

Safety Data Sheet

 COLTENE

Coltene Inc.

CanalPro® EDTA 17%

Internal Document Number: 48220C

Revision Date: May 2018

Section 1 - IDENTIFICATION

Product Names: CanalPro® EDTA 17%

Product Codes: 60011158 (120ml), 60011157 (480ml)

Recommended Use: Intended for removing smear layer and dentin mud when performing root canal therapy.

Restrictions on Use: Intended for use by a licensed physician

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USA & Canada: 1 800 535 5053

Copies of this SDS can be found at
www.coltene.com

Section 2 - HAZARD(S) IDENTIFICATION

Classification in accordance with paragraph (d) of 29 CFR 1910.1200.

Hazard Category, Subcategory: Serious Eye Damage / Eye Irritation – Category - 2B
Skin Corrosion / Irritation – Category - 2

GHS Label Elements:

Symbol(s)



Signal Word:

Warning

Hazard Statement(s):

Causes eye irritation
Causes skin irritation

Precautionary Statement(s):

Prevention:

Wash hands thoroughly after handling

Response:

If in eyes: Rinse cautiously with water with several minutes. Remove contact lenses, if present and it's easy to do so. Continue rinsing for at least 15 minutes.

If on skin: Wash with plenty of soap and water. If skin irritation or rash occurs, get medical advice and attention.

Storage:

None specified but keep out of reach of children

Disposal:

Dispose of in accordance with local, state and federal regulations.

Statement(s) of Unknown Acute Toxicity:

Zero % of the mixture consists of ingredient(s) of unknown acute toxicity.

Other Hazards which do not result in classification:

None noted.

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Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	CAS number	Percent (w/w%)
Disodium Ethylenediaminetetraacetate Dehydrate (EDTA)	6381-92-6	17%

Section 4 - FIRST AID MEASURES

Description of Necessary Measures

Inhalation: Not a likely route of exposure. If having difficulty breathing move to fresh air.

Skin: Not expected to affect skin upon contact however, if exposed wash skin thoroughly with soap and water. If irritation develops and persists contact a physician.

Eyes: Flush eyes with copious amounts of water for at least 15 minutes. If irritation, pain, swelling, lacrimation or photophobia persist, contact a physician

Ingestion: Do not induce vomiting. Contact a physician.

Section 5 - FIRE-FIGHTING MEASURES

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

Unsuitable Extinguishing Media: None known

Specific Hazards Arising from the Chemical: None known

Special Protective Equipment and Precautions for Firefighters: Wear protective equipment and self-contained breathing apparatus (SCBA) per fire department's SOP.

Section 6 - ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures: Use personal protective equipment recommended in Section 8.

Methods and Materials for Containment and Cleaning Up: Small spills wear gloves and safety glasses and collect spills with paper towels or disposable cloths. Dispose of absorbent material in a suitable container and wash the exposed areas with soap and water. Large spills are highly unlikely but should be absorbed with inert, non-combustible material, such as vermiculite or sand. Dispose of in a suitable container and flush area with water.

Section 7 - HANDLING AND STORAGE

Precautions for Safe Handling: Use with adequate ventilation. Do not use near ignition sources.

Conditions for Safe Storage, Including Any Incompatibilities: Store in a cool, dry location. Keep container closed as material is hygroscopic. Avoid contact with aluminum.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Component Exposure Limits:

There are no reported exposure limits for the product

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ACGIH - Threshold Limit Values - Biological Exposure Indices (BEI)

There are no biological limit values for any of this product's components.

