

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

071718741

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

071718659 071718691 071718907 071718915 071718923

**Material Safety Data Sheet**

May be used to comply with  
OSHA's Hazard Communication Standard,  
29 CFR 1910.1200. Standard must be  
consulted for specific requirements.

**U.S. Department of Labor**

Occupational Safety and Health Administration  
(Non-Mandatory Form)  
Form Approved  
OMB No. 1218-0072



IDENTITY (As Used on Label and List)

Dyca Base

Note: Blank spaces are not permitted. If any item is not applicable, or no information is available, the space must be marked to indicate that.

**Section I**

|  |  |
|--|--|
| Manufacturer's Name<br>Caulk/Dentsply  | Emergency Telephone Number<br>(202) 422-4511       |
| Address (Number, Street, City, State, and ZIP Code)<br>Lakewood & Clarke Avenues<br>Milford, DE 19963-0359 | Telephone Number for Information<br>(202) 422-4511 |
|  | Date Prepared<br>1/13/07                           |
|  | Signature of Preparer (optional)                   |

**Section II — Hazardous Ingredients/Identity Information**

| Hazardous Components (Specific Chemical Identity; Common Name(s)) | OSHA PEL | ACGIH TLV               | Other Limits Recommended | % (optional) |
|---|----------|-------------------------|--------------------------|--------------|
| Zinc Oxide  |          | 5 mg/m <sup>3</sup> TWA |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |
|   |          |                         |                          |              |

**Section III — Physical/Chemical Characteristics**

|  |   |
|--|---|
| Boiling Point<br>N.A.  | Specific Gravity (H <sub>2</sub> O = 1)<br>1.98 |
| Vapor Pressure (mm Hg.)<br>N.A.  | Melting Point<br>N.E.                           |
| Vapor Density (AIR = 1)<br>N.A.  | Evaporation Rate<br>(Butyl Acetate = 1)<br>N.A. |
| Solubility in Water<br>Not soluble                                       |   |
| Appearance and Odor<br>Tan paste with characteristic odor of wintergreen |   |

**Section IV — Fire and Explosion Hazard Data**

|  |                          |             |             |
|--|--------------------------|-------------|-------------|
| Flash Point (Method Used)<br>N.A.            | Flammable Limits<br>N.A. | LEL<br>N.A. | UEL<br>N.A. |
| Extinguishing Media<br>Carbon dioxide, Halon |                          |             |             |
| Special Fire Fighting Procedures<br>None     |                          |             |             |
| Unusual Fire and Explosion Hazards<br>None   |                          |             |             |

(Reproduce locally)

OSHA 174, Sept. 1985

N.A. Data does not apply to this product.

N.E. Value has not been established for this product.

**Section V — Reactivity Data**

|           |          |   |                     |
|-----------|----------|---|---------------------|
| Stability | Unstable |   | Conditions to Avoid |
|           | Stable   | X | None                |

Incompatibility (Materials to Avoid)

None

Hazardous Decomposition or Byproducts

None

|                          |                |   |                     |
|--------------------------|----------------|---|---------------------|
| Hazardous Polymerization | May Occur      |   | Conditions to Avoid |
|                          | Will Not Occur | X | None                |

**Section VI — Health Hazard Data**

|                    |             |       |            |
|--------------------|-------------|-------|------------|
| Route(s) of Entry: | Inhalation? | Skin? | Ingestion? |
|                    | No          | Yes   | Possibly   |

Health Hazards (Acute and Chronic)

May cause minor skin irritation (redness). Avoid prolonged or repeated skin contact.

|                  |      |                  |                 |
|------------------|------|------------------|-----------------|
| Carcinogenicity: | NTP? | IARC Monographs? | OSHA Regulated? |
|                  | No   | No               | No              |

Signs and Symptoms of Exposure

Minor skin irritation (redness)

Medical Conditions

Generally Aggravated by Exposure

Skin irritation and redness

Emergency and First Aid Procedures

Wash thoroughly with soap and water if prolonged contact is made.

If irritation persists please consult a physician.

**Section VII — Precautions for Safe Handling and Use**

Steps to Be Taken in Case Material Is Released or Spilled

Wipe up with clean cloth or paper towel. Scrub area with alcohol.

