

SAFETY DATA SHEET

Product name: PROCLINIC

SDS Drawn up: 2011-08-31 SDS Revised: 2016-04-29

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

Trade name: Proclinic
Chemical name: Calcium hydroxide with radiopacity
Field of application: Temporary root filling, isolation
Supplier: Directa AB
Postal address: Box 723 Telephone no: +46 4(0)8- 506 505 75
Postcode and town: SE- 194 27 Website: www.directadental.com
Upplands Väsby
Country: Sweden E-mail: info@directadental.com
Emergency telephone: Poison Center 112

2. Hazards identification

Classification: Hazardous in contact with eye or skin.

Adverse physicochemical effects: The product has a pH-value of 12,4

Adverse human health effects: May causes severe burns and eye damage (category 1). May cause skin irritation (category 2).

Adverse environmental effects: Water hazard class 1 (self-assessment); slightly hazardous for water.

Classification of the mixture In accordance with regulation (EC) No 1272/2008:

Serious eye injury (category 1).

According to European Directive 67/548/EEC as amended:

Skin irritation, may cause serious burn damage in eyes.

Label information:



Pictograms:

Signal words: Danger

Hazard identification: H318; Causes serious eye damage. H315; Causes skin irritation.

Precautionary measures: P280; Wear protective gloves / eye protection / face 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.

P337 + P313; If eye irritation persists. Get medical attention.

3. Composition / information on ingredients

Component	CAS-no	Einecs-no	Content (%)	Classification
Calcium hydroxide	1305-62-0	215-137-3	41-46	Eye Dam. 1, Skin irrit. 2 H318, H315*
Barium sulphate	7727-43-7	231-784-4	5-10	-
Ringer solution	-	-	45-54	-

*The full wordings of the phrases are listed in section 16

4. First aid measures

Inhalation:-

Skin contact: Wash off with plenty of water.

Eye contact: Keep the eyelids wide apart and flush with plenty of water for at least 15 minutes. Get medical attention.

Ingestion: Immediately drink ca. 0,5 L of water, or preferably milk. Get medical attention as soon as possible.

Further information: Clothing soiled by the product shall be immediately removed. 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

Suitable extinguishing media: The product is not flammable. Customize the fire fighting measures to the surrounding.

Extinguishing media which must not be used:-

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases: Metal oxide fume can be released.

Special protective equipment: Use breathing apparatus that is independent of the ambient air.

Further information:-

6. Accidental release measures

Personal precautions: Eye bath should be available in the premises. Avoid skin contact. Eye protectors should be used.

Environmental precautions: Do not allow the material to be released to the environment without proper governmental permit.

Methods for cleaning up: Use neutralising agents.

7. Handling and storage

Handling: The product should be handled with care and in accordance with strict hygiene practises.

Storage: Do not store together with strong acids, anhydrides and nitro compounds. Store at room temperature, do not refrigerate. Avoid exposure to direct sunlight.

8. Exposure controls / personal protection

Exposure limit values: Calcium hydroxide: OSHA Permissible Exposure Limit (PEL): Time Weighted Average (TWA) 15 mg/m³ (total) 5 mg/m³ (resp). NIOSH Recommended Exposure Limit (REL): TWA 5 mg/m³. Barium sulphate: OSHA PEL: TWA 15 mg/m³ (total) TWA 5 mg/m³ (resp). NIOSH REL: TWA 10 mg/m³ (total) TWA 5 mg/m³ (resp).

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.

Occupational exposure controls:

- **respiratory protection:-**
- **hand protection:** Protective gloves should be used in order to avoid exposure.
- **eye protection:** Eye protectors should be used in order to avoid exposure.
- **skin protection:-**

Environmental exposure controls:-

9. Physical and chemical properties

General information:

- Appearance: White paste.
- Odour: No odour.

Important health, safety and environmental information:

- | | | | |
|---|----------|-----------------------------------|------------|
| · pH: | 12,4 | · Boiling point/interval: | - |
| · Flash point: | - | · Flammability (solid, gas): | - |
| · Explosive properties: | - | · Oxidising properties: | - |
| · Vapour pressure: | - | · Density: | - |
| · Water solubility: | Mixable. | · Solubility in organic solvents: | Insoluble. |
| · Vapour density: | - | · Evaporation rate: | - |
| · Partition coefficient: n-octanol/water: | - | · Viscosity: | - |

10. Stability and reactivity

Conditions to avoid:-

Materials to avoid: Strong acids, anhydrides and nitro compounds.

Hazardous decomposition products:-

11. Toxicological information

Dangerous-to-health effects and symptoms related to:

- **inhalation:-**
- **ingestion:** The product is strongly alkaline (pH-value 12,4). May be harmful if swallowed.
- **skin contact:** The product is strongly alkaline (pH-value 12,4). Can cause skin irritation. May be harmful if absorbed through skin.
- **eye contact:** The product is strongly alkaline (pH-value 12,4). Causes serious eye irritation.
LD/LC value that are relevant for classification (for calcium hydroxide):
 - Oral, LD50:7300 mg/kg (moues), 7340 mg/kg (rat).
 - Irritation of eyes, severe: 10 mg (rabbit).

12. Ecological information

General notes: Water hazard class 1 (self-assessment); slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system. Do not allow material to be released to the environment without proper governmental permits.

Persistence and degradability: Not degradable.

Bioaccumulative potential:-

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 (Land transport):

Not classified as dangerous goods

ICAO/IATA (Air transport):

Not classified as dangerous goods

IMO/IMDG (Maritime transport):

Not classified as dangerous goods

15. Regulatory information

Health, safety and environmental information shown on the label:

According to GHS (CLP):

Pictograms:



Signal word: Danger

Hazard identifications: H318 Causes serious eye damage. H315; Causes skin irritation.

Precautions measures: P280, Wear protective gloves / eye protection / face protection.

P305; IF IN EYES: + P351; Rinse cautiously with water for several minutes.

P338; Remove contact lenses, if present and easy to do. Continue rinsing. + P337; If eye irritation persists +

P313 Get medical attention.

According to European Directive 67/548/EEC as amended:

Hazard symbol:



Categories of danger: C, Corrosive

Risk phrases: R41 Risk of serious damage to eyes.

Safety phrases: S25 Avoid contact with eyes. S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Further information: Safety Data Sheet according to REACH EC 1907/2006. Classification, labelling and packing of substances and mixtures (CLP) EC 1272/2008.

This product meets the demands of MDD 93/42/EEC. The product is CE-marked.

16. Other information

Full wording of the phrases referred to in section 3: Eye Dam 1 = eye damage (Category 1), Skin Irrit 2 = skin irritation (Category 2).

H318 Causes serious eye damage. H315 Skin irritation.

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.