Appropriate Engineering Controls:

General ventilation is sufficient

Individual Protection Measures, such as Personal Protective Equipment (non-molten state):

Eye/Face protection:

Chemical safety goggles or face shield

Skin Protection:

Wear protective gloves

Respiratory Protection:

Not required with adequate ventilation.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Clear	Physical State	Liquid
Odor	Odorless	Color	Clear
Odor Threshold	Not available	pH	10-12
Melting Point	Not applicable	Flammability class	None
Boiling Point	100°C (212°F)	Freezing point	Not available
Evaporation Rate	Not applicable	Molecular Weight	Not available
Autoignition Temperature	Not applicable	Flash Point	Not available
Lower Explosive Limit	Not applicable	Decomposition temperature	Not available
Upper Explosive Limit	Not applicable	Vapor Pressure	Not applicable
Vapor Density (air=1)	Not available	Relative Density(water=1)	~ 1.1
Water Solubility	Soluble	Partition coefficient: n-octanol/water	Not available
Viscosity	Not available	Kinematic viscosity	Not available
Solubility (Other)	Not available	Density	Not available

Section 10 - STABILITY AND REACTIVITY

Chemical Stability:

Chemically Stable

Possibility of Chemical Reactions:

Reactive with oxidizing agents

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Incompatible Materials:

Strong oxidizers. Aqueous solutions will emit hydrogen on contact with aluminum.

Hazardous Decomposition Products:

Product will decompose into carbon monoxide, carbon dioxide, ammonia and/or derivatives.

Section 11 - TOXICOLOGICAL INFORMATION

Information on Routes of Exposure:

Skin, eyes, ingestion

Skin: May cause irritation with prolonged exposure.

Eye Contact: Irritation, pain, swelling, lacrimation and or photophobia

Ingestion: May cause irritation to the digestive tract.

Inhalation: Not a likely route of exposure

Section 12 - ECOLOGICAL INFORMATION

Non-Mandatory Section

Ecotoxicity

Component Analysis - Aquatic Toxicity:

Material is not considered harmful to the environment

Persistence and Degradability:

This material degrades rapidly in the environment

Bioaccumulative Potential:

The material will not bioconcentrate in fish and aquatic organisms nor will it absorb to sediment and suspended organic matter

Mobility in Soil:

Moderate to high mobility in soil

Other Adverse Effects:

None known

The product does not contain persistent, bioaccumulative and toxic chemicals (PBT) nor does this product contain any very persistent and very bioaccumulative chemicals (vPvB)

Section 13 - DISPOSAL CONSIDERATIONS

Non-Mandatory Section

Disposal Methods:

Dispose of in accordance with local, state and federal regulations

Component Waste Numbers:

The U.S. EPA has not published waste numbers for this products components

Additional Disposal Considerations:

Dispose of is shelf-life is exceeded.

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Section 14 - TRANSPORT INFORMATION

Non-Mandatory Section

Emergency Response Guide Number: Not applicable

DOT & TDG Information:

Not Regulated

Environmental Hazards:

None

International Bulk Chemical Code

The product does not contain any chemicals required by the IBC Code to be defined as dangerous chemicals in bulk

IATA & IMDG Information:

Not Regulated

Section 15 - REGULATORY INFORMATION

Non-Mandatory Section

U.S. Federal Regulations

None of this product's components are listed under SARA Sections 302/304 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65), CERCLA (40 CFR 302.4), TSCA 12(b), or require an OSHA process safety plan.

SARA Section 311/312 (40 CFR 370 Subparts B and C) reporting categories

[Classification according to SARA Section 311/312.]

Not Classified

U.S. State Regulations

None of this product's components are listed on the state lists from CA, MA, MN, NJ or PA.

The following statement(s) are provided under the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):

Not listed under California Proposition 65.

Canada Regulations:

CEPA – Priority Substance list

None of this product's components are on the list

Ozone Depleting Substances:

None of this product's components are on the list

Council of Ministers of the Environment – Soil Quality Guidelines

None of this product's components are on the list

Council of Ministers of the Environment – Water Quality Guidelines

None of this product's components are on the list

Section 16 - OTHER INFORMATION

HMIS and NFPA Ratings are not required, but are often found in Section 16.