Waste Disposal Method

Approved landfill

Precautions to Be Taken in Handling and Storing

Store at room temperature. Avoid storage above 50°C (122°F)

Other Precautions

None

**Section VIII — Control Measures**

Respiratory Protection (Specify Type)

Local exhaust

|               |                      |         |
|---------------|----------------------|---------|
| Local exhaust | Local Exhaust        | Special |
|               | Yes                  | N.A.    |
|               | Mechanical (General) | Other   |
|               | N.A.                 | N.A.    |

Protective Gloves

Rubber gloves

Eye Protection

Safety Shield

Other Protective Clothing or Equipment

Rubber apron

Work Hygienic Practices

Wash hands with soap and water. Avoid excessive contact with skin.

N.A. Data does not apply to this product.

N.E. Value has not been established for this product.

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 23.10.2017

Version number 6

Revision: 23.10.2017

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

- **1.1 Product identifier**
- **Trade name: Dycal Base**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** Material for pulp capping
- **Uses advised against** No further relevant information available.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Dentsply DeTrey GmbH  
De-Trey-Str. 1  
D-78467 Konstanz  
GERMANY  
Tel.: +49-(0)7531-583-0  
Fax: +49-(0)7531-583-104  
email: KonstanzDEU.info-sdb@dentsplysirona.com
- **Further information obtainable from:**
  - Departement Research & Development for technical information
  - Departement Marketing & Sales for distribution of the safety data sheets
- **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

### **SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
- Skin Irrit. 2      H315 Causes skin irritation.
- Eye Irrit. 2      H319 Causes serious eye irritation.
- Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07    GHS09

- **Signal word** Warning
- **Hazard statements**  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H411 Toxic to aquatic life with long lasting effects.
- **Precautionary statements**  
P273                      Avoid release to the environment.  
P280                      Wear protective gloves / eye protection / face protection.  
P305+P351+P338 **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P332+P313              If skin irritation occurs: Get medical advice/attention.  
P337+P313              If eye irritation persists: Get medical advice/attention.  
P501                      Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Additional information:**  
As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation 1272/2008.

(Contd. on page 2)

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 23.10.2017

Version number 6

Revision: 23.10.2017

**Trade name: Dycal Base**

(Contd. of page 1)

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

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

- **Dangerous components:**

|                                     |  |          |
|-------------------------------------|--|----------|
| CAS: 73240-13-8                     | 1,3- Butylenglykoldisalicylat<br>⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319 | 25-50%   |
| CAS: 1314-13-2<br>EINECS: 215-222-5 | zinc oxide<br>⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410             | 2.5-<10% |

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

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **After inhalation** Supply fresh air; consult doctor in case of complaints.
- **After skin contact** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact**  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Information for doctor** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents** Water with full jet.
- **5.2 Special hazards arising from the substance or mixture**  
Formation of toxic gases is possible during heating or in case of fire.
- **5.3 Advice for firefighters**
- **Protective equipment:** Self-contained respiratory protective device.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
- **6.2 Environmental precautions:**  
Do not allow product to reach sewage system or any water course.  
Inform respective authorities in case of seepage into water course or sewage system.
- **6.3 Methods and material for containment and cleaning up:**  
Pick up mechanically.  
Ensure adequate ventilation.  
Dispose contaminated material as waste according to item 13.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling  
See Section 8 for information on personal protection equipment.

(Contd. on page 3)

-GB

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 23.10.2017

Version number 6

Revision: 23.10.2017

**Trade name: Dycal Base**

(Contd. of page 2)

See Section 13 for disposal information.

### **SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling**  
Observe normal care for working with chemicals.  
Ensure good ventilation/exhaustion at the workplace.
- **Handling** Product is intended for dental use only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

### **SECTION 8: Exposure controls/personal protection**

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures**  
Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.
- **Respiratory protection:** Not necessary if room is well-ventilated.
- **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.

(Contd. on page 4)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 23.10.2017

Version number 6

Revision: 23.10.2017

Trade name: Dycal Base

(Contd. of page 3)

· **Eye protection:**

Tightly sealed goggles.

· **Body protection:** Protective work clothing.

