

1. IDENTIFICATION OF SUBSTANCES / PREPARATION AND COMPANY

Product Name: Schottlander 17% EDTA Solution
 Product Code: 229-9

Application: The irrigation of root canals during endodontic procedures.

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2. HAZARD IDENTIFICATION

GHS Classification:

| Health | Environmental | Physical |
|--|----------------|----------------|
| Skin Irritation – Category 3 – H316 | Not applicable | Not applicable |
| Serious Eye Damage – Category 2B – H320 | Not applicable | Not applicable |
| Acute Toxicity, Oral – Category 5 – H303 | Not applicable | Not applicable |

GHS Label:
 OSHA HCS 2013



WARNING

Hazard Statements

H316: Causes mild skin irritation
 H320: Causes eye irritation
 H303: May be harmful if swallowed

Precautionary Statements

P264: Wash hands thoroughly after handling
 P280: Wear protective gloves/eye protection
 P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
 P302+P352: IF ON SKIN: Wash with plenty of soap and water.

3. COMPOSITION / INFORMATION ON INGREDIENTS

| CAS No. | Chemical Components | Weight % | EINECS |
|-----------|---|----------|-----------|
| 7732-18-5 | Water | 77 | 231-791-2 |
| 6381-92-6 | EDTA (Disodium ethylenediaminetetraacetate dehydrate) | 17 | unlisted |
| N/A | Proprietary ingredients | 6 | unlisted |

4. FIRST AID MEASURES

Eye Contact: Flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid if irritation persists.

Skin Contact: Flush skin with plenty of soap and water for at least 15 minutes while removing contaminated clothing and shoes. Get medical aid if irritation develops or persists.

Ingestion: If victim is conscious and alert give 2-4 cupfuls of milk or water. Never give anything by mouth to an unconscious person. Do not induce vomiting unless medical advice is given from a professional. Get medical aid if symptoms worsen.

Inhalation: No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to high level of dusts or fumes remove from exposure and move to fresh air immediately. Get medical aid if cough or other symptoms develop.

Most important symptoms and effects, both acute and delayed

Symptoms/injuries: Mill irritation/redness in eyes or on skin after contact.

Indication of immediate medical attention and special treatment needed

Consult a physician or contact Poison Control Centre if chemical solution is ingested in large amounts. Physicians are required to treat victim symptomatically.

5. FIRE FIGHTING MEASURES

Suitable Extinguishing media:

Use dry chemical, foam or carbon dioxide to extinguish fire.

Fire fighting procedures:

Do not flush down sewers or other drainage systems. Exposed fire fighters must wear NIOSH approved positive pressure, self-contained breathing apparatus with full-face mask and full protective clothing.

Unusual Fire and Explosion Hazards:

None

Combustion Products:

Ammonia and nitrogen oxides under fire conditions.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Wear proper personal protective equipment as indicated in Section 8. Follow instructions listed below.

Environmental Precautions

Follow all government regulations for waste disposal. Prevent release to the environment if possible. Do not flush waste into sewer or waterways.

Methods and Materials for Containment and Cleaning Up

Small spills: Wear gloves and safety glasses and pick up spill with absorbent material, such as paper towels or disposable cloths. Dispose of absorbent material in suitable container and wash the exposed area with soap and water.

Large spills: Wear proper protective equipment and absorb spill with inert, non-combustible material (e.g. vermiculite, sand or earth). Dispose of non-combustible material in suitable container and flush area with water.

7. HANDLING AND STORAGE

Handling:

For intraoral use only by trained and experienced dental professionals. Follow good hygiene practices. Do not smoke, eat or drink while using. Use suitable protective equipment when handling. Wash thoroughly after handling and avoid any chemical contact with eyes, skin and

clothing. Keep container tightly closed to avoid inhalation or accidental ingestion. Use with adequate ventilation.

Storage:

Store in a tightly closed container. Store container at room temperature in a cool, dry, well ventilated area away from incompatible substances. Keep containers upright when not in use. Shelf life is thirty months from date of manufacture, provided that it is stored properly.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits/Engineering controls:

| Chemical Components | ACGIH | NIOSH | OSHA – Final PELs |
|---|---------------|---------------|-------------------|
| Water | Not available | Not available | Not available |
| EDTA (Disodium ethylenediaminetetraacetate dehydrate) | Not available | Not available | Not available |

Engineering Controls: Use adequate ventilation to keep airborne concentrations low.

Personal Protective Equipment (PPE) Information:

Eye Protection: Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN 166.

Skin Protection: Wear appropriate protective gloves and lab coat to prevent skin exposure. Use good personal hygiene and wash hands after use.

Clothing Protection: Wear appropriate protective clothing to prevent skin exposure.