HMIS Rating

Health: [1] Fire: [0] Reactivity: [0]

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard

NFPA Ratings

Health: [1] Fire: [0] Reactivity: [0] Other:

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

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REVISION HISTORY

REVISION	DATE	ECN #	CHG BY	CHK BY	APPR. BY	DESCRIPTION OF CHANGE
A	9/25/14	14400	SBL	TG	SBL	Updated MSDS to GHS/SDS format. 48220 Revision A supersedes 48130 Revision A
B	6/03/15	14972	SBL	SBL	AT	Removed Eye Damage Category 1A and Acute Toxicity Category 4 and added Eye Irritant Category 2B. Updated corresponding hazard and precautionary statements
C	5/07/18		PMc		PMc	Added Skin Irritant Category 2 and updated to WHMIS 2015 Regulations

Key / Legend

ACGIH - American Conference of Governmental Industrial Hygienists; ADR - European Road Transport; AU - Australia; BOD - Biochemical Oxygen Demand; C - Celsius; CA - Canada; CA/MA/MN/NJ/PA - California/Massachusetts/Minnesota/New Jersey/Pennsylvania*; CAS - Chemical Abstracts Service; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CFR - Code of Federal Regulations (US); CLP - Classification, Labelling, and Packaging; CN - China; CPR - Controlled Products Regulations; DFG - Deutsche Forschungsgemeinschaft; DOT - Department of Transportation; DSD - Dangerous Substance Directive; DSL - Domestic Substances List; EC - European Commission; EEC - European Economic Community; EIN - European Inventory of (Existing Commercial Chemical Substances); EINECS - European Inventory of Existing Commercial Chemical Substances; ENCS - Japan Existing and New Chemical Substance Inventory; EPA - Environmental Protection Agency; EU - European Union; F - Fahrenheit; F - Background (for Venezuela Biological Exposure Indices); IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; ICAO - International Civil Aviation Organization; IDL - Ingredient Disclosure List; IDLH - Immediately Dangerous to Life and Health; IMDG - International Maritime Dangerous Goods; ISHL - Japan Industrial Safety and Health Law; IUCLID - International Uniform Chemical Information Database; JP - Japan; Kow - Octanol/water partition coefficient; KR KECI Annex 1 - Korea Existing Chemicals Inventory (KECI) / Korea Existing Chemicals List (KECL); KR KECI Annex 2 - Korea Existing Chemicals Inventory (KECI) / Korea Existing Chemicals List (KECL) , KR - Korea; LD50/LC50 - Lethal Dose/ Lethal Concentration; LEL - Lower Explosive Limit; LLV - Level Limit Value; LOLI - List Of Lists™ - ChemADVISOR's Regulatory Database; MAK - Maximum Concentration Value in the Workplace; MEL - Maximum Exposure Limits; MX - Mexico; Ne - Non-specific; NFPA - National Fire Protection Agency; NIOSH - National Institute for Occupational Safety and Health; NJTSR - New Jersey Trade Secret Registry; Nq - Non-quantitative; NSL - Non-Domestic Substance List (Canada); NTP - National Toxicology Program; NZ - New Zealand; OSHA - Occupational Safety and Health Administration; PEL - Permissible Exposure Limit; PH - Philippines; RCRA - Resource Conservation and Recovery Act; REACH - Registration, Evaluation, Authorisation, and restriction of Chemicals; RID - European Rail Transport; SARA - Superfund Amendments and Reauthorization Act; Sc - Semi-quantitative; STEL - Short-term Exposure Limit; TCCA - Korea Toxic Chemicals Control Act; TDG - Transportation of Dangerous Goods; TLV - Threshold Limit Value; TSCA - Toxic Substances Control Act; TW - Taiwan; TWA - Time Weighted Average; UEL - Upper Explosive Limit; UN/NA - United Nations /North American; US - United States; VLE - Exposure Limit Value (Mexico); VN (Draft) - Vietnam (Draft); WHMIS - Workplace Hazardous Materials Information System (Canada).

Other Information:

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