### SECTION 9: Physical and chemical properties

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

|                           |                 |
|---------------------------|-----------------|
| · <b>Form:</b>            | Pasty           |
| · <b>Colour:</b>          | Dark            |
| · <b>Odour:</b>           | Characteristic  |
| · <b>Odour threshold:</b> | Not determined. |

· **pH-value:** Not determined.· **Change in condition**

|   |               |
|---|---------------|
| · <b>Melting point/freezing point:</b>            | undetermined  |
| · <b>Initial boiling point and boiling range:</b> | Undetermined. |

· **Flash point:** Not applicable· **Flammability (solid, gaseous)** Not applicable.· **Ignition temperature:** Not applicable· **Decomposition temperature:** Not determined.· **Auto-ignition temperature:** Product is not selfigniting.· **Explosive properties:** Product does not present an explosion hazard.· **Explosion limits:**

|                 |                 |
|-----------------|-----------------|
| · <b>Lower:</b> | Not determined. |
| · <b>Upper:</b> | Not determined. |

· **Vapour pressure:** Not determined.· **Density at 20 °C:** 1.98 g/cm<sup>3</sup>· **Relative density** Not determined.· **Vapour density** Not determined.· **Evaporation rate** Not determined.· **Solubility in / Miscibility with**· **Water:** Not miscible or difficult to mix· **Partition coefficient: n-octanol/water:** Not determined.· **Viscosity:**

|                     |                 |
|---------------------|-----------------|
| · <b>dynamic:</b>   | Not determined. |
| · <b>kinematic:</b> | Not determined. |

· **Solvent content:**· **Organic solvents:** 0.0 %· **Solids content:** 60.0 %· **9.2 Other information** No further relevant information available.

GB

(Contd. on page 5)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 23.10.2017

Version number 6

Revision: 23.10.2017

Trade name: Dycal Base

(Contd. of page 4)

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

|  |                         |
|--|-------------------------|
| · <b>LD/LC50 values relevant for classification:</b> |                         |
| <b>ATE (Acute Toxicity Estimate)</b>                 |                         |
| Oral   | LD50 >6,452 mg/kg (rat) |

|                                  |                         |
|----------------------------------|-------------------------|
| <b>CAS: 1314-13-2 zinc oxide</b> |                         |
| Oral                             | LD50 >5,000 mg/kg (rat) |

- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Causes skin irritation.
- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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** Based on available data, the classification criteria are not met.
- **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**

|                                  |                                      |
|----------------------------------|--------------------------------------|
| · <b>Aquatic toxicity:</b>       |                                      |
| <b>CAS: 1314-13-2 zinc oxide</b> |                                      |
| LC50/96h                         | 1.1 mg/l (Fish acute toxicity study) |
| EC50/48h                         | 0.098 mg/L (daphnia magna)           |

- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Toxic for fish
- **Additional ecological information:**
- **General notes:**

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

Also poisonous for fish and plankton in water bodies.

Toxic for aquatic organisms

- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

(Contd. on page 6)



**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 23.10.2017

Version number 6

Revision: 23.10.2017

**Trade name: Dycal Base**

(Contd. of page 5)

- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**



Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- **European waste catalogue**

|           |  |
|-----------|--|
| 18 01 06* | chemicals consisting of or containing hazardous substances |
| HP 4      | Irritant - skin irritation and eye damage                  |
| HP 14     | Ecotoxic   |

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, IMDG, IATA** UN3082

- **14.2 UN proper shipping name**
- **ADR** 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (zinc oxide)
- **IMDG** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (zinc oxide), MARINE POLLUTANT
- **IATA** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (zinc oxide)

- **14.3 Transport hazard class(es)**

- **ADR**



- **Class** 9 (M6) Miscellaneous dangerous substances and articles.
- **Label** 9

- **IMDG, IATA**



- **Class** 9 Miscellaneous dangerous substances and articles.
- **Label** 9

- **14.4 Packing group**
- **ADR, IMDG, IATA** III

- **14.5 Environmental hazards:** Product contains environmentally hazardous substances: zinc oxide
- **Marine pollutant:** Symbol (fish and tree)

(Contd. on page 7)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 23.10.2017

Version number 6

Revision: 23.10.2017

**Trade name: Dycal Base**

(Contd. of page 6)

|  |   |
|--|---|
| · <b>Special marking (ADR):</b>  | Symbol (fish and tree)  |
| · <b>Special marking (IATA):</b>   | Symbol (fish and tree)  |
| · <b>14.6 Special precautions for user</b>                                       | Warning: Miscellaneous dangerous substances and articles.   |
| · <b>Danger code (Kemler):</b>   | 90  |
| · <b>EMS Number:</b>   | F-A,S-F   |
| · <b>Stowage Category</b>  | A   |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable.   |
| · <b>Transport/Additional information:</b>                                       |   |
| · <b>ADR</b>   |   |
| · <b>Limited quantities (LQ)</b>   | 5L  |
| · <b>Excepted quantities (EQ)</b>  | Code: E1<br>Maximum net quantity per inner packaging: 30 ml<br>Maximum net quantity per outer packaging: 1000 ml  |
| · <b>Transport category</b>  | 3   |
| · <b>Remarks:</b>  | Exemption according to ADR special provision 375:<br>This substance is not subject to the other provisions of the ADR if packed in net quantities of 5L or 5kg per individual or inner packaging, provided that sub-sections 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8 are complied with. |
| · <b>IMDG</b>  |   |
| · <b>Limited quantities (LQ)</b>   | 5L  |
| · <b>Excepted quantities (EQ)</b>  | Code: E1<br>Maximum net quantity per inner packaging: 30 ml<br>Maximum net quantity per outer packaging: 1000 ml  |
| · <b>UN "Model Regulation":</b>  | UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (ZINC OXIDE), 9, III  |

