and seek medical advice.

S 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S 28B After contact with skin, wash immediately with plenty of water and soap.

H 319 Causes serious eye irritation. Category 2.

H 315 Causes skin irritation. Category 2.

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.

Date of SDS Preparation/Revision: 08/15/2014 rev0

Data Sources: Supplier

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