

CanalPro EDTA 17%

Revision Date: September 2014

Internal Document Number: 48220

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Section 1: PRODUCT AND COMPANY IDENTIFICATION**Product Name:** CanalPro EDTA 17%**Product Code(s):** 60011158 (120ml), 60011157 (480ml)**Relevant identified uses of the mixture and uses advised against:** for removing smear layer and dentin mud when performing root canal therapy. Intended for use by a licensed physician.**Synonyms:** EDTA**Manufacturer**

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Copies of this SDS can be found at

www.coltene.com**Section 2: HAZARDS IDENTIFICATION****Classifications:** Eye Damage Category 1A, Acute Toxicity Category 4**Appearance:** Clear, odorless liquid**Contains:** Tetrasodium Ethylene Diamine Tetraacetate (EDTA)**Route(s) of Exposure:** Dermal (Eye/Skin), Ingestion**NOTE:** This product is intended to be used for removing smear layer and dentin mud when performing root canal therapy by a licensed physician; hence, small amounts are intended to be used within a patient's mouth. When exposed to amounts of the solution beyond the intended use, consider the following precautions.**Labeling Elements:****Hazard Category**

Eye Damage Category 1A

Acute Toxicity Category 4

Signal Word:

DANGER

Hazard Statements:

Causes severe Eye Damage

Harmful if swallowed

**Prevention:**

Wear protective gloves / protective clothing / eye protection. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product

Response:

If swallowed: Rinse mouth. Do NOT induce vomiting. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water / shower. Wash contaminated clothing before reuse. If inhaled: Remove person to fresh air and keep comfortable for breathing. Immediately call a physician to specify the appropriate source of emergency medical advice. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Storage:

Store locked up.

Disposal:

Dispose of contents/container in accordance with local/ regional/ national/ international regulations.

Other Known Hazards: none known

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Section 3: COMPOSITION / INFORMATION ON INGREDIENTS

Substance	CAS	Percent (w/w%)
Tetrasodium Ethylene Diamine Tetraacetate (EDTA)	64-02-8	17

Section 4: FIRST AID MEASURES

Inhalation: Not a likely route of exposure. If having difficulty breathing move to fresh air. Call 911 or emergency medical service and provide oxygen if breathing is difficult.

Eyes: Irrigate exposed eyes with copious amounts of room temperature water for at least 15 minutes. If irritation, pain, swelling, lacrimation, or photophobia persist, the patient should be seen in a health care facility.

Skin: Not expected to affect skin upon contact; however, if a reaction occurs, remove contaminated clothing and wash exposed area thoroughly with soap and water. A physician may need to examine the area if irritation or pain persists.

Ingestion: Do not induce vomiting, give water if conscious and contact a physician.

Section 5: FIRE FIGHTING MEASURES

Extinguishing Media: Water, CO₂, dry chemical, or foam are acceptable extinguishing media.

Specific Hazards Arising from the Chemical: None

Protective Equipment and Precautions for Firefighters: standard protection for all firefighters stated in this subsection of the SDS text should include self-contained breathing apparatus (SCBA) and full firefighting turn-out gear (Bunker gear).

Section 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment, and Emergency Procedures: use personal protection recommended in Section 8.

Methods for Containment and Clean-up: Ventilate contaminated area, remove all sources of ignition, stop or reduce discharge if it can be done safely.

Other Information: None noted

Section 7: HANDLING AND STORAGE

Precautions for Safe Handling: use with adequate ventilation, do not use near ignition sources.

Conditions for Safe Storage, Including Incompatibilities: Keep out of reach of children. Keep away from flame sources. Keep container closed as product is hygroscopic. Avoid contact with aluminum.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Component Exposure Limits:

Component:	Concentration:	NIOSH REL:	OSHA PEL:	IDLH:	AIHA WEEL	STEL's	Notation
Tetrasodium Ethylene Diamine Tetraacetate (EDTA)	17	None	400 ppm	None	None	None	None

Appropriate Engineering Controls: sufficient exhaust & general ventilation should be provided to keep vapor concentration below recommended levels.

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Personal Protective Equipment (Eyes and Face): wear safety goggles or face shield.**Personal Protective Equipment (Skin):** wear protective gloves**Personal Protective Equipment (Respiratory):** none needed**Section 9: PHYSICAL AND CHEMICAL PROPERTIES**

Appearance:	Clear Liquid	Viscosity:	No data
Odor:	none	Odor Threshold:	No data
pH:	10 - 12	Boiling Point:	100°C (212°F)
Melting Point:	No data	Solubility (H ₂ O):	Soluble in water
Specific Gravity:	No data	Density:	1.2 g/cc (25°C)
Octanol / H ₂ O Coefficient:	No data	Evaporation Rate:	No data
Molecular Weight:	No data	Decomposition Temp:	No data
Auto Ignition:	No data	LFL:	No data
Flash Point:	No data	UFL:	No data
Vapor Density:	No data	Vapor Pressure:	No data
VOC:	No data	Flammability Class:	Nonflammable

