

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

Revision date: 02-May-2017

Print date: 02-May-2017

Version: 2.0

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Cp-CAP Pulver

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name/designation:

Cp-CAP Pulver

Article No.:

0032304 (15 g)

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

Use of the substance/mixture:

Medical device for dental application.
for professional use only.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

lege artis Pharma GmbH + Co. KG

Breitwasenring 1
72135 Dettenhausen
GERMANY

Telephone: +49 (0) 71 57 / 56 45 - 0

Telefax: +49 (0) 71 57 / 56 45 - 50

E-mail: info@legeartis.de

Website: www.legeartis.de

E-mail (competent person): sicherheitsdatenblaetter@legeartis.de

1.4 Emergency phone number

24h: +49 (0) 551 / 192 40, +49 (0) 71 57 / 56 45 - 0 (Only available during office hours.)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]:

Hazard classes and hazard categories	Hazard statements	Classification procedure
Serious eye damage/eye irritation (<i>Eye Dam. 1</i>)	H318: Causes serious eye damage.	Calculation
Skin corrosion/irritation (<i>Skin Irrit. 2</i>)	H315: Causes skin irritation.	Calculation
Respiratory or skin sensitisation (<i>Skin Sens. 1</i>)	H317: May cause an allergic skin reaction.	Calculation
STOT-single exposure (<i>STOT SE 3</i>)	H335: May cause respiratory irritation.	Calculation
Hazardous to the aquatic environment (<i>Aquatic Chronic 1</i>)	H410: Very toxic to aquatic life with long lasting effects.	Calculation
Respiratory or skin sensitisation (<i>Resp. Sens. 1</i>)	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.	Calculation

Additional information:

Contains: Calcium hydroxide, Zinc oxide, Rosin

Precautionary statements - General:

Avoid release to the environment. Do not breathe dust. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Wear protective gloves/protective clothing/eye protection/face protection.

IF ON SKIN: Wash with plenty of soap and water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical advice/attention. If experiencing respiratory symptoms: Call a doctor.

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2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

According to EC directives or the corresponding national regulations the product does not have to be labelled.

Additional information:

As a medical device this product is not subject to Regulation (EC) no. 1272/2008 [CLP] and do not require labeling according this regulation.

2.3 Other hazards

No data available.

SECTION 3: Composition / information on ingredients

3.2 Mixtures

Ingredients:

Product identifiers	Substance name Classification according to Regulation (EC) No. 1272/2008 [CLP]	Content
CAS No.: 1305-62-0 EC No.: 215-137-3	Calcium dihydroxide Eye Dam. 1, STOT SE 3, Skin Irrit. 2 Danger H315-H318-H335	30 - 40 Wt %
CAS No.: 1314-13-2 EC No.: 215-222-5 REACH No.: 01-2119463881-32	Zinc oxide Aqua. Acute 1, Aqua. Chronic 1 Warning H410	20 - 30 Wt %
CAS No.: 8050-09-7 EC No.: 232-475-7	Rosin Resp. Sens. 1, Skin Sens. 1 Danger H317-H334	5 - 10 Wt %

Full text of H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Take off immediately all contaminated clothing. If unconscious place in recovery position and seek medical advice. Do not leave affected person unattended.

Following inhalation:

Provide fresh air. In case of allergic symptoms, especially in the breathing area, seek medical advice immediately.

In case of skin contact:

Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention.

After eye contact:

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical advice/attention.

After ingestion:

Rinse mouth thoroughly with water. Let water be drunken in little sips (dilution effect). Do NOT induce vomiting. Get immediate medical advice/attention.

4.2 Most important symptoms and effects, both acute and delayed

Causes serious eye damage. Causes skin irritation. May cause respiratory irritation. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Product does not burn. Use extinguishing measures to suit surroundings.

5.2 Special hazards arising from the substance or mixture

No special fire protection measures are necessary.

Hazardous combustion products:

In case of fire may be liberated: CALCIUM OXIDE, gases/vapours, toxic

5.3 Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

Suppress gases/vapours/mists with water spray jet.

5.4 Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Personal precautions:

Avoid dust formation. Avoid breathing dust. Avoid contact with eyes and skin. Remove persons to safety.

Protective equipment:

Wear protective gloves/protective clothing/eye protection/face protection.

6.1.2 For emergency responders

Personal protection equipment:

Personal protection equipment: see section 8

6.2 Environmental precautions

Do not allow to enter into surface water or drains.

6.3 Methods and material for containment and cleaning up

For containment:

Take up mechanically.