Respiratory Protection: Follow OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Always use a NIOSH or European Standard EN 149 approved respirator when necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance/Colour:

Physical State: Liquid

Appearance: Clear, colourless liquid

Odour: Odourless or no characteristic odour

Odour Threshold: Not applicable

Important health, safety and environmental information:

Flashpoint: Not applicable

Auto ignition Temperature: Not applicable

Boiling Point: 100°C/212°F

Melting Point: Not determined

Freezing Point: Not determined

SAFETY DATA SHEET

| | |
|---|----------------|
| Vapour Pressure: | Not determined |
| Relative Density: | Not determined |
| Vapour Density (Air⁻¹): | Not determined |
| Solubility in Water: | Soluble |
| Decomposition Temperature: | Not determined |
| Pour Point: | Not applicable |
| Lower Flammability Limit: | Not applicable |
| Upper Flammability Limit: | Not applicable |
| Specific Gravity: | ~ 1.1 |
| Evaporation Rate (Water⁻¹): | Not applicable |
| Viscosity: | Not determined |
| Octanol/Water Partition Coefficient: | Not determined |
| pH: | 8.5 |
| Molecular Weight: | Mixture |

10. STABILITY AND REACTIVITY

| | |
|--|---|
| Chemical stability: | Stable. |
| Hazardous Polymerisation: | Has not been reported. |
| Incompatible materials: | Strong oxidising agents. |
| Hazardous decomposition products: | Nitrogen oxides, carbon monoxide, carbon dioxide, ammonia and/or derivatives. |

11. TOXICOLOGY INFORMATION

| | |
|--|--|
| Signs and Symptoms of Overexposure: | Eye and skin irritation on contact |
| Eye contact: | May cause eye irritation |
| Skin Contact: | May cause slight irritation |
| Inhalation: | May cause respiratory tract irritation |
| Ingestion: | May cause respiratory and digestive tract irritation |

Additional Toxicity Information

| | |
|-------------------------|----------------------|
| Target Organ(s): | None known |
| Chronic Effects: | No information found |
| Acute Toxicity: | Not toxic |

Acute Toxicity Values:

RTECS#

CAS# 7732-18-5: ZC0110000

CAS# 6381-92-6: AH4410000

CAS# 139-33-3: AH4375000

LD50/LC50:

CAS# 7732-18-5:

Oral, rat: LD50 = >90 mL/kg; <BR

CAS# 6381-92-6: <BR

CAS# 139-33-3:

Oral, mouse: LD50 = 2050 mg/kg;

Oral, rabbit: LD50 = 2300 mg/kg;

Oral, rat: LD50 = 2 gm/kg; <BR

Carcinogenicity:

CAS# 7732-18-5: Not listed by ACGIH, IARC, NTP or CA Prop 65

CAS# 6381-92-6: Not listed by ACGIH, IAR, NTP or CA Prop 65

SAFETY DATA SHEET

CAS# 139-33-3: Not listed by ACGIH, IARC, NTP or CA Prop 65

Epidemiology: No data available.
Teratogenicity: No data available.
Reproductive effects: No data available.
Neurotoxicity: No data available.
Mutagenicity: No data available.
Other studies: No data available.

Clinical Experience: EDTA, 17% solution has been in the global market for more than 15 years. EDTA, 17% solution has been used for root canal treatment for over 20 years. EDTA, 17% solution is industry-accepted and approved for endodontic practice. EDTA is considered to be safe and effective when used by dental professionals.

12. ECOLOGICAL INFORMATION

No information available.

13. DISPOSAL CONSIDERATIONS

By waste contractor in accordance with local regulations.

14. TRANSPORT INFORMATION

Unrestricted.

15. REGULATORY INFORMATION

No chemicals are reportable under Section 313

Clean Air: This material does not contain any hazardous air pollutants. This material does not contain any Class 1 Ozone depleters. This material does not contain any Class 2 Ozone depleters.

Clean Water: None of the chemicals in this product are listed as Hazardous Substances. None of the chemicals in this product are listed as Priority Pollutants. None of the chemicals in this product are listed as Toxic Pollutants.

WGK (Water Danger/Protection)

CAS# 7732-18-5: No information available

CAS# 6381-92-6: 2

CAS# 139-33-3: 2

Canada – DSL/NDSL

CAS# 7732-18-5 is listed on Canada's DSL List

CAS# 6381-92-6 is listed on Canada's DSL List

CAS# 139-33-3 is listed on Canada's DSL List

Canada – WHMIS

WHMIS: Not available

Canadian Ingredient Disclosure List

16. FURTHER INFORMATION

The data given above covers exclusively the safety requirements of the product(s) and is based on our current knowledge and experience. It does not signify any warranty with regards to the products properties. This product is only supplied for specific uses in dentistry and must be used in accordance with the directions for use.