

Sealapex Canal Sealant Base

1 . Identification of the material and supplier

Names

Product name : Sealapex Canal Sealant Base
ADG : UN3077
Manufacturer : **SybronEndo Endodontics**
 Unit 10, 112-118 Talavera Road
 North Ryde, NSW 2113
 Australia
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Emergency telephone number : 61 401 690 670 (24 hours)

Uses

Area of application : Professional applications.
Material uses : Dental product: Endodontic Obturation Systems and Fill Products
Product type : Paste.

2 . Hazards identification

Classification : Xi; R41, R37/38
 N; R50

Risk phrases : R41- Risk of serious damage to eyes.
 R37/38- Irritating to respiratory system and skin.
 R50- Very toxic to aquatic organisms.

Safety phrases : S26- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
 S39- Wear eye/face protection.
 S61- Avoid release to the environment. Refer to special instructions/safety data sheet.

Statement of hazardous/dangerous nature : HAZARDOUS SUBSTANCE. DANGEROUS GOODS.

Health effects are based on the uncured material.

3 . Composition/information on ingredients

Mixture : Yes.

Ingredient name	CAS number	Concentration
calcium oxide	1305-78-8	30-60
Zinc oxide (dust)	1314-13-2	<10
zinc distearate	557-05-1	<10
titanium dioxide	13463-67-7	<10

Other ingredients, determined not to be hazardous according to Safe Work Australia criteria, and not dangerous according to the ADG Code, make up the product concentration to 100%.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

4 . First-aid measures

First-aid measures

- Inhalation** : No special measures required. If inhaled, remove to fresh air. Get medical attention if symptoms occur.
- Ingestion** : Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Get medical attention if adverse health effects persist or are severe.
- Skin contact** : No special measures required. In case of contact, immediately flush skin with plenty of water. Get medical attention if symptoms occur.
- Eye contact** : No special measures are required. In case of contact with eyes, rinse immediately with plenty of water. Get medical attention if symptoms occur.
- Protection of first-aiders** : In case of major fire and large quantities: No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.
- Advice to doctor** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

5 . Fire-fighting measures

Extinguishing media

- Suitable** : Use an extinguishing agent suitable for the surrounding fire.
- Not suitable** : None known.
- Special exposure hazards** : In case of major fire and large quantities: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. This material is very toxic to aquatic organisms. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.
No specific fire or explosion hazard.
- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
sulfur oxides
phosphorus oxides
metal oxide/oxides
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.
- Hazchem code** : 2Z

6 . Accidental release measures

- Personal precautions** : Low release. For professional use only. Handling of product in very small amounts or in situations where release is highly unlikely
- Environmental precautions** : Low release. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities.
- Methods for cleaning up**
- Small spill** : Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.
- Large spill** : Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.

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7 . Handling and storage

- Handling** : No special measures are required for small quantities under normal and intended conditions of product use. For professional use only. Put on appropriate personal protective equipment (see Section 8). Handle with care and dispose of in a safe manner.
- Storage** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination.
- Combustible liquid** Not applicable.

8 . Exposure controls/personal protection

Occupational exposure limits

Ingredient name	Exposure limits
calcium oxide	Safe Work Australia (Australia, 4/2013). TWA: 2 mg/m ³ 8 hours.
Zinc oxide (dust)	Safe Work Australia (Australia, 1/2014). TWA: 10 mg/m ³ 8 hours. Form: Dust STEL: 10 mg/m ³ 15 minutes. Form: Fume
zinc distearate	TWA: 5 mg/m ³ 8 hours. Form: Fume Safe Work Australia (Australia, 4/2013). TWA: 10 mg/m ³ 8 hours.
titanium dioxide	Safe Work Australia (Australia, 1/2014). TWA: 10 mg/m ³ 8 hours.

- Recommended monitoring procedures** : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to appropriate monitoring standards. Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

Exposure controls

- Engineering measures** : No special measures are required for small quantities under normal and intended conditions of product use.
- Hygiene measures** : No special measures are required for small quantities under normal and intended conditions of product use.
- Eyes** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.
- Hands** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Respiratory** : No special measures are required for small quantities under normal and intended conditions of product use.
- Skin** : No special measures are required for small quantities under normal and intended conditions of product use.
- Environmental exposure controls** : No special measures are required for small quantities under normal and intended conditions of product use.

9 . Physical and chemical properties

Physical state	: Solid. [Viscous. Paste.]
Colour	: Off-white.
Odour	: Odourless.
Boiling point	: Not available.
Melting point	: Not available.
Vapour pressure	: Not available.
Relative density	: 1.3 [Water = 1]
Flash point	: Not available.
Flammable limits	: Not available.
Vapour density	: Not available.
pH	: Not available.
Viscosity	: Not available.
Auto-ignition temperature	: Not available.
Solubility	: Insoluble in the following materials: cold water and hot water.

10 . Stability and reactivity

Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur. Under normal conditions of storage and use, hazardous polymerisation will not occur.
Conditions to avoid	: No specific data.
Materials to avoid	: No specific data.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11 . Toxicological information

Potential acute health effects

Inhalation	: Irritating to respiratory system. Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
Ingestion	: Irritating to mouth, throat and stomach.
Skin contact	: Irritating to skin.
Eye contact	: Severely irritating to eyes. Risk of serious damage to eyes.

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
zinc distearate	LC50 Inhalation Dusts and mists	Rat	>200 mg/l	1 hours
	LD50 Oral	Rat	>10 g/kg	-

Conclusion/Summary : Based on the criteria of the protocol, this product is considered non-cytotoxic per ISO 10993-5.

Potential chronic health effects

Chronic toxicity

Conclusion/Summary : Not available.

