

SAFETY DATA SHEET

Date of issue: 29/04/16

Version: 1.2

Revised: 20/03/17

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: **Calasept EDTA 17%**

REACH registration numbers:

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified use(s): Chemical and mechanical preparation of root canal

1.3. Details of the supplier of the safety data sheet

Address: Directa AB
Box 723
SE-194 27 UPPLANDS VÄSBY
SWEDEN
Telephone: +46-8-506 505 75
E-mail: info@directadental.com

1.4. Emergency telephone number: +46-8-33 12 31 (Swedish Poisons Information Centre)

2. Hazards identification

2.1. Classification of the substance or mixture

Classification: The preparation is not classified as hazardous according to Regulation (EC) CLP, No. 1272/2008

HEALTH

May cause transient mild eye irritation. Repeated or prolonged skin contact may cause mild skin irritation.

ENVIRONMENT

The product does not contain any substances classified as hazardous for the environment.

FIRE

The product is not flammable.

2.2. Label elements

Hazard pictogram(s): None

Signal word(s): None

Hazard statement(s): Not applicable

Precautionary statement(s): Not applicable

2.3. Other hazards

PBT/vPvB: Not relevant.

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3. Composition/information on ingredients

3.2. Mixtures

Classification of substances according to CLP, 1272/2008/EC

Hazardous substances	Content, %	CAS No	EC No	Hazard class(es)/ Category code(s)	Hazard statements
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Other substances

EDTA	15-20	6381-92-6	205-358-3	NC	NC
Sodium hydroxide	< 0.1	1310-73-2	215-185-5	Skin Corr. 1A	H314

Hazard statements, full text; H314 = Causes severe skin burns and eye damage, NC = Not classified.

4. First aid measures

4.1. Description of first aid measures

Inhalation

Move affected person to fresh air.

Skin contact

Remove all contaminated clothing. Wash off with soap and water.

Contact with eyes

Irrigate thoroughly with eyewash solution or clean water, holding the eyelids apart, for at least 5 minutes. If discomfort persists, obtain medical attention

Ingestion

Not relevant.

4.2. Most important symptoms and effects, both acute and delayed

Inhalation

Under normal conditions the product is not considered an inhalation hazard.

Skin contact

Repeated or prolonged skin contact may cause mild skin irritation.

Contact with eyes

May cause transient mild eye irritation.

Ingestion

Not relevant.

4.3 Indication of any immediate medical attention and special treatment needed

As a general rule, and in all cases of doubt or when symptoms persist, always seek medical attention.

Never give anything by mouth to an unconscious person.

5. Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

The product is not combustible. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2. Special hazards arising from the substance or mixture

In combustion emits toxic fumes of carbon dioxide/carbon monoxide.

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5.3. Advice for firefighters

Selection of respiratory protection for firefighting: follow the general fire precautions indicated in the workplace.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes. Follow precautions for safe handling described in this safety data sheet.

6.2. Environmental precautions

Prevent liquid from entering sewers, watercourses, underground or low areas. Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

6.3. Methods and material for containment and cleaning up

Contain spillage with sand, earth or other suitable non-combustible material. Absorb in vermiculite, dry sand or earth and place into containers. Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority.

6.4 Reference to other sections

For personal protection, see section 8.

For waste disposal, see section 13.

7. Handling and storage

7.1. Precautions for safe handling

7.1.1 Safety handling advice:

Do not eat, drink or smoke when using this product. Eye wash facilities must be available when handling this product. Good personal hygiene procedures should be implemented. Take off contaminated clothing and wash it before reuse. Wash with soap and water if skin becomes contaminated.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures for safe storage:

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Keep away from strong acids, strong alkalis and strong oxidisers.

7.3. Specific end use(s)

The product is to be used for chemical and mechanical preparation of root canal in clinical dentistry.

8. Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limit value (EH40/2005 WELs, United Kingdom (UK), 12/2011)

Sodium hydroxide STEL: 2 mg/m³ (15 minutes)
TWA: -

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Provide adequate ventilation. Provide access to washing facilities incl. soap.

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8.2.2. Individual protection measures, such as personal protective equipment

Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

a) Eye/face protection

Eyewear complying with an approved standard should be worn if a risk assessment indicates eye contact is possible. The following protection should be worn: Chemical splash goggles.

b) Skin protection

Wear protective gloves. Nitrile rubber gloves are recommended. Frequent change is advisable. Other types of gloves can be recommended by the glove supplier.

c) Respiratory protection

Respiratory protection is normally not required.

