

SAFETY DATA SHEET

Product name: Calasept EDTA Page: 1/11
Revision: Print date: 2023-02-07
Product No.: SDS-ID: EU-EN/1.0

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name: Calasept EDTA

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

Supplier: Directa AB
P.O. Box 723
SE-194 27 Upplands Väsby
Tel:+46 850650575
Fax:+46 85903060
info@directadental.com

1.4. Emergency telephone number

Emergency telephone: National Poison Control Centres are available in Member Countries. or
+4608331231 (Only during office hours)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

CLP: The product is not classified.

2.2. Label elements

The substance/mixture does not meet the criteria for classification, but the following labelling must be applied:

Safety data sheet available on request.

2.3. Other hazards

PBT/vPvB: This product does not contain any PBT or vPvB substances.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2. Mixtures

CLP:

%:	CAS-No.:	EC No.:	REACH Reg. No:	Chemical name:	Hazard classification:	Notes:
15-20	6381-92-6	-	-	EDTA, disodium salt dihydrate	-	
<1	1310-73-2	215-185-5	-	Sodium hydroxide	Skin Corr. 1A;H314	

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<u>Chemical name:</u>	<u>SCL</u>	<u>M (ac)</u>	<u>M (chr)</u>	<u>ATE(o)</u>	<u>ATE(d)</u>	<u>ATE(i)</u>	<u>ATE(i)</u>	<u>ATE(i)</u>
				<u>(mg/kg</u>	<u>(mg/kg</u>	<u>(dust/</u>	<u>(gas,</u>	<u>(vapou</u>
				<u>bw)</u>	<u>bw)</u>	<u>mist,</u>	<u>ppmV)</u>	<u>r,</u>
						<u>mg/L)</u>		<u>mg/L)</u>

EDTA, disodium salt dihydrate		-	-	-	-	-	-	-
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Sodium hydroxide	Skin Corr. 1A;H314: C ≥ 5 %	-	-	-	-	-	-	-
	Skin Corr. 1B;H314: 2 % ≤ C < 5 %							
	Skin Irrit. 2;H315: 0,5 % ≤ C < 2 %							
	Eye Irrit. 2;H319: 0,5 % ≤ C < 2 %							

References: The full text for all hazard statements is displayed in section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation: General first aid, rest, warmth and fresh air.

Skin contact: Remove contaminated clothing. Wash skin with soap and water.

Eye contact: Immediately flush with plenty of water for at least 15 minutes. Remove any contact lenses and open eyelids widely. If irritation persists: Seek medical attention and bring along these instructions.

Ingestion: Not relevant.

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

Symptoms/effects: See section 11 for more detailed information on health effects and symptoms.

4.3. Indication of any immediate medical attention and special treatment needed

Medical attention/treatments: Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Extinguishing media: This product is not flammable. Use fire-extinguishing media appropriate for surrounding materials.

5.2. Special hazards arising from the substance or mixture

Specific hazards: During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Protective equipment for fire-fighters: Selection of respiratory protection for fire fighting: follow the general fire precautions indicated in the workplace.

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SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Follow precautions for safe handling described in this safety data sheet.

6.2. Environmental precautions

Environmental precautions: Avoid discharge into water courses or onto the ground.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Small spillages: Collect spillage with a moist cloth.
Large Spillages: Absorb spilled substance with sand or earth. Sweep up and place into an appropriate container.

6.4. Reference to other sections

References: For personal protection, see section 8.
For waste disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Safe handling advice: Observe good chemical hygiene practices. Ventilate well. Wash hands before breaks and before smoking, eating or drinking.
Avoid contact with eyes and prolonged skin contact.

Technical measures: Keep the workplace clean.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures for safe storage: No special precautions.

Storage conditions: Store in tightly closed original container in a well-ventilated place. Store at room temperature.

7.3. Specific end use(s)

Specific use(s): Not relevant.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No occupational exposure limit assigned.

Please note that there may be national occupational exposure limits.

DNEL/PNEC: Not available.

8.2. Exposure controls

Engineering measures: Provide adequate ventilation. Observe Occupational Exposure Limits and minimise the risk of inhalation of vapours. Provide access to washing facilities incl. soap, skin cleanser and fatty cream.

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

Respiratory equipment: Under normal conditions of use respiration protection should not be required. In case of inadequate ventilation use suitable respirator.

Hand protection: Risk of contact: Wear protective gloves.
Nitrile gloves are recommended. Frequent change is advisable.
The most suitable glove must be chosen in collaboration with the supplier of gloves, who can inform about the breakthrough time of the glove material.

Eye protection: Risk of splashes: Wear approved safety goggles.

Skin protection: Wear appropriate clothing to prevent repeated or prolonged skin contact.

Hygiene measures: Wash hands after handling. Wash contaminated clothing before reuse.