Irritation/Corrosion

11 . Toxicological information

Product/ingredient name	Result	Species	Score	Exposure	Observation
Zinc oxide (dust)	Eyes - Mild irritant	Rabbit	-	24 hours 500 milligrams	-
	Skin - Mild irritant	Rabbit	-	24 hours 500 milligrams	-

Conclusion/Summary : Not available.

Sensitiser

Conclusion/Summary

Skin : Kligman score: Grade I (weak sensitizer)

Carcinogenicity

Conclusion/Summary : Not available.

Mutagenicity

Conclusion/Summary : No mutagenic effect.

Teratogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

Chronic effects : No known significant effects or critical hazards.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Over-exposure signs/symptoms

Inhalation : Adverse symptoms may include the following:
respiratory tract irritation
coughing

Ingestion : No specific data.

Skin : Adverse symptoms may include the following:
irritation
redness

Eyes : Adverse symptoms may include the following:
pain or irritation
watering
redness

Target organs : Contains material which may cause damage to the following organs: lungs, digestive system, gastrointestinal tract, upper respiratory tract, skin, eye, lens or cornea.

12 . Ecological information

Ecotoxicity : Very toxic to aquatic organisms.

Aquatic ecotoxicity

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12 . Ecological information

Product/ingredient name	Result	Species	Exposure
calcium oxide	Chronic NOEC 100 mg/l Fresh water	Fish - Oreochromis niloticus - Juvenile (Fledgling, Hatchling, Weanling)	46 days
Zinc oxide (dust)	Acute EC50 0.042 mg/l Fresh water	Algae - Pseudokirchneriella subcapitata - Exponential growth phase	72 hours
	Acute LC50 98 µg/l Fresh water	Daphnia - Daphnia magna - Neonate	48 hours
	Acute LC50 1.1 ppm Fresh water	Fish - Oncorhynchus mykiss	96 hours
	Chronic NOEC 0.017 mg/l Fresh water	Algae - Pseudokirchneriella subcapitata - Exponential growth phase	72 hours
titanium dioxide	Acute EC50 5.83 mg/l Fresh water	Algae - Pseudokirchneriella subcapitata - Exponential growth phase	72 hours
	Acute LC50 3 mg/l Fresh water	Crustaceans - Ceriodaphnia dubia - Neonate	48 hours
	Acute LC50 5.5 ppm Fresh water	Daphnia - Daphnia magna - Juvenile (Fledgling, Hatchling, Weanling)	48 hours
	Acute LC50 1000 mg/l Fresh water	Fish - Pimephales promelas	96 hours
	Acute LC50 >1000000 µg/l Marine water	Fish - Fundulus heteroclitus	96 hours
	Chronic NOEC 0.984 mg/l Fresh water	Algae - Pseudokirchneriella subcapitata - Exponential growth phase	72 hours

Conclusion/Summary : Not available.

Other ecological information

Persistence/degradability

Conclusion/Summary : Not available.

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
calcium oxide	-	2.34	low
Zinc oxide (dust)	-	60960	high
zinc distearate	1.2	-	low
titanium dioxide	-	352	high

Other adverse effects : No known significant effects or critical hazards.


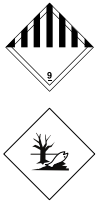
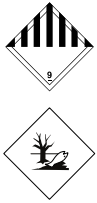
13 . Disposal considerations

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

14 . Transport information



International transport regulations

14 . Transport information

Regulation	UN number	Proper shipping name	Classes	PG*	Label	Additional information
ADG	UN3077	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N. O.S. (zinc oxide)	9	III		<p>The product is not regulated as a dangerous good when transported by road or rail in either an IBC, or in other container types if ≤ 500 kg. The environmentally hazardous substance mark is not required when transported in sizes of ≤ 5 L or ≤ 5 kg.</p> <p>Hazchem code 2Z</p> <p>Special provisions 179, 274, 331, 335, AU01</p>
ADR	UN3077	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N. O.S. (zinc oxide)	9	III		<p>The environmentally hazardous substance mark is not required when transported in sizes of ≤ 5 L or ≤ 5 kg.</p> <p>Hazard identification number 90</p> <p>Limited quantity 5 kg</p> <p>Special provisions 274, 335, 601</p> <p>Tunnel code (E)</p>
IMDG	UN3077	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N. O.S. (zinc oxide). Marine pollutant (zinc oxide)	9	III		<p>The marine pollutant mark is not required when transported in sizes of ≤ 5 L or ≤ 5 kg.</p> <p>Emergency schedules (EmS) F-A, S-F</p> <p>Special provisions 274, 335, 966, 967</p>

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14 . Transport information

IATA	UN3077	Environmentally hazardous substance, solid, n.o.s. (zinc oxide)	9	III	 	The environmentally hazardous substance mark is not required when transported in sizes of ≤5 L or ≤5 kg. <u>Passenger and Cargo Aircraft</u> Quantity limitation: 400 kg Packaging instructions: 956 <u>Cargo Aircraft Only</u> Quantity limitation: 400 kg Packaging instructions: 956 <u>Limited Quantities - Passenger Aircraft</u> Quantity limitation: 30 kg Packaging instructions: Y956 <u>Special provisions</u> A97, A158, A179
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PG* : Packing group

15 . Regulatory information

[Standard Uniform Schedule of Medicine and Poisons](#)

Not regulated.

[Control of Scheduled Carcinogenic Substances](#)

No listed substance

Australia inventory (AICS) : All components are listed or exempted.

EU Classification : Xi; R41, R37/38
N; R50/53

16 . Other information

Person who prepared the MSDS : IHS

Date of previous issue : No previous validation.

Date of issue/ Date of revision : 4/7/2015.

Version : 1

 Indicates information that has changed from previously issued version.

Disclaimer

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.