For cleaning up:

Water (with cleaning agent)

6.4 Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

6.5 Additional information

Use appropriate container to avoid environmental contamination.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Protective measures

Advices on safe handling:

Avoid dust formation. Avoid breathing dust. Avoid contact with eyes and skin. Take off immediately all contaminated clothing. Wear personal protection equipment (refer to section 8).

Fire prevent measures:

No special measures are necessary.

Environmental precautions:

Discharge into the environment must be avoided.

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Advices on general occupational hygiene

When using do not eat, drink or smoke. Wash hands and face before breaks and after work and take a shower if necessary. Wash contaminated clothing before reuse. Apply skin care products after work.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place.

Recommended storage temperature: 15 - 25°C

Requirements for storage rooms and vessels:

Floors should be impervious, resistant to liquids and easy to clean. Keep/Store only in original container.

Hints on storage assembly:

Do not store together with: Acids

Keep away from food, drink and animal feedingstuffs.

Storage class: 13 - Non-combustible solids that cannot be assigned to any of the above storage classes

7.3 Specific end use(s)

Recommendation:

Medical device for dental application .

SECTION 8: Exposure controls / Personal protection

8.1 Control parameters

8.1.1 Occupational exposure limit values

Limit value type (country)	Substance name	① Long-term occupational exposure limit value ② Short-term occupational exposure limit value ③ Instantaneous value ④ Monitoring and observation processes ⑤ Remark
IOELV (EU)	Calcium dihydroxide CAS No.: 1305-62-0	① 5 mg/m ³
WEL (GB)	Calcium dihydroxide CAS No.: 1305-62-0	① 5 mg/m ³
MEL/OES (GB)	Zinc oxide CAS No.: 1314-13-2	① 5 mg/m ³ ② 10 mg/m ³ ⑤ Smoke
WEL (GB)	Rosin CAS No.: 8050-09-7	① 0.05 mg/m ³ ② 0.15 mg/m ³

8.1.2 Biological limit values

No data available.

8.1.3 DNEL-/PNEC-values

No data available.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment.

8.2.2 Personal protection equipment



Eye/face protection:

Eye glasses with side protection (EN 166).

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Skin protection:

Tested protective gloves must be worn (EN 374).

Suitable material: NBR (Nitrile rubber)

Thickness of the glove material: $\geq 0,11$ mm

Breakthrough time (maximum wearing time): ≥ 480 min

The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. The exact break through time has to be obtained from the protective glove manufacturer and must be observed. Check leak tightness/ impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well.

Respiratory protection:

Usually no personal respirative protection necessary. Provide adequate ventilation.

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

Filtering device (full mask or mouthpiece) with filter: P2/P3

Other protection measures:

Wear suitable protective clothing.

8.2.3 Environmental exposure controls

No data available.

8.3 Additional information

No data available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: solid, Powder

Colour: white

Odour: odourless

Safety relevant basic data

Parameter		at	Method	Remark
pH	12.3	20 °C		(10%)
Melting point	<i>not determined</i>			
Freezing point	<i>not determined</i>			
Initial boiling point and boiling range	<i>not determined</i>			
Decomposition temperature	<i>not determined</i>			
Flash point	<i>not applicable</i>			
Evaporation rate	<i>not determined</i>			
Ignition temperature	<i>not applicable</i>			
Upper/lower flammability or explosive limits	<i>not applicable</i>			
Vapour pressure	<i>not determined</i>			
Vapour density	<i>not determined</i>			
Relative density	<i>not determined</i>			
Bulk density	0.8 g/cm ³	20 °C		
Water solubility	slightly soluble			
Partition coefficient: n-octanol/ water	<i>not determined</i>			
Dynamic viscosity	<i>not determined</i>			
Kinematic viscosity	<i>not determined</i>			

9.2 Other information

No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity

See section 10.3

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10.2 Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

Exothermic reaction with: Acids, Light metals

10.4 Conditions to avoid

Humidity.

10.5 Incompatible materials

Acids, Light metals

10.6 Hazardous decomposition products

In case of fire may be liberated: CALCIUM OXIDE, gases/vapours, toxic

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity:

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

Acute dermal toxicity:

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

Acute inhalation toxicity:

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

Skin corrosion/irritation:

Causes skin irritation.

Eye damage/irritation:

Causes serious eye damage.

Respiratory or skin sensitisation:

May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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:

May cause respiratory irritation.

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.