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- Directive 2012/18/EU
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category E2** Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 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.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

- **Relevant phrases**
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.

(Contd. on page 8)

GB

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 23.10.2017

Version number 6

Revision: 23.10.2017

**Trade name: Dycal Base**

(Contd. of page 7)

*H400 Very toxic to aquatic life.*

*H410 Very toxic to aquatic life with long lasting effects.*

- **Department issuing SDS:** Research & Development
- **Contact:** HotLine for urgent technical support: +49-7531-583-350
- **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*  
*IATA: International Air Transport Association*  
*GHS: Globally Harmonised System of Classification and Labelling of Chemicals*  
*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)*  
*LC50: Lethal concentration, 50 percent*  
*LD50: Lethal dose, 50 percent*  
*PBT: Persistent, Bioaccumulative and Toxic*  
*vPvB: very Persistent and very Bioaccumulative*  
*Skin Irrit. 2: Skin corrosion/irritation – Category 2*  
*Eye Irrit. 2: Serious eye damage/eye irritation – Category 2*  
*Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1*  
*Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1*  
*Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2*
- **\* Data compared to the previous version altered.**

GB

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 20.10.2017

Version number 7

Revision: 20.10.2017

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

- **1.1 Product identifier**
- **Trade name: Dycal Catalyst**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** Material for pulp capping
- **Uses advised against** No further relevant information available.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Dentsply DeTrey GmbH  
De-Trey-Str. 1  
D-78467 Konstanz  
GERMANY  
Tel.: +49-(0)7531-583-0  
Fax: +49-(0)7531-583-104  
email: KonstanzDEU.info-sdb@dentsplysirona.com
- **Further information obtainable from:**
  - Departement Research & Development for technical information
  - Departement Marketing & Sales for distribution of the safety data sheets
- **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
- Skin Irrit. 2 H315 Causes skin irritation.
- Eye Dam. 1 H318 Causes serious eye damage.
- STOT SE 3 H335 May cause respiratory irritation.
- Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS05 GHS07 GHS09

- **Signal word** Danger
- **Hazard-determining components of labelling:**  
calcium dihydroxide
- **Hazard statements**  
H315 Causes skin irritation.  
H318 Causes serious eye damage.  
H335 May cause respiratory irritation.  
H411 Toxic to aquatic life with long lasting effects.
- **Precautionary statements**  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P280 Wear protective gloves / eye protection / face protection.  
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P310 Immediately call a POISON CENTER/doctor.  
P405 Store locked up.  
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

(Contd. on page 2)

GB

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 20.10.2017

Version number 7

Revision: 20.10.2017

**Trade name: Dycal Catalyst**

(Contd. of page 1)

**Additional information:**

As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation 1272/2008.

**2.3 Other hazards****Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

**SECTION 3: Composition/information on ingredients****3.2 Chemical characterisation: Mixtures**

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

**Dangerous components:**

|                   |  |          |
|-------------------|--|----------|
| CAS: 1305-62-0    | calcium dihydroxide  | 50-100%  |
| EINECS: 215-137-3 | ☠ Eye Dam. 1, H318; ☠ Skin Irrit. 2, H315; STOT SE 3, H335 |          |
| CAS: 1314-13-2    | zinc oxide   | 2.5-<10% |
| EINECS: 215-222-5 | ☠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410           |          |

· **Additional information** For the wording of the listed hazard phrases refer to section 16.

**SECTION 4: First aid measures****4.1 Description of first aid measures**

· **General information** Immediately remove any clothing soiled by the product.

· **After inhalation** Supply fresh air; consult doctor in case of complaints.

**After skin contact**

Immediately wash with water and soap and rinse thoroughly.

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**

Call a doctor immediately.

Rinse out mouth and then drink plenty of water.

· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **Information for doctor** No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

**SECTION 5: Firefighting measures****5.1 Extinguishing media****Suitable extinguishing agents**

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· **For safety reasons unsuitable extinguishing agents** Water with full jet.

· **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

**5.3 Advice for firefighters**

· **Protective equipment:** Self-contained respiratory protective device.

**SECTION 6: Accidental release measures**

· **6.1 Personal precautions, protective equipment and emergency procedures** Wear protective clothing.

· **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

**6.3 Methods and material for containment and cleaning up:**

Pick up mechanically.

Dispose contaminated material as waste according to item 13.

(Contd. on page 3)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 20.10.2017

Version number 7

Revision: 20.10.2017

**Trade name: Dycal Catalyst**

(Contd. of page 2)

*Ensure adequate ventilation.***· 6.4 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.***SECTION 7: Handling and storage****· 7.1 Precautions for safe handling***Ensure good ventilation/exhaustion at the workplace.**Observe normal care for working with chemicals.***· Handling** *Product is intended for dental use only.***· Information about fire - and explosion protection:** *No special measures required.***· 7.2 Conditions for safe storage, including any incompatibilities****· Storage****· Requirements to be met by storerooms and receptacles:** *Store only in the original receptacle.***· Information about storage in one common storage facility:** *Not required.***· Further information about storage conditions:** *Keep receptacle tightly sealed.***· 7.3 Specific end use(s)** *No further relevant information available.***SECTION 8: Exposure controls/personal protection****· Additional information about design of technical facilities:** *No further data; see item 7.***· 8.1 Control parameters****· Ingredients with limit values that require monitoring at the workplace:***The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.***· Additional information:** *The lists valid during the making were used as basis.***· 8.2 Exposure controls****· Personal protective equipment****· General protective and hygienic measures***Immediately remove all soiled and contaminated clothing**Wash hands before breaks and at the end of work.**Avoid contact with the eyes and skin.***· Respiratory protection:** *Not necessary if room is well-ventilated.***· 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.*

(Contd. on page 4)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 20.10.2017

Version number 7

Revision: 20.10.2017

Trade name: Dycal Catalyst

(Contd. of page 3)

· **Eye protection:**

Tightly sealed goggles.

· **Body protection:** Protective work clothing.

**SECTION 9: Physical and chemical properties**

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

|                           |                  |
|---------------------------|------------------|
| · <b>Form:</b>            | Pasty            |
| · <b>Colour:</b>          | White            |
| · <b>Odour:</b>           | Product specific |
| · <b>Odour threshold:</b> | Not determined.  |

· **pH-value at 20 °C:** 11.5· **Change in condition**

· **Melting point/freezing point:** undetermined  
 · **Initial boiling point and boiling range:** Undetermined.

· **Flash point:** Not applicable· **Flammability (solid, gaseous)** Not applicable.· **Ignition temperature:** Not applicable· **Decomposition temperature:** Not determined.· **Auto-ignition temperature:** Product is not selfigniting.· **Explosive properties:** Product does not present an explosion hazard.· **Explosion limits:**

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

· **Vapour pressure:** Not determined.· **Density at 20 °C:** 1.82 g/cm<sup>3</sup>· **Relative density** Not determined.· **Vapour density** Not determined.· **Evaporation rate** Not determined.· **Solubility in / Miscibility with**· **Water:** Not miscible or difficult to mix· **Partition coefficient: n-octanol/water:** Not determined.· **Viscosity:**

· **dynamic:** Not determined.  
 · **kinematic:** Not determined.

· **Solvent content:**· **Organic solvents:** 0.0 %· **Solids content:** 65.0 %· **9.2 Other information** No further relevant information available.

GB

(Contd. on page 5)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 20.10.2017

Version number 7

Revision: 20.10.2017

Trade name: Dycal Catalyst

(Contd. of page 4)

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

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

**ATE (Acute Toxicity Estimate)**

|      |      |                    |
|------|------|--------------------|
| Oral | LD50 | >3,922 mg/kg (rat) |
|------|------|--------------------|

**CAS: 1305-62-0 calcium dihydroxide**

|      |      |                    |
|------|------|--------------------|
| Oral | LD50 | >2,000 mg/kg (rat) |
|------|------|--------------------|

**CAS: 1314-13-2 zinc oxide**

|      |      |                    |
|------|------|--------------------|
| Oral | LD50 | >5,000 mg/kg (rat) |
|------|------|--------------------|

- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Causes skin irritation.
- **Serious eye damage/irritation**  
Causes serious eye damage.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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**

