

SAFETY DATA SHEETS

This SDS packet was issued with item:

071718733

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071718659 071718691 071718907 071718915 071718923

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).

071718741

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

Ventilation	Local Exhaust	Special
	Yes	N.A.
Local exhaust	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.

Obtained by Global Safety Management, www.globalsafety.net, (877) 683-7460

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

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



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.

Manufacturer's Name Caulk/Dentsply	Emergency Telephone Number (302) 422-4511
Address (Number, Street, City, State, and ZIP Code) Lakeview & Clarke Avenues	Telephone Number for Information (302) 422-4511
Milford, DE 19963-0359	Date Prepared 1/13/87
	Signature of Preparer (optional)

[illegible]

Boiling Point	N.A.	Specific Gravity ($H_2O = 1$)	1.82
Vapor Pressure (mm Hg.)	N.A.	Melting Point	N.E.
Vapor Density (AIR = 1)	N.A.	Evaporation Rate (Butyl Acetate = 1)	N.A.
Solubility in Water Slightly			
Appearance and Odor White, creamy paste with slight odor			

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

OSHA 174, Sept. 1985

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)

Avoid contact of catalyst paste with strong acids.

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? No	Skin? Yes	Ingestion? Possibly
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Health Hazards (Acute and Chronic)

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

Carcinogenicity:	NTP? No	IARC Monographs? No	OSHA Regulated? No
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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 before material hardens. Scrub area with alcohol.

Waste Disposal Method

Approved landfill

Precautions to Be Taken in Handling and Storing

Store at room temperature. Avoid storage below 20°C (68°F) or above 50°C (122°F)

Other Precautions

None

Section VIII — Control Measures

Respiratory Protection (Specify Type)

Local exhaust

Ventilation	Local Exhaust	Yes	Special	N.A.
	Local exhaust	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.

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Trade name: Dycal Base

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- **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- Butylenglykoldisaliclat ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	25-50%
CAS: 1314-13-2 EINECS: 215-222-5	zinc oxide ⚠ 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**
CO₂, 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.

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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.

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· **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:**

Form:	Pasty
Colour:	Dark
Odour:	Characteristic
Odour threshold:	Not determined.

· **pH-value:** Not determined.· **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:** 1.98 g/cm³· **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: 60.0 %

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

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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	>6,452 mg/kg (rat)
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CAS: 1314-13-2 zinc oxide

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

· Aquatic toxicity:

CAS: 1314-13-2 zinc oxide

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

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- **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)

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· 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
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	5L
· 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)	5L
· 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 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.

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Trade name: Dycal Base

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*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.

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according to 1907/2006/EC, Article 31

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Version number 7

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Trade name: Dycal Catalyst

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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**

CO2, 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.

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*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.*

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· **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:**

Form:	Pasty
Colour:	White
Odour:	Product specific
Odour threshold:	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/cm³· **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.

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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

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- **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

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· 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

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- **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.**

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

- **1.1 Product identifier**
- **Trade name:** Dycal Catalyst
- **Application:** Catalyst paste
- **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@dentsply.com
- **Further information obtainable from:**
 - Departement Analytical Research / 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**


Met. Corr. 1	H290 May be corrosive to metals.
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**
 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.
 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**
 - H290 May be corrosive to metals.
 - 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/protective clothing/eye protection/face protection.

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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.

- **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	3-<10%
EINECS: 215-222-5	☠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410	

- **Additional information** For the wording of the listed risk 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.
- **After eye contact** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing**
Rinse out mouth and then drink plenty of water.
Call a doctor immediately.
- **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**
CO2, 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:**
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.

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- **6.3 Methods and material for containment and cleaning up:**
Pick up mechanically.
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** *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.

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· 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:**

Form:	Pasty
Colour:	White
· Odour:	Product specific
· Odour threshold:	Not determined.

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

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

· Flash point: Not applicable**· Flammability (solid, gaseous)** Not applicable.**· Ignition temperature:** Not applicable**· Decomposition temperature:** Not determined.**· 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 at 20 °C:** 1.82 g/cm³**· Relative density** Not determined.**· Vapour density** Not determined.**· Evaporation rate** Not determined.**· Solubility in / Miscibility with****Water:** Insoluble**· Partition coefficient (n-octanol/water):** Not determined.**· Viscosity:**

dynamic:	Not determined.
kinematic:	Not determined.