Section 10: STABILITY AND REACTIVITY**Reactivity:** Reactive with oxidizing agents**Chemical Stability:** chemically stable**Possibility of Hazardous Reactions:** this product is not known to be susceptible to chemical reactions that can result in undesirable effect(s).**Conditions to Avoid:** Strong oxidizers**Incompatibility:** Aqueous solution will emit hydrogen on contact with aluminum**Hazardous Decomposition Products:** Carbon monoxide**Section 11: TOXICOLOGICAL INFORMATION****Likely Routes of Exposure:** Dermal (Eye), Ingestion**Hazardous Component:** Sodium Xylenesulphonate, Tetrasodium Ethylene Diamine Tetraacetate**Toxicity:** The severity of the tissue damage is a function of its concentration, the length of tissue contact time, and local tissue conditions. After exposure there may be a time delay before irritation and other effects occur. This material is a strong irritant and is corrosive to the eyes, and mucous membranes.**Eye Contact:** irritation, pain, swelling, lacrimation, or photophobia persist**Skin Contact:** essentially nonirritating to skin.**Ingestion:** may cause irritation to digestive tract.**Inhalation:** not a likely route of exposure.**Sensitization:** not a sensitizer.**Carcinogenicity:** does not contain any substances classified as carcinogens by NTP, ACGIH, IARC or OSHA**Mutagenicity:** not mutagenic

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Reproductive Toxicity: not toxic for reproduction nor is this product tetrogenic.**Section 12: ECOLOGICAL INFORMATION****Ecotoxicity:** No data**Persistence / Degradability:** This material degrades rapidly in the environment**Bioaccumulative Potential:** will not bioconcentrate in fish and aquatic organisms nor will it adsorb to sediment and suspended organic matter.**Mobility in Soil:** moderate to high mobility in soil**Other Adverse Effects:** none known.

This product does not contain persistent, bioaccumulative and toxic chemicals (PBT's) nor does this product contain any very persistent and very bioaccumulative chemicals (vPvB's).

Section 13: DISPOSAL CONSIDERATIONS**Disposal:** Dispose of in accordance with federal, state and local regulations.**Additional Disposal Considerations:** Dispose if shelf-life has been exceeded.**Section 14: TRANSPORT INFORMATION**

Agency	Proper Shipping name	Technical Shipping Name	UN-No.	Hazard Class	Label
DOT	NOT REGULATED FOR TRANSPORTATION				
Sea Transport IMDG/GGV Sea					
Air Transport ICAO-Ti and IATA-DGR					

Section 15: REGULATORY INFORMATION**SARA Sections 302 and 304:** This product does not contain Extremely Hazardous Substances (EHS) and is not subject to emergency planning requirements.**CERCLA:** This product does not contain CERCLA Hazardous Substances and is not subject to reporting requirements.**SARA Section 313:**

Tetrasodium Ethylene Diamine Tetraacetate (EDTA)	CAS #: 64-02-8	17%w/w
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International Inventories:

US (TSCA): The components within this product are included on the TSCA Inventory of Chemical Substances

Canada (DSL): All ingredients are on the inventory or exempt from listing.

European Union (EINECS): All ingredients conform to the EU requirements.

Japan (ENCS): All other ingredients are on the inventory or exempt from listing.

Philippines (PICCS): All other ingredients are on the inventory or exempt from listing.

South Korea (KECL): All ingredients are on the Inventory or exempt from listing.

Australia (AICS): All ingredients are on the Inventory or exempt from listing.

New Zealand (NZIoC): All ingredients are on the Inventory or exempt from listing.

China (IECSC): All ingredients are on the Inventory or exempt from listing.

California Proposition 65: There are no chemicals within this mixture on the Proposition 65 List.

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Canadian Regulations require the inclusion of the following statements under "Regulatory Information": This product has been classified in accordance with the hazard criteria of the controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.

Section 16: OTHER INFORMATION**NFPA Ratings:**

Health: 1
Fire: 0
Reactivity: 0

HMIS Ratings:

Health: 1
Fire: 0
Reactivity: 0

(NFPA and HMIS Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe)

REVISION HISTORY

REVISION	DATE	ECN#	CHG BY	APPR BY	DESC. OF CHANGE
A	9/25/14	14400	TG	SBL	Updated MSDS to GHS/SDS Format. 48220 Revision A was 48130 revision A.

The information and recommendations set forth herein are presented in good faith and are believed to be correct as of the date hereof. Coltène/Whaledent Inc., however, makes no representations as to the completeness of this information and supplies it on the condition that the persons receiving same will make their own determination as to its suitability of their purposes prior to use. In no event will Coltène/Whaledent Inc. be responsible for damages of any nature whatsoever resulting from use of or reliance upon information.