If ventilation is inadequate, suitable respiratory protection must be worn. Seek advice from supervisor on the company's respiratory protection standards. Respiratory protection complying with an approved standard should be worn if a risk assessment indicates inhalation of contaminants is possible.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Colourless liquid
Odour	Odourless
Odour threshold	Not determined
pH	Ca 8
Melting point/freezing point	Not determined
Boiling point / range	Ca 100°C
Flash point	Not determined
Evaporation rate (BuAc = 1)	Not determined
Flammability (solid, gas)	Not determined
Explosion limits	Not determined
Vapour pressure	Not determined
Vapour density (air = 1)	Not determined
Relative density	Ca 1100 kg/m ³
Solubility - water	Soluble
Partition coefficient: n-octanol/water	Not determined
Auto-ignition temperature	Not determined
Decomposition temperature	255°C
Viscosity	Not determined
Explosive properties	Not applicable
Oxidising properties	Non-oxidising

9.2. Other information

Not available.

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10. Stability and reactivity

10.1. Reactivity

The product is not reactive under recommended storage and handling conditions.

10.2. Chemical stability

The product is stable under recommended storage and handling conditions.

10.3. Possibility of hazardous reactions

No specific hazardous reactions are expected to occur.

10.4. Conditions to avoid

Avoid heat, flames and other sources of ignition.

10.5. Incompatible materials

Reacts with strong acids, alkalis and oxidisers.

10.6. Hazardous decomposition products

No known decomposition products.

11. Toxicological information

11.1. Information on toxicological effects

Symptoms related to the physical, chemical and toxicological characteristics

Inhalation

Under normal conditions the product is not considered an inhalation hazard.

Skin contact

Repeated or prolonged skin contact may cause mild skin irritation.

Contact with eyes

May cause transient mild eye irritation.

Ingestion

Not relevant.

11.1.2. Mixtures

11.1.2.1. The relevant effects, for which information shall be provided, are:

Sodium hydroxide

Relevant hazard class	Effective dose/ concentration	Species	Method	Result
Acute oral toxicity	n/a			Not classified
Acute dermal toxicity	n/a			Not classified
Acute toxicity inhalation	n/a			Not classified
Skin corrosion/irritation	n/a			H314 (Causes severe skin burns and eye damage)
Serious eye damage/ irritation	n/a			H318 (Causes serious eye damage)
Respiratory or skin sensitisation	n/a			Not classified
Germ cell mutagenicity	n/a			Negative (not mutagenic)
Carcinogenicity	n/a			Negative (not carcinogenic)

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Reproductive toxicity	n/a			Negative (not toxic for reproduction)
Specific organ toxicity – single exposure	n/a			Not classified
Specific organ toxicity – repeated exposure	n/a			Not classified
Aspiration hazard	n/a			Not classified

12. Ecological information

12.1. Toxicity

EDTA

L(E)C₅₀, aquatic organisms: > 100 mg/l

12.2. Persistence and degradability

EDTA

Not readily biodegradable. Slow microbial decomposition in soil and the aquatic environment. In natural waters EDTA forms readily biodegradable metal complexes, mainly with iron.

12.3. Bioaccumulative potential

EDTA

Not expected to have the potential for bioaccumulation in aquatic organisms.

12.4. Mobility in soil

The product is water soluble and may be adsorbed to soil particles.

12.5. Results of PBT and vPvB assessment

None of the substances in this product fulfil the criteria for being regarded as PBT or vPvB substances.

12.6. Other adverse effects

No other adverse effects are observed.

13. Disposal considerations

13.1. Waste treatment methods

Chemical residues, including contaminated containers, are generally classified as hazardous waste, and as such are covered by regulations which vary according to location. Contact your local waste disposal authority for advice, or pass to a licensed chemical disposal company.

14. Transport information

The product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID)

14.1. UN number:

14.2. UN proper shipping name:

14.3. Transport hazard class(es):

14.4. Packing group: -

14.5. Environmental hazards:

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14.6. Special precautions for user: -**14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on Classification, Labelling and Packaging of substances and mixtures (CLP), amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, with amendments.

Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

The Control of Substances Hazardous to Health Regulations (COSHH) 2002 (S.I. 2002 No. 2677) with amendments.

EH40/2005, Workplace exposure limits 2005, with amendments.

The List of Wastes (England) (Amendment) Regulations 2005 (S.I. 2005 No 895) with amendments.

15.2. Chemical Safety Assessment

The supplier has not performed a Chemical Safety Assessment of this mixture.

16. Other information

The following sections have been amended since the last version of the safety data sheet (dated 29/04/16):

Section 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16

Key literature references and sources for data:

Safety Data Sheet, Calasept EDTA 17%, Directa AB, 29/04/16.

- End of safety data sheet -