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

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

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- **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**

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

ATE (Acute Toxicity Estimates)

Oral	LD50	3922 mg/kg
------	------	------------

1305-62-0 calcium dihydroxide

Oral	LD50	>2000 mg/kg (rat)
------	------	-------------------

1314-13-2 zinc oxide

Oral	LD50	>5000 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:**

1305-62-0 calcium dihydroxide

LC50/96h	160 mg/l (Fish acute toxicity study)
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1314-13-2 zinc oxide

EC50/48h	0.098 mg/L (daphnia magna)
----------	----------------------------

LC50/96h	1.1 mg/l (Fish acute toxicity study)
----------	--------------------------------------

- **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.
Also poisonous for fish and plankton in water bodies.
Toxic for aquatic organisms

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- **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 dangerous substances
-----------	--

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

SECTION 14: Transport information

- | | |
|--|---|
| · 14.1 UN-Number | UN3077 |
| · ADR, IMDG, IATA | |
| · 14.2 UN proper shipping name | 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide) |
| · ADR | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), MARINE POLLUTANT |
| · IMDG | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide) |
| · 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 |
| · IMDG, IATA | |
| | |
| · Class | 9 Miscellaneous dangerous substances and articles. |
| · Label | 9 |
| · 14.4 Packing group | III |
| · ADR, IMDG, IATA | |
| · 14.5 Environmental hazards: | Product contains environmentally hazardous substances: zinc oxide |
| · Marine pollutant: | Yes
Symbol (fish and tree) |

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· 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
· 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
· Tunnel restriction code	E
· 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":	UN3077, 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**
No further relevant information available.
- **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 MSDS:** Analytical Research
- **Contact:** HotLine for urgent technical support: +49-7531-583-350

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

Printing date 15.07.2015

Version number 5

Revision: 15.07.2015

Trade name: Dycal Catalyst

(Contd. of page 7)

· 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

Met. Corr. 1: Corrosive to metals, Hazard Category 1

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

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

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

Aquatic Acute 1: Hazardous to the aquatic environment - Acute Hazard, Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2

· * Data compared to the previous version altered.

GB

**DENTSPLY/International
DENTSPLY/Caulk
Safety Data Sheet**

523899

1. Identification

Product Name DYCAL[®] Radiopaque Calcium Hydroxide Composition	SDS Code Number 523899
Substance Identity DYCAL[®] Radiopaque Calcium Hydroxide Composition	Date of Last Revision 02/21/14
Manufacturer: DENTSPLY Caulk	Address 38 West Clarke Avenue Milford DE 19963-1805 http://www.caulk.com http://www.dentsply.com
Grades or Minor Variant Identities Not Applicable	Information Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada) Not Applicable	Emergency Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)

2. Hazard(s) Identification



**WARNING
CAUSES SKIN IRRITATION**

Wash hands thoroughly after handling.
Wear protective gloves.
IF ON SKIN: Wash with plenty of soap and water.
If skin irritation occurs: Get medical advice/ attention.
Take off contaminated clothing and wash before reuse.

3. Composition/Information on Ingredients - Base Paste

Hazardous Components	C.A.S. Number	Exposure Limits	%
Calcium Tungstate	7790-75-2	5 mg/M ³	< than 20
Zinc Oxide	1314-13-2	10 mg/M ³	< than 15
Disalicylate ester of 1,3 butylene glycol	73240-13-8	Not Established	< than 50

Other Information: Colorants are synthetic inorganic iron oxides.

3. Composition/Information on Ingredients - Catalyst Paste

Hazardous Components	C.A.S. Number	Exposure Limits	%
Calcium Hydroxide	1305-62-0	5 mg/M ³	< than 55
Zinc Oxide	1314-13-2	10 mg/M ³	< than 15
Titanium Dioxide	13463-67-7	10 mg/M ³	< than 10

3. Hazard Identification

Emergency Overview: Material is an irritant.					
Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)
Eye	Material may cause irritation.	Single & Repeated	Moderate	Irritation and possible corneal damage due to the caustic nature of ingredient used in the product.	Not Applicable
Skin	Material may cause irritation.	Single & Repeated	Mild	Irritation or possible allergic response.	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material may cause irritation.	Not Applicable	Mild	Irritation due to the caustic nature of ingredients used in the product.	Not Applicable
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Medical Conditions Aggravated by Exposure Open sores and wounds of the skin.					
Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.					

Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.
 NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 0, Reactivity = 0

4. First Aid Measures

Routes of Exposure	First Aid Instructions	Immediate Medical Attention	Delayed Effects
Eye	Rinse opened eye for several minutes under running water. If symptoms persist consult physician.	Not Applicable	Not Applicable
Skin	Immediately wash with soap and water and rinse thoroughly.	Not Applicable	Not Applicable
Inhalation	Supply fresh air, If symptoms persist consult physician. This may not be of concern when using clinically relevant quantities.	Not Applicable	Not Applicable
Ingestion	Rinse out mouth and then drink plenty of water. Consult a physician immediately. This may not be of concern when using clinically relevant quantities.	Not Applicable	Not Applicable
Other	Not Applicable	Not Applicable	Not Applicable
Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically.			