Environmental Exposure Controls: Not available.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state: Colourless liquid.
Odour: Odourless.
Odour threshold: Not available.
pH: ~ 8
Melting point / freezing point: Not available.
Boiling point: ~ 100 C
Flash point: Not available.
Evaporation rate: Not available.
Flammability (solid, gas): Not available.
Explosion limits: Not available.
Vapour pressure: Not available.
Vapour density: Not available.
Relative density: ~ 1100 kg/m³
Solubility: Soluble in water.
Partition coefficient (n-octanol/water): Not available.
Auto-ignition temperature (°C): Not available.
Decomposition temperature (°C): 255 °C
Viscosity: Not determined.
Explosive properties: Not applicable.
Oxidising properties: Non-oxidizing
9.2. Other information
Other data: Not available.

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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity: Not reactive.

10.2. Chemical stability

Stability: Stable under normal temperature conditions.

10.3. Possibility of hazardous reactions

Hazardous Reactions: None under normal conditions.

10.4. Conditions to avoid

Conditions/materials to avoid: Avoid heat, flames and other sources of ignition.

10.5. Incompatible materials

Incompatible materials: Keep away from strong oxidants, strong acids and strong bases.

10.6. Hazardous decomposition products

Hazardous decomposition products: None under normal conditions.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

<u>Acute Toxicity (Oral):</u>	Based on available data, the classification criteria are not met.
<u>Acute Toxicity (Dermal):</u>	Based on available data, the classification criteria are not met.
<u>Acute Toxicity (Inhalation):</u>	Based on available data, the classification criteria are not met.
<u>Skin Corrosion/Irritation:</u>	Based on available data, the classification criteria are not met.
<u>Serious eye damage/irritation:</u>	Based on available data, the classification criteria are not met.
<u>Respiratory or skin sensitisation:</u>	Based on available data, the classification criteria are not met.
<u>Germ cell mutagenicity:</u>	Based on available data, the classification criteria are not met.
<u>Carcinogenicity:</u>	Based on available data, the classification criteria are not met.
<u>Reproductive Toxicity:</u>	Based on available data, the classification criteria are not met.
<u>STOT - Single exposure:</u>	Based on available data, the classification criteria are not met.
<u>STOT - Repeated exposure:</u>	Based on available data, the classification criteria are not met.
<u>Aspiration hazard:</u>	Based on available data, the classification criteria are not met.
 <u>Inhalation:</u>	 Not relevant at normal room temperatures. When heated, irritating vapours may be formed.
 <u>Skin contact:</u>	 Prolonged contact may cause redness and irritation.
 <u>Eye contact:</u>	 May irritate and cause redness and pain.
 <u>Ingestion:</u>	 May cause irritation to the mouth and throat.

11.2. Information on other hazards

<u>Endocrine disrupting properties:</u>	The product does not contain any substance identified as having endocrine disrupting properties.
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SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity: Not classified as dangerous to the environment.

12.2. Persistence and degradability

Degradability: This product is expected to be not readily biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential: No data available on bioaccumulation.

12.4. Mobility in soil

Mobility: The product is soluble in water. May adsorb to soil particles.

12.5. Results of PBT and vPvB assessment

PBT/vPvB: This product does not contain any PBT or vPvB substances.

12.6. Endocrine disrupting properties

Endocrine disrupting properties: The product does not contain any substance identified as having endocrine disrupting properties.

12.7. Other adverse effects

Other adverse effects: None known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste and residues in accordance with local authority requirements.

Waste from residues: EWC-code: 18 01 07

Contaminated packaging: Dispose of contaminated packings as residue.

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SECTION 14: TRANSPORT INFORMATION

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

14.1. UN number

UN-No: -

14.2. UN proper shipping name

Proper Shipping Name: -

14.3. Transport hazard class(es)

Class: -

14.4. Packing group

PG: -

14.5. Environmental hazards

Marine pollutant: -

Environmentally Hazardous substance: -

14.6. Special precautions for user

Special precautions: Not relevant.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Transport in bulk: Not relevant.

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SECTION 15: REGULATORY INFORMATION

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

National regulation:

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, with amendments.

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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 with amendments.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work, with amendments.

Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, with amendments.

Commission Directive 91/322/EEC of 29 May 1991 on establishing indicative limit values by implementing Council Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work, with amendments.

Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, with amendments.

Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work, with amendments.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, with amendments.

2014/955/EC: Commission Decision of 18 December 2014 amending Decision 2000/532/EC as regards the list of wastes.

15.2. Chemical Safety Assessment

CSA status: No chemical safety assessment has been carried out.

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SECTION 16: OTHER INFORMATION

The user must be instructed in the proper work procedure and be familiar with the contents of these instructions.

Abbreviations and acronyms used in the safety data sheet: CSA = Chemical Safety Assessment.
PBT = Persistent, Bioaccumulative and Toxic.
vPvB = very Persistent and very Bioaccumulative.
SCL = Specific Concentration Limit.

Additional information: Classification according to Regulation (EC) No. 1272/2008: Calculation method.

Wording of H-statements:

H314 Causes severe skin burns and eye damage.

The information on this data sheet represents our current data and is reliable provided that the product is used under the prescribed conditions and in accordance with the application specified on the packaging and/or in the technical guidance literature. Any other use of the product which involves using the product in combination with any other product or any other process is the responsibility of the user.

Made by DHI - Environment and Toxicology, Artens Allé 5, DK-2970 Hørsholm, Denmark.
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