

**Safety Data Sheet
by choice according to 1907/2006/EC, Article 31**



Product name: CALXYL® Dentin 10

Revision Date: 11.01.2016
Version: 2.0

Printing date: 11.01.2016

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

1.1 Product identifier

Product name: CALXYL® DENTIN 10

Reach Registration Number:

A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline.

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

Identified use: Calcium hydroxide paste, exclusively for dental use

1.3 Details of the supplier of the safety data sheet.

Manufacturer/Supplier: OCO Präparate GmbH *67246 Dirmstein*Germany*
Responsible Department: E-Mail: info@oco-praeparate.de
Phone: +49(0)6238 9268110
Fax: +49(0)6238 9268112

1.4 Emergency telephone number: Please contact the regional company representation in country
Inside Germany: Poisons Line +49 6131 / 19 24 0 (German and English language)

2. Hazards identification

Classification of the substance or mixture (EG) Nr. 1272/2008:

Serious eye damage; category 1; H318
Skin irritation; category 2; H315

For the full text of the H-Statements mentioned in this section, see Section 16.

Classification (67/548/EEC or 1999/45/EC)
Xi; Irritant R38/ 41

R-phrase(s): R 38: Irritating to skin. und R 41: Risk of serious damage to eyes

S-Phrase(s): S 26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 39: Wear eye/face protection.

2.2 Label elements

Labelling (Regulation (EC) No. 1272/2008)
Hazard pictograms



GHS05



GHS07

Signal words: Danger

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Hazard statements

H315 causes skin irritation
H318 causes serious eye damage

Precautionary statements

P280 Wear eye protection.
P302 + P352 IF ON SKIN: wash with plenty of soap and water.:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes.
Remove contact lenses, if present and easy to do. Continue rinsing
P313 Get medical advice/attention.

2.3 Other hazards:

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable

3. Composition/information on ingredients

Chemical nature: slaked lime

3.1 Substance: not applicable

3.2 Mixture

SUBSTANCES:

-CALCIUM HYDROXIDE

-Formula:	Ca (OH) ₂	H ₂ CaO ₂ (Hill)
-CAS-No.:	1305-62-0	
-EC-No.:	EINECS: 215-137-3	
-REACH-Registration No.:	01-2119475151-45 ;	
-Molar Mass:	74,09 g/mol	
-Weight portion:	≈ 25-50 %	

- Barium sulfate

- Formula:	Ca ₅ (OH)(PO ₃) ₃	HCA ₅ O ₁₃ P ₃ (Hill)
-CAS-No.:	1306-06-5	
-EC-No.:	231-784-4	
-Molar mass:	502,31 g/mol	
-Weight portion :	≈ 5-20 %	

Hazardous components(Regulation (EC) 1272/2008) [CLP] :

H318 – Serious eye damage; Category 1;
H315 – Skin irritation; Category 2
H335 – Specific target toxicity – single exposure; Category 3

Regulation 67/548/EC : Xi; Irritant; R37/38-41

Additional information:

For the full text of the H-Statements mentioned in this section, see Section 16.

4. First aid measures

4.1 Description of first aid measures

After eye contact: Rinse opened eye for several minutes under running water.

Immediately call in ophthalmologist.

In case of skin contact: Rinse skin with water/shower.

After swallowing: Immediately make victim drink water. Consult a physician

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4.2 Most important symptoms and effects, both acute and delayed

Irritation and corrosion,
Risk of corneal clouding
Risk of serious damage to eyes
Risk of blindness

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

No available.

5. Firefighter measures

5.1 Extinguishing media

Suitable extinguishing agents:

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment

Unsuitable extinguishing agents:

For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

Not combustible.
Ambient fire may liberate hazardous vapours.

5.3 Advice for firefighters

Special protective equipment for firefighters

Stay in danger area only with self-contained breathing apparatus.
Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

Further information

Prevent fire extinguishing water from contaminating surface water or the ground water system

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Wear protective equipment.
Keep unprotected persons away. Avoid direct substance contact
Ensure adequate ventilation.

6.2 Environmental precautions:

Do not empty into drains

6.3 Methods and material for containment and cleaning up:

Cover drains, collect the material. Observe possible material restrictions (see 7,8,10 and 13).
Take up dry. Dispose of properly. Clean up affected area.

6.4 Reference to other sections

Indications about waste treatment see section 13.

7. Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Open and handle receptacle with care. Observe label precautions. Ensure good ventilation

Hygiene measures

Immediately change contaminated clothing. Apply preventive skin protection.
Wash hands after working with the product

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7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Do not use light-weight-metal containers.

Storage conditions

Tightly closed; Dry; Normal ambient temperature

7.3 Specific end use(s)

No further relevant information available. See section 1.2

8. Exposure controls/personal protection

8.1 Control parameters

Derived No Effect Level (DNEL)

Is not applicable, due of it's less concentration on the working place, it is saturated and no dust or vapour will be generated.

Predicted No Effect Concentration (PNEC)

PNEC Fresh water	0,4 mg/l
PNEC Marine water	0,32 mg/l
PNEC Aquatic intermittent release	0,49 mg/l
PNEC Soil	1080 mg/kg
PNEC Sewage treatment plant	3 mg/l

8.2 Exposure controls

Engineering measures

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment. Personal protective equipment:

See section 7.1

Individual protection measures

Protective clothing needs to be selected specifically for the working place, depending on the concentration and quantities of the hazardous substances handle. The chemical resistance of the protective equipment should be enquired respective supplier.