5. Fire and Explosion Data

Flashpoint Method: Not Applicable	Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable	Autoignition Temperature: Not Applicable	Other: Not Applicable
Flame Propagation or Burning Rate (for Solids): Not Applicable	Properties Contributing to Fire Intensity: Not Applicable	Flammability Classification: Not Applicable	
Extinguishing Media: Use fire extinguishing methods suitable to surrounding conditions.		Extinguishing Media to Avoid: Not Applicable	
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.			
Unusual Fire and Explosion Hazards: Formation of toxic gases is possible during heating or in case of fire.			

6. Accidental Release Measures

Containment Techniques: Material is a high viscosity paste, but will flow somewhat.		
Spill/Leak Clean-up Procedures and Equipment: Absorb with liquid binding material (sand, vermiculite, diatomite, acid binders, universal binders or sawdust). Scoop up bulk material and place in a labeled plastic or metal container.		
Evacuation Procedures: Not Applicable	Special Instructions: Not Applicable	Reporting Requirements: Not Applicable

7. Handling and Storage

Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals.
Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Store away from food and beverages.

8. Exposure Control / Personal Protection



Individual Protection Measures	Personal Protective Equipment for Normal Use	Personal Protective Equipment for Emergencies
Eye/Face	Safety Glasses	Not Applicable
Skin	The glove material has to be impermeable and resistant to the product.	Not Applicable
Inhalation	Not Required. This may not be of concern when using clinically relevant quantities.	Not Applicable
Body Protection	Protective work clothing	Not Applicable
Occupational Exposure Limits: Not Applicable		Engineering Controls: Not Applicable

9. Physical and Chemical Characteristics

Appearance: Base-light yellow colored paste, catalyst-white paste.		Odor: Base odor of cloves, Catalyst Odorless.
Normal Physical State: Paste		Melting Point: Not Applicable
Specific Gravity: Base 2.0 g/cm ³ Catalyst 1.8 g/cm ³	Solubility in Water: Not soluble	pH: Base-Not Applicable, Catalyst- 11.5
Vapor Pressure (mm Hg): Not Applicable	Vapor Density (AIR=1): Not Applicable	Evaporation Rate (Butyl Acetate =1): Not Applicable
Flashpoint - Method: Not Applicable	Flammable (Explosive) Limits in Air LEL: Not Applicable UEL: Not Applicable	Autoignition Temperature: Not Applicable
Other: Not Applicable		

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Not Applicable	
Hazardous Products Produced During Decomposition: Not Applicable	
Hazardous Polymerization: <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> May Not Occur	Conditions to Avoid: None known
Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable	Conditions to Avoid: None known

11. Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data:
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Irritating to skin and mucous membranes.					
Emergency Overview: Material is an irritant.					
Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)
Eye	Material may cause irritation.	Single & Repeated	Moderate	Irritation and possible corneal damage due to the caustic nature of ingredient used in the product.	Not Applicable
Skin	Material may cause irritation.	Single & Repeated	Mild	Irritation or possible allergic response.	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material may cause irritation.	Not Applicable	Mild	Irritation due to the caustic nature of ingredients used in the product.	Not Applicable
Other	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Medical Conditions Aggravated by Exposure Open sores and wounds of the skin.					
Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.					
Potential Environmental Effects: Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.					
NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 0, Reactivity = 0					

12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system. Toxic to fish. Also poisonous for fish and plankton in water bodies. Toxic for aquatic organisms.



Danger
Hazardous to aquatic life

13. Disposal Considerations

Regulations: Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations
Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

14. Transport Information

Regulated for Shipping: No. Not Regulated	DOT Shipping Name: Not Regulated	Packing Group: Not Applicable
Do Changes in Quantities, packaging, or shipment method change product classification? No	DOT Hazard Class: Not Applicable	UN Number: Not Applicable

15. Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.
U.S. Federal Regulations: <u>CERCLA 103 Reportable Quantity</u> : This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations
Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None
Section 302 Extremely Hazardous Substances (TPQ): None
EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory.
U.S. State Regulations California Proposition 65: This product does not contain any chemicals, which are on the California Proposition 65 list.
International Regulations: <u>Canadian Environmental Protection Act</u> : This product is a medical device and not subject to chemical notification requirements.
<u>European Community Labeling</u> : Not a dangerous preparation. These R and S phrases apply to base and catalyst: R36/38 Irritating to eyes and skin. R51/53 Toxic to aquatic organisms, may cause long-term effects in the environment. S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S28 After contact with skin, wash immediately with plenty of water. S37 Wear suitable gloves. S57 Use appropriate container to avoid environmental contamination. S60 This material and its container must be disposed of as hazardous waste. These R and S phrases apply to catalyst: R41 Risk of serious damage to eyes. R50/53 Very toxic to aquatic organisms, may cause long-term effects in the environment. S24 Avoid contact with skin.
<u>European Inventory of New and Existing Chemicals Substances (EINECS)</u> : This product is a medical device and not subject to chemical notification requirements.
Other: Not Applicable

16. Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex.
All components are synthetically produced; none are derived from animal products.
This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products 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.