

SAFETY DATA SHEET

Product name: CALASEPT EDTA 17%

SDS Drawn up: 2010-06-21 SDS Revised: 2011-12-01

1. Identification of the substance / preparation and of the company

Trade name: CALASEPT EDTA 17%
Chemical name: EDTA, solution
Field of application: Chemical and mechanical root canal preparation
Supplier: Nordiska Dental AB
Postal address: Box 1082 Telephone no: +46 431 443 360
Postcode and town: S-262 21 Ängelholm Fax no: +46 431 443 399
Country: Sweden E-mail: mail@nordiskadental.se
Emergency telephone: +46 431 443 360 Contact: Ewa-Lotte Pedersen

2. Hazards identification

Classification: No harmful.

Classification according to EU directive no 1272/2008: The composition is not classified as hazardous.

Label information: The product does not need to be labelled in accordance with EU directives.

3. Composition / information on ingredients

Component	CAS-no	Einecs-no	Content (%)	Classification
Ethylenedinitrilotetraacetic acid disodium salt dihydrate	6381-92-6	205-358-3	15-20	--
Sodium hydroxide	1310-73-2	215-185-5	<0,1%	--

4. First aid measures

Inhalation: Fresh air. If the person not breathes, give artificial respiration or oxygen by trained personnel. Seek medical advice immediately.

Skin contact: Wash with soap and water. Seek medical advice if irritation occurs or persists.

Eye contact: IMPORTANT! Keep the eyelids wide apart and flush with plenty of water. Get medical attention if irritation persists.

Ingestion: Drink water. Do not induce vomiting. Get medical attention if symptom persisting.

Further information: Never give any food and/or drink to an unconscious person. Please show this safety data sheet to the doctor on duty. Get medical attention in case of uncertainty.

5. Fire-fighting measures

FIRE FIGHTING PROCEDURES: General: Evacuate all personnel, use protective equipment for fire fighting.

Suitable extinguishing media: Water, CO₂, foam, powder.

Extinguishing media which must not be used: Extinguishing media which may assessed on the basis from which other products and chemicals stored in the vicinity of this product.

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases: In a fire, possible release of dangerous fumes containing nitrogen oxides, sodium hydroxide and ammonia.

Special protective equipment: Do not stay in dangerous zone without self-contained breathing apparatus.

Further information: Contain escaping vapours with water. Prevent fire-fighting water from entering surface water or groundwater.

6. Accidental release measures

Personal precautions: Avoid contact with eyes and skin.

Environmental precautions: Do not allow to enter sewerage system.

Methods for cleaning up: Take up with absorbent material, such as paper or cloth flush area with water, observe the precautions in paragraph 8 (Exposure controls / Personal protection). Spills and wastes should be disposed of in accordance with local and national regulations.

7. Handling and storage

Handling: The product should be handled with care and in accordance with strict hygiene practises. Avoid inflicting damage on the packing. Use appropriate protective equipment.

Storage: Store at room temperature not >25°C. Keep away from heat / ignition sources.

8. Exposure controls / personal protection

Exposure limit values: -

Exposure controls: All work should be carried out in accordance with strict hygiene practises. All work should take place in suitable premises, in accordance with the existing legislation and regulations. See also heading 7. Handling and storage.

- **personal protective equipment:** Wear gloves and goggles.
- **respiratory protection:** Not necessary under normal use.
- **hand protection:** Glove material nitrile rubber layer thickness 0.11 mm breakthrough time >480 Min. The protective gloves to be used must comply with the specifications of EC directive 89/686/EEC. Please contact a supplier of EC-approved gloves e.g. KCL GmbH, Germany Internet: www.kcl.de.
- **eye protection:** Use safety glasses.
- **skin protection:** In case of direct contact with the substance use protective clothing.
- **further information:** Change contaminated clothing. Wash hands after working with substance.

Environmental exposure controls: Avoid release to the environment.ets.

9. Physical and chemical properties

General information:

- Appearance: Colourless liquid.
- Odour: Odourless.

Important health, safety and environmental information:

- | | | | | |
|-----------------------------|---------------|---|----------------------------|------------------------|
| · pH: | Approx. 8 | · | : | |
| · Flash point: | Not available | | Boiling point | Approx. 100 °C |
| · Explosion limits: | Not available | · | Flammability (solid, gas): | - |
| · Melting Point: | - | · | Oxidising properties: | - |
| · Solubility in water: | Soluble | · | Density: | ~1,1 g/cm ³ |
| · Vapour density: | - | · | Evaporation rate: | - |
| · Decomposition temperature | 255 °C | · | : Viscosity | - |

10. Stability and reactivity

Conditions to be avoided: Avoid high temperatures of the product.

Substances to be avoided: Violent reactions possible with strong oxidizers, acids and bases.

Hazardous decomposition products: In the event of fire see chapter 5.

11. Toxicological information

Acute toxicity: LD₅₀ (oral rat):>2000 mg/kg (dry substance)

Eye effects: May cause irritation.

Skin effects: May cause mild irritation.

Further toxicological information:

- **After swallowing:** slow absorption, disturbed electrolyte balance.
- **After swallowing of large amounts:** damage of kidneys.
- **Other notes:** Sensitization is possible for predisposed persons.
- **Further data:** The product should be handled with the care usual when dealing with chemicals.

12. Ecological information

Biologic degradation: Not readily biodegradable.

Ecotoxic effects:-

Biological effects: -

Fish toxicity: P.reticulata: LC₅₀ : ~320mg/1/96 h (dry substance) (IUCLID).

Bacterial toxicity: Ps.putida EC₅₀ :56mg/1/8 h (dry substance) (IUCLID); activated sludge EC₅₀ :403mg/1/3 h (OECD 209).

Further ecologic data: Do not allow to enter waters, waste water or soil.

13. Disposal considerations

Product: Should be disposed of in accordance with local regulations and national legislation.

Contaminated packaging: Should be disposed of in accordance with local regulations and national legislation.

14. Transport information

ADR/RID:

Not classified as dangerous goods

ICAO/IATA:

Not classified as dangerous goods

IMO/IMDG:

Not classified as dangerous goods

15. Regulatory information

Health, safety and environmental information shown on the label:

The product is not labelled. It must be used according to manufacturer's recommendations and managed by medically qualified person.

Precautions: P305; IF IN EYES: + P351; Rinse cautiously with water for several minutes + P338; Remove contact lenses, if present and easy to do. Continue rinsing.

Further information: Safety Data Sheet according to REACH 1907/2006/EC. Classification, labelling and packing of substances and mixtures (CLP) EC 1272/2008 This product meets the demands MDD 93/42/EEC. The product is CE-marked.

16. Other information

Reason for update of the safety data sheet: Update to the new regulation EU 1272/2008 (CLP).

The information in this safety data sheet is based upon our present knowledge. The information is presented with the intention of describing the safest way of handling the product. The safety data sheet is therefore not to be regarded as a complete chemical description of the product. Consequently, the user is responsible for making sure that the product is meant to be used in the actual field of application and that it serves the purpose intended.