Eye/face protection

Tightly fitting safety goggles

Hand protection:

full contact: **Glove material: Nitril rubber**
 Glove thickness: 0,11 mm
 Break through time > 480 min

splash contact: **Glove material: Nitril rubber**
 Glove thickness: 0,11 mm
 Break through time > 480 min

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The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those in EN374 please contact the supplier of CE-approved gloves.

Other protective equipment

protective clothing

Environmental exposure controls

Do not empty into drains.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form:	pasty
Colour:	white
Odour:	odourless
Odour threshold:	not applicable
PH-value:	12.6 at 20 °C (saturated solution)
Melting point/Melting range:	550 °C (decomposition)
Boiling point/Boiling range:	no information available
Flash point:	does not flash
Flammability (solid, gaseous):	this product is not flammability
Lower explosion limit:	not applicable
Upper explosion limit:	not applicable
Vapour pressure at 20 °C:	not applicable
Relative vapour density:	no information available
Density:	2,24 g/cm ³
Relative density:	no information available
Water solubility at 20 °C:	1,7 g/l
Partition coefficient: n-octanol/water:	not applicable
Auto-ignition temperature:	no information available
Decomposition temperature:	550 - 600°C
Viscosity, dynamic:	no information available
Explosive properties:	not classified as explosive
Oxidizing properties:	none

9.2 Other data

Ignition temperature:	not combustible
Bulk density:	ca. 400 kg/m ³

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10 Stability and reactivity

10.1 Reactivity

resolving in acid

10.2 Chemical stability

Generates carbonate in contact with the ambient air. Desiccation

10.3 Possibility of hazardous reactions

Exothermic reaction with:

Hydrogen sulphide, light metals, phosphorus, organic nitro compounds, acids

Risk of explosion with: Anhydrides

10.4 Conditions to avoid

Exposure to ambient air. Desiccation

10.5 Incompatible materials

Light metals

10.6 Hazardous decomposition products

no information available

11 Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity

Calcium hydroxide, CAS-No.: 215-137-3

LD₅₀ (rat): 7340 mg/kg (IUCLID)

Symptoms: Irritations of gastrointestinal tract

Acute inhalation toxicity

**Symptoms: mucosal irritations, cough, shortness of breath,
possible damages: damage of respiratory tract**

Acute dermal toxicity: This information is not available.

Skin irritation:

Rabbit

Result: No irritation; OECD Test Guideline 404

In case of perspiration/moisture corrosive. Causes skin irritation.

Eye irritations

Rabbit

Result: Severe irritations (RTECS) Risk of corneal clouding. Risk of blindness !

Cause serious eye damage.

Sensitisation

This information is not available

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Germ cell mutagenicity: This information is not available.
Carcinogenicity: This information is not available.
Reproductive toxicity: This information is not available.
Teratogenicity: This information is not available.
Specific target organ toxicity – single exposure: May cause respiratory irritation.
Specific target organ toxicity – repeated exposure: This information is not available.
Aspiration hazard: This information is not available

11.2 Further information:

Other dangerous properties cannot be excluded. Handle in accordance with good industrial hygiene and safety practice

12. Ecological information

12.1 Toxicity

Toxicity to fish: LC50 *Gambusia affinis* (Mosquito fish): 160 mg/l; 96 h (IUCLID)

12.2 Persistence and degradability: Biodegradability

The methods for determining the biological degradability are not applicable to inorganic substances

12.3 Bioaccumulative potential: Partition coefficient: n-octanol/water : not applicable

12.4 Mobility in soil: no information available.

12.5 Results of PBT and vPvB assessment: PBT/vPvB : Not applicable for inorganic substances.

12.6 Other adverse effects

Additional ecological information:

Harmful effect due to pH shift. Forms corrosive mixture with water even diluted.
Neutralization possible in waste water treatment plants.
Discharge into the environment must be avoided.

13 Disposal considerations:

Waste treatment methods

See www.retrologistik.com for processes regarding the return of chemicals and containers, or contact us.

14 Transport information

14.1 Not supposed in transport regulations nor land, air or sea transports. Not classified as
-14.6 dangerous in the meaning of transport regulations. So not applicable

15 Regulatory information

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

Major Accident Hazard Legislation 96/82/EC; Directive 96/82/EC does not apply
Occupational restrictions: Take note of Dir 94/33/EC on the protection of young people at work.
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: not regulated
Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29. April 2004
on persistent organic pollutants and amending Directive 79/117/EEC: not regulated

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Regulation (EC) NO 689/2008 concerning the export and import of dangerous chemicals:
not regulated

Substances of very high concern (SVHC): This product does not contain substances of very high concern according to Regulation (EC) No 1907/2006 (REACH), Article 57 above the respective regulatory concentration limit of $\geq 0.1\%$ (w/w).

15.2 Chemical Safety Assessment has been carried out for calcium hydroxide according to regulation (EC) No. 1907/2006(REACH)

GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

Hazard pictograms



GHS05

GHS07

Signal word

Danger

16. Other Information

Full text of H-Statements referred to under sections 2 and 3.

H315 Causes skin irritation

H318 Causes serious eye damage.

H335 Specific target toxicity – single exposure; Category 3

Full text of R-phrases referred to under sections 2 and 3

R 38 Irritating to skin

R41 Risk of serious damage to eyes

Training advice

Provide adequate information, instruction and training for operators.

Labelling (67/548/EEC or 1999/45/EC)

Symbol(s)



Xi Irritant

EC-No. 215-137-3

S-Phrase(s) 26 and 39 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear eye/face protection.