

SAFETY DATA SHEET

Product name: Calasept Plus Page: 1/11
Revision: Print date: 2022-12-07
Product No.: 1240100 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 Plus

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

Identified use(s): Temporary root filling, isolation. Medical device. Directly invasive.

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 a medical device and CLP requirements on classification and labelling do not apply.

2.2. Label elements

This product is a medical device and does not require a hazard label. The information which would have appeared on the label is shown here.

EUH210 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:
41-46	1305-62-0	215-137-3	-	Calcium dihydroxide	Skin Irrit. 2;H315 Eye Dam. 1;H318	

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

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SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation: IF exposed or concerned: Not relevant, due to the form of the product. Move into fresh air and keep at rest.

Skin contact: Wash the skin immediately with soap and water. Contact physician if irritation continues or sores develop.

Eye contact: Not relevant during normal use. In case of contact: Do not rub eye. 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: Immediately rinse mouth and drink 1-2 glasses of water. Keep person under observation. If uncomfortable: Transportation to hospital. Bring along these instructions.

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: Avoid contact with skin and eyes. 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: Absorb in vermiculite, dry sand or earth and place into containers.

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: Avoid contact with eyes and prolonged skin contact. Observe good chemical hygiene practices. Ventilate well.

Technical measures: Keep the workplace clean.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: Store in tightly closed original container in a dry, cool and well-ventilated place. Keep away from strong acids.

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

Occupational exposure limits:

<u>CAS-No.:</u>	<u>Chemical name:</u>	<u>As:</u>	<u>Exposure limits:</u>	<u>Type:</u>	<u>Notes:</u>	<u>References:</u>
1305-62-0	Calcium dihydroxide, respirable fraction	-	1 mg/m3	-	-	EC
		-	4 mg/m3	-	15min	

Notes:

EC: Commission Directives 2009/148/EC, 2004/37/EC, 2000/39/EC and 91/322/EEC, with amendments.

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.

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: Respiratory protection not required.

Hand protection: Risk of contact: Wear protective gloves. Nitrile gloves are recommended, but be aware that the liquid may penetrate the gloves. 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 contact: 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.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state: Paste.
Colour: White
Odour: Odourless.
Odour threshold: Not available.
pH: ~ 12,4
Melting point / freezing point: Not available.
Boiling point: Not available.
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: Not available.
Solubility: Miscible with water.
Partition coefficient (n-octanol/water): Not available.
Auto-ignition temperature (°C): Not available.
Decomposition temperature (°C): Not available.
Viscosity: Not available.
Explosive properties: Non-explosive
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 and recommended use.

10.3. Possibility of hazardous reactions

Hazardous Reactions: None known.

10.4. Conditions to avoid

Conditions/materials to avoid: None known.

10.5. Incompatible materials

Incompatible materials: Strong acids.

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

Acute Toxicity (Oral): Based on available data, the classification criteria are not met.

Acute Toxicity (Dermal): Based on available data, the classification criteria are not met.

Acute Toxicity (Inhalation): Based on available data, the classification criteria are not met.

Skin Corrosion/Irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation: Based on available data, the classification criteria are not met.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive Toxicity: Based on available data, the classification criteria are not met.

STOT - Single exposure: Based on available data, the classification criteria are not met.

STOT - Repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

Inhalation: Not relevant at normal room temperatures. When heated, irritating vapours may be formed.

Skin contact: Causes skin irritation.

Eye contact: Irritating and may cause redness and pain. May cause chemical conjunctivitis and corneal damage with direct eye contact.

Ingestion: May cause irritation to the mouth and throat.

Toxicological data: LD50 (oral, rat):
Calcium dihydroxide 7340 mg/kg bw

11.2. Information on other hazards

Endocrine disrupting properties: The product contains no substances identified as having endocrine disrupting properties in humans.

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SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity: The product is not expected to be hazardous to the environment.

Calcium dihydroxide:
LC50, Aquatic organisms: > 100 mg/l

12.2. Persistence and degradability

Degradability: This product mainly consists of inorganic compounds which are not biodegradable. The remaining compounds of the product are expected to be easily 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 contains no substances identified as having endocrine disrupting properties in aquatic organisms.

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.

Empty packaging: Empty clean packaging should be collected for reuse.

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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

Environmentally Hazardous substance: -

14.6. Special precautions for user

Special precautions: -

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

Transport in bulk: -

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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.
LC50 = Lethal Concentration 50%.
LD50 = Lethal Dose 50%.
PBT = Persistent, Bioaccumulative and Toxic.
vPvB = very Persistent and very Bioaccumulative.

Wording of H-statements:

H315	Causes skin irritation.
H318	Causes serious 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, Artvej 5, DK-2970 Hørsholm, Denmark.
www.dhigroup.com.