SECTION 12: Ecological information

12.1 Toxicity

CAS No.	Substance name	Toxicological information
1314-13-2	Zinc oxide	LC₅₀: 1.1 mg/L 4 d (Oncorhynchus mykiss (Rainbow trout)) IC₅₀: 0.17 mg/L 3 d

Aquatic toxicity:

Very toxic to aquatic life with long lasting effects.

12.2 Persistence and degradability

Biodegradation:

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

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12.3 Bioaccumulative potential

Accumulation / Evaluation:

No indication of bioaccumulation potential.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6 Other adverse effects

No data available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Waste treatment options

Appropriate disposal / Product:

Dispose of waste according to applicable legislation. Consult the appropriate local waste disposal expert about waste disposal.

Appropriate disposal / Package:

Completely emptied packages can be recycled.

Other disposal recommendations:

The allocation of waste code numbers / waste names must be carried out in accordance with the European Waste Catalogue (EWC). Collect in closed and suitable containers for disposal.

13.2 Additional information

Waste for disposal is to be classified and labelled.

SECTION 14: Transport information

Land transport (ADR / RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.1 UN-No.			
3077	3077	3077	3077
14.2 UN proper shipping name			
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ZINC OXIDE)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ZINC OXIDE)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ZINC OXIDE)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ZINC OXIDE)
14.3 Transport hazard class(es)			
 9	 9	 8	 8
14.4 Packing group			
III	III	III	III
14.5 Environmental hazards			
		 MARINE POLLUTANT	

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Land transport (ADR / RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO- TI / IATA-DGR)
14.6 Special precautions for user			
Special provisions: 274, 335, 375, 601 Limited Quantity (LQ): 5 kg Hazard identification on number (Kemler No.): 90 Classification code: M7 Tunnel restriction code: E Remark: -	Special provisions: not determined Limited Quantity (LQ): not determined Classification code: M7 Remark: -	Special provisions: not determined Limited Quantity (LQ): not determined EmS-No.: F-A; S-B Remark: -	Special provisions: not determined Limited Quantity (LQ): not determined Remark: -

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

not applicable

Additional information:

Small amounts: Transport as "Limited Quantity" according to chapter 3.4 ADR/RID / Transport as "Excepted Quantity" according to chapter 3.5 ADR/RID.

SECTION 15: Regulatory information

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

15.1.1 EU legislation

Other EU regulations:

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 Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers. Directive 93/42/EEC concerning medical devices.

15.1.2 National regulations

No data available.

15.2 Chemical Safety Assessment

No data available.

15.3 Additional information

No data available.

SECTION 16: Other information

16.1 Indication of changes

Changes with version 2.0:

Section 2: Hazardous ingredients

Section 3: Hazards identification

General revision

16.2 Abbreviations and acronyms

See overview table at www.euphrac.eu

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16.3 Key literature references and sources for data

European Chemicals Agency (ECHA): <http://www.echa.europa.eu>

ECHA, C&L Inventory: <http://echa.europa.eu/information-on-chemicals/cl-inventory-database>

ECHA, Registered substances: <http://echa.europa.eu/information-on-chemicals/registered-substances>

GESTIS (Gefahrstoffinformationssystem der DGUV): <http://www.dguv.de/ifa/GESTIS/index.jsp>

Hörath Gefährliche Stoffe und Gemische, 8. Auflage, Dr. Angela Schulz

Safety data sheets of the manufacturers

16.4 Classification for mixtures and used evaluation method according to regulation (EC) No. 1272/2008 [CLP]

Classification according to Regulation (EC) No. 1272/2008 [CLP]:

Hazard classes and hazard categories	Hazard statements	Classification procedure
Serious eye damage/eye irritation (<i>Eye Dam. 1</i>)	H318: Causes serious eye damage.	Calculation
Skin corrosion/irritation (<i>Skin Irrit. 2</i>)	H315: Causes skin irritation.	Calculation
Respiratory or skin sensitisation (<i>Skin Sens. 1</i>)	H317: May cause an allergic skin reaction.	Calculation
STOT-single exposure (<i>STOT SE 3</i>)	H335: May cause respiratory irritation.	Calculation
Hazardous to the aquatic environment (<i>Aquatic Chronic 1</i>)	H410: Very toxic to aquatic life with long lasting effects.	Calculation
Respiratory or skin sensitisation (<i>Resp. Sens. 1</i>)	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.	Calculation

16.4 Full text of relevant H-codes in Section 3

Hazard statements	
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

16.5 Preparation and revision information

No data available.

16.6 Additional information

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.