· **Aquatic toxicity:**

**CAS: 1305-62-0 calcium dihydroxide**

|          |                                      |
|----------|--------------------------------------|
| LC50/96h | 160 mg/l (Fish acute toxicity study) |
|----------|--------------------------------------|

**CAS: 1314-13-2 zinc oxide**

|          |                                      |
|----------|--------------------------------------|
| LC50/96h | 1.1 mg/l (Fish acute toxicity study) |
| EC50/48h | 0.098 mg/L (daphnia magna)           |

- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Toxic for fish

(Contd. on page 6)



**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 20.10.2017

Version number 7

Revision: 20.10.2017

**Trade name: Dycal Catalyst**

(Contd. of page 5)

- **Additional ecological information:**
- **General notes:**  
Do not allow product to reach ground water, water course or sewage system.  
Also poisonous for fish and plankton in water bodies.  
Toxic for aquatic organisms
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**



Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- **European waste catalogue**

|           |  |
|-----------|--|
| 18 01 06* | chemicals consisting of or containing hazardous substances |
| HP 4      | Irritant - skin irritation and eye damage                  |
| HP 5      | Specific Target Organ Toxicity (STOT)/Aspiration Toxicity  |
| HP 14     | Ecotoxic   |

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, IMDG, IATA** UN3077

- **14.2 UN proper shipping name**
- **ADR** 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)
- **IMDG** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), MARINE POLLUTANT
- **IATA** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)

- **14.3 Transport hazard class(es)**

- **ADR**



- **Class** 9 (M7) Miscellaneous dangerous substances and articles.
- **Label** 9

(Contd. on page 7)

GB

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 20.10.2017

Version number 7

Revision: 20.10.2017

**Trade name: Dycal Catalyst**

(Contd. of page 6)

· **IMDG, IATA**

· **Class** 9 Miscellaneous dangerous substances and articles.  
 · **Label** 9

· **14.4 Packing group**  
 · **ADR, IMDG, IATA** III

· **14.5 Environmental hazards:** Product contains environmentally hazardous substances: zinc oxide  
 · **Marine pollutant:** Symbol (fish and tree)  
 · **Special marking (ADR):** Symbol (fish and tree)  
 · **Special marking (IATA):** Symbol (fish and tree)

· **14.6 Special precautions for user** Warning: Miscellaneous dangerous substances and articles.  
 · **Danger code (Kemler):** 90  
 · **EMS Number:** F-A,S-F  
 · **Stowage Category** A  
 · **Stowage Code** SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.

· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.

· **Transport/Additional information:**

· **ADR**  
 · **Limited quantities (LQ)** 5 kg  
 · **Excepted quantities (EQ)** Code: E1  
 Maximum net quantity per inner packaging: 30 ml  
 Maximum net quantity per outer packaging: 1000 ml  
 · **Transport category** 3  
 · **Remarks:** Exemption according to ADR special provision 375:  
 This substance is not subject to the other provisions of the ADR if packed in net quantities of 5L or 5kg per individual or inner packaging, provided that sub-sections 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8 are complied with.

· **IMDG**  
 · **Limited quantities (LQ)** 5 kg  
 · **Excepted quantities (EQ)** Code: E1  
 Maximum net quantity per inner packaging: 30 ml  
 Maximum net quantity per outer packaging: 1000 ml

· **UN "Model Regulation":** UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ZINC OXIDE), 9, III

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category E2** Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t

(Contd. on page 8)

GB

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 20.10.2017

Version number 7

Revision: 20.10.2017

**Trade name: Dycal Catalyst**

(Contd. of page 7)

- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### **SECTION 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.*

*The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.*

*For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.*

- **Relevant phrases**

*H315 Causes skin irritation.*

*H318 Causes serious eye damage.*

*H335 May cause respiratory irritation.*

*H400 Very toxic to aquatic life.*

*H410 Very toxic to aquatic life with long lasting effects.*

- **Department issuing SDS:** Research & Development

- **Contact:** HotLine for urgent technical support: +49-7531-583-350

- **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*

*IATA: International Air Transport Association*

*GHS: Globally Harmonised System of Classification and Labelling of Chemicals*

*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)*

*LC50: Lethal concentration, 50 percent*

*LD50: Lethal dose, 50 percent*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*

*Skin Irrit. 2: Skin corrosion/irritation – Category 2*

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

*STOT SE 3: Specific target organ toxicity (single exposure) – Category 3*

*Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1*

*Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1*

*Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2*

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

GB