

**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 04/28/2015

Version number 5

Reviewed on 04/01/2015


**1 Identification**

- **Product identifier**
- **Trade name:** *ApexCal*
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Calcium hydroxide dressing
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent Inc.  
175 Pineview Drive, Amherst, N.Y. 14228  
USA  
Tel. +1 800 533 6825  
Fax +1 716 691 2285
  
- Ivoclar Vivadent Inc.  
1-6600 Dixie Road  
Mississauga, Ontario  
L5T 2Y2  
Canada  
Phone: +1 905 670 8499  
Fax: +1 905 670 3102
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**  
24 Hour Emergency Assistance:  
Emergency-Call USA - Infotrac: 1-800-535-5053  
Emergency-Call Canada - Canutec: 1-613-996-6666
  
- General SDS Assistance:  
US: 1-800-533-6825  
Canada: 1-800-263-8182


**2 Hazard(s) identification**

- **Classification of the substance or mixture**  
Skin Corr. 1A H314 Causes severe skin burns and eye damage.  
Eye Dam. 1 H318 Causes serious eye damage.  
STOT SE 3 H335 May cause respiratory irritation.

---

  - **Label elements**
  - **GHS label elements**  
The product is classified and labeled according to the Globally Harmonized System (GHS).
  - **Hazard pictograms**
- 

GHS05



GHS07
- **Signal word** *Danger*
  - **Hazard-determining components of labeling:**  
calcium dihydroxide
  - **Hazard statements**  
Causes severe skin burns and eye damage.

(Contd. on page 2)

# Safety Data Sheet

## acc. to OSHA HCS

Printing date 04/28/2015

Version number 5

Reviewed on 04/01/2015

Trade name: **ApexCal**

(Contd. of page 1)

May cause respiratory irritation.

· **Precautionary statements**

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

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If swallowed: Rinse mouth. Do NOT induce vomiting.

· **Additional information:**

Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMIS-ratings (scale 0 - 4)**



· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

### 3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

25322-68-3	Polyethylene glycol	25-50%
1305-62-0	calcium dihydroxide	20-<25%
56-81-5	glycerol	2.5-<10%
1314-13-2	zinc oxide	1-<2.5%

### 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.

(Contd. on page 3)

US

## Safety Data Sheet acc. to OSHA HCS

Printing date 04/28/2015

Version number 5

Reviewed on 04/01/2015

Trade name: **ApexCal**

(Contd. of page 2)

- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, extinguishing 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.

### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling**  
Only adequately trained personnel should handle this product.  
For use in dentistry only.
- **Information about protection against explosions and fires:** 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 systems:** No further data; see item 7.
- **Control parameters**

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

#### 25322-68-3 Polyethylene glycol

WEEL	Long-term value: 10 mg/m <sup>3</sup> (H); MW>200
------	--

#### 1305-62-0 calcium dihydroxide

PEL	Long-term value: 15* 5** mg/m <sup>3</sup> *total dust **respirable fraction
-----	---

REL	Long-term value: 5 mg/m <sup>3</sup>
-----	--------------------------------------

TLV	Long-term value: 5 mg/m <sup>3</sup>
-----	--------------------------------------

(Contd. on page 4)

## Safety Data Sheet acc. to OSHA HCS

Printing date 04/28/2015

Version number 5

Reviewed on 04/01/2015

Trade name: **ApexCal**

(Contd. of page 3)

**56-81-5 glycerol**

PEL	Long-term value: 15* 5** mg/m <sup>3</sup> mist; *total dust **respirable fraction
TLV	TLV withdrawn-insufficient data human occup. exp.

· **Additional information:** The lists that were valid during the creation 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.

· **Breathing equipment:** 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.

