



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

- **Product identifier**
- **Trade name:** *ApexCal*
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Calcium hydroxide dressing
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent AG
Bendererstrasse 2
FL-9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN
-
- **Tel:** +423 235 35 35
Fax: +423 235 33 60
- **Further information obtainable from:**
Regulatory Affairs
msds@ivoclarvivadent.com
- **Emergency telephone number:** +423 / 235 33 13

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
 Xi; Irritant
- **R41:** Risk of serious damage to eyes.
- **R52/53:** Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- **Label elements**
- **Labelling according to EU guidelines:**
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.
- **Code letter and hazard designation of product:**
 Xi Irritant
- **Risk phrases:**
41 Risk of serious damage to eyes.
52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- **Safety phrases:**
24 Avoid contact with skin.
26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
39 Wear eye/face protection.
60 This material and its container must be disposed of as hazardous waste.
61 Avoid release to the environment. Refer to special instructions/safety data sheets.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

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· **vPvB:** Not applicable.**3 Composition/information on ingredients**

- **Chemical characterization: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 1305-62-0 EINECS: 215-137-3	calcium dihydroxide	 Xi R41	10-25%
CAS: 56-81-5 EINECS: 200-289-5	glycerol		2.5-10%
CAS: 1314-13-2 EINECS: 215-222-5	zinc oxide	 N R50/53	≤ 2.5%

- **Additional information:** For the wording of the listed risk phrases refer to section 16.

4 First aid measures

- **Description of first aid measures**
- **After inhalation:**
Supply fresh air; consult doctor in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**
Rinse with water.
If skin irritation continues, consult a doctor.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

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7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

1305-62-0 calcium dihydroxide	
WEL ()	Long-term value: 5 mg/m ³
56-81-5 glycerol	
WEL ()	Long-term value: 10 mg/m ³

- **Additional information:** The lists valid during the making were used as basis.

- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Usual hygienic measures for dental practice.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Keep away from foodstuffs, beverages and feed.
- **Respiratory protection:** Not required.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

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· **Eye protection:**

Tightly sealed goggles

9 Physical and chemical properties

· **Information on basic physical and chemical properties**· **General Information**· **Appearance:**

· Form:	Pasty
· Colour:	According to product specification
· Odour:	Characteristic
· Odour threshold:	Not determined.

· **pH-value:** >12.5· **Change in condition**

· Melting point/Melting range:	Undetermined.
· Boiling point/Boiling range:	Undetermined.

· **Flash point:** Not applicable.· **Self-igniting:** Product is not selfigniting.· **Danger of explosion:** Product does not present an explosion hazard.· **Explosion limits:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapour pressure:** Not determined.· **Density:** Not determined.· **Relative density** Not determined.· **Vapour density** Not determined.· **Evaporation rate** Not determined.· **Solubility in / Miscibility with water:**

Soluble.

· **Segregation coefficient (n-octanol/water):** Not determined.· **Viscosity:**

· Dynamic:	Not determined.
· Kinematic:	Not determined.

· **Other information** No further relevant information available.

10 Stability and reactivity

· **Reactivity** No further relevant information available.· **Chemical stability** Stable under normal handling and storage conditions.· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.· **Possibility of hazardous reactions** No dangerous reactions known.· **Conditions to avoid** No further relevant information available.· **Incompatible materials:** No further relevant information available.

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- **Hazardous decomposition products:** None under normal conditions of storage and use.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

- **LD/LC50 values relevant for classification:**

1314-13-2 zinc oxide

Oral	LD50	> 5000 mg/kg (rat)
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- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** Strong irritant with the danger of severe eye injury.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Irritant

12 Ecological information

- **Toxicity**
- **Acquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
Harmful to aquatic organisms
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

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14 Transport information

- **Land transport ADR/RID (cross-border)**
- **ADR/RID class:** -

- **Maritime transport IMDG:**
- **IMDG Class:** -
- **Marine pollutant:** No

- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -

- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to the EC-directive 93/42/EEC.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Relevant phrases

R41 Risk of serious damage to eyes.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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