

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

Product name: **CALXYL®**, **CALXYL® Radiopaque** and
CALXYL® Dentin 10

Revision Date: 03.06.2024
Version: 4.0

OCO-Präparate®



Date of issue: 03.06.2024

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

1.1 Product identifier

Product name: **CALXYL®; CALXYL® Radiopaque and
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-praeperate.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-phrases: 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

3.1 Substance: not applicable

3.2 Mixture

SUBSTANCES:

-CALCIUM HYDROXIDE

-Formula: Ca (OH)₂ H₂CaO₂ (Hill)
-Molar Mass: 74,09 g/mol

Component	Classification	Concentration
Calcium hydroxide CAS-No.: 1305-62-0 EC-No.: 215-137-3	Eye Dam. 1 - H318, Skin Irrit. 2; - H315 H335	25-50 %

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

General advice: Show this material safety data sheet to the doctor in attendance.

After eye contact: Rinse opened eye for several minutes under running water.
Immediately call in ophthalmologist. Remove contact lenses.

After swallowing: Immediately make victim drink water (two glasses at most).
Consult a physician

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

After inhalation: Inhale fresh air.

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4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

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

Not required.

6.2 Environmental precautions:

Do not let product enter 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

See Section 7 for information on safe handling

See Section 8 for information on personal protection

See section 13 for disposal information.

7. Handling and storage

7.1 Precautions for safe handling

For precautions see section 2.2.

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. See product label.

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 vapor 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

Safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Hand protection:

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

splash contact: **Glove material: Nitrile 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
Color:	white
Odor:	odorless
Odor 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

No data available

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. Keep the container closed

10.5 Incompatible materials

Light metals

10.6 Hazardous decomposition products

In the event of fire: see section 5

11 Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity

LD50 Oral - Rat - female - > 2,000 mg/kg (OECD Test Guideline 425)

LC50 Inhalation - Rat - male and female - 4 h - > 6.04 mg/l (OECD Test Guideline 436)

LD50 Dermal - Rabbit - male and female - > 2,500 mg/kg (OECD Test Guideline 402)

Acute dermal toxicity: This information is not available.

Skin irritation:

Skin - Rabbit

Result: Irritating to skin; OECD Test Guideline 404

Serious eye / eye irritations

Eyes - Rabbit

Result: Irreversible effects on the eye (OECD Test Guideline 405)

Risk of corneal clouding. Risk of blindness!

Respiratory and skin sensitization

This information is not available

Germ cell mutagenicity

Test Type: In vitro mammalian cell gene mutation test

Test system: mouse lymphoma cells

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 476

Result: negative

Test Type: Ames test

Test system: Escherichia coli/Salmonella typhimurium

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 471

Result: negative

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Test Type: Chromosome aberration test in vitro
Test system: Human lymphocytes
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative
Carcinogenicity: No data available
Reproductive toxicity: No data available
Specific target organ toxicity – single exposure: Inhalation may cause irritation.
Specific target organ toxicity – repeated exposure: No data available.
Aspiration hazard: No data available

11.2 Additional Information

No data available

12. Ecological information

12.1 Toxicity

Toxicity to fish: static test LC50 - *Oncorhynchus mykiss* (rainbow trout) - 50.6 mg/l - 96 h
(OECD Test Guideline 203)

Toxicity to daphnia and other aquatic invertebrates:

static test EC50 - *Daphnia magna* (Water flea) - 49.1 mg/l - 48 h (OECD Test Guideline 202)

Toxicity to algae:

static test ErC50 - *Pseudokirchneriella subcapitata* (green algae) - 184.6 mg/l - 72 h
(OECD Test Guideline 201)

12.2 Persistence and degradability: Biodegradability

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

12.3 Bioaccumulative potential: Does not bioaccumulate.

12.4 Mobility in soil: No data 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

Product

Waste material must be disposed of in accordance with the national and local regulations.
Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself. See www.retrologistik.com for processes regarding the return of chemicals and containers, or contact us there if you have further questions.
Notice Directive on waste 2008/98/EC.

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

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15 Regulatory information

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

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical Safety Assessment

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

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

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.