· **Eye protection:**



Tightly sealed goggles

### 9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

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

· **pH-value:** >12.5

· **Change in condition**

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

(Contd. on page 5)

## Safety Data Sheet

acc. to OSHA HCS

Printing date 04/28/2015

Version number 5

Reviewed on 04/01/2015

Trade name: **ApexCal**

(Contd. of page 4)

· <b>Flash point:</b>	Not applicable.
· <b>Auto igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapor pressure:</b>	Not determined.
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with Water:</b>	Soluble.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
· <b>Other information</b>	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.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

### 11 Toxicological information

#### · Information on toxicological effects

#### · Acute toxicity:

#### · LD/LC50 values that are relevant for classification:

1314-13-2 zinc oxide

Oral LD50 &gt; 5000 mg/kg (rat)

#### · 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:** No further relevant information available.

#### · Carcinogenic categories

#### · NTP (National Toxicology Program)

None of the ingredients is listed.

(Contd. on page 6)

## Safety Data Sheet

acc. to OSHA HCS

Printing date 04/28/2015

Version number 5

Reviewed on 04/01/2015

Trade name: **ApexCal**

(Contd. of page 5)

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior 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 (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 packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |   |                 |
|---|-----------------|
| · <b>UN-Number</b><br>· DOT, ADR, ADN, IMDG, IATA                             | Void            |
| · <b>UN proper shipping name</b><br>· DOT, ADR, ADN, IMDG, IATA               | Void            |
| · <b>Transport hazard class(es)</b><br>· DOT, ADR, ADN, IMDG, IATA<br>· Class | Void            |
| · <b>Packing group</b><br>· DOT, ADR, IMDG, IATA                              | Void            |
| · <b>Environmental hazards:</b><br>· <b>Marine pollutant:</b>                 | No              |
| · <b>Special precautions for user</b>   | Not applicable. |

(Contd. on page 7)

US

## Safety Data Sheet

acc. to OSHA HCS

Printing date 04/28/2015

Version number 5

Reviewed on 04/01/2015

Trade name: **ApexCal**

(Contd. of page 6)

- |  |  |
|--|--|
| <b>· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable.  |
| <b>· Transport/Additional information:</b>                                       | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| <b>· UN "Model Regulation":</b>  | -  |

### 15 Regulatory information

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

- Sara

- Section 355 (extremely hazardous substances):

None of the ingredients is listed.

- Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

- TSCA (Toxic Substances Control Act):

All ingredients are listed.

- Proposition 65

- Chemicals known to cause cancer:

None of the ingredients is listed.

- Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

- Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

- Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

- Carcinogenic categories

- EPA (Environmental Protection Agency)

1314-13-2 zinc oxide

II

- TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

- NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

- GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

- Hazard pictograms



GHS05 GHS07

- Signal word Danger

- Hazard-determining components of labeling:

calcium dihydroxide

(Contd. on page 8)

## Safety Data Sheet acc. to OSHA HCS

Printing date 04/28/2015

Version number 5

Reviewed on 04/01/2015

**Trade name: ApexCal**

(Contd. of page 7)

- **Hazard statements**

*Causes severe skin burns and eye damage.*

*May cause respiratory irritation.*

- **Precautionary statements**

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

*If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.*

*If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.*

*Continue rinsing.*

*If swallowed: Rinse mouth. Do NOT induce vomiting.*

- **National regulations:**

- **Other regulations, limitations and prohibitive regulations**

*The product is a medical device according to the Directive 93/42/EEC.*

*This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.*

- **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.*

- **Date of preparation / last revision** 04/28/2015 / 4

- **Abbreviations and acronyms:**

*ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)*

*IMDG: International Maritime Code for Dangerous Goods*

*DOT: US Department of Transportation*

*IATA: International Air Transport Association*

*ACGIH: American Conference of Governmental Industrial Hygienists*

*EINECS: European Inventory of Existing Commercial Chemical Substances*

*ELINCS: European List of Notified Chemical Substances*

*CAS: Chemical Abstracts Service (division of the American Chemical Society)*

*NFPA: National Fire Protection Association (USA)*

*HMIS: Hazardous Materials Identification System (USA)*

*LC50: Lethal concentration, 50 percent*

*LD50: Lethal dose, 50 percent*

*Skin Corr. 1A: Skin corrosion/irritation, Hazard Category 1A*

*Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1*

*STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3*

- **\* Data compared to the previous version altered.**

US