

Material Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product and must be read in conjunction with the Safety Data Sheet (SDS) attached

Product Name: OraSeal Caulk - OraSeal Putty

Manufacturer: Ultradent

SDS Expiry: 7 August 2028

Supplier Details: Henry Schein New Zealand
243-249 Bush Road, Rosedale, Auckland, 0632
PO Box 101 140, North Shore, Auckland 0745
Ph. 0800 808 855
www.henryschein.co.nz

Emergency Contacts: Poisons/Hazardous Chemical Info Centre –
0800POISON/0800764766 (24 Hours)
Phone 111 for Fire, Ambulance or Police

HSNO Class/Category: 6

HSNO Group Standard: Dental Products Carcinogenic Group Standard 2020
HSR002560

Statements/Pictograms: As per attached Safety Data Sheet (SDS)

Date Prepared: This coversheet was prepared – August 2023

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.

Safety Data Sheet
according to WHS Regulations

Printing date 07.08.2023

Revision: 07.08.2023

1 Identification

- **Product identifier**
- **Trade name:** *OraSeal™ Caulk - OraSeal™ Putty*
- **Article number:** *SDS 87-001.09R02, 10322, 10321*
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Caulking & Sealing Materials
- **Application of the substance / the mixture** *Professional Dental Caulking & Sealing Materials*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
*Ultradent Products, Inc.
505 W. Ultradent Drive (10200 S)
South Jordan, UT 84095-3942
USA
onlineordersupport@ultradent.com*
-
- Ultradent Australia Pty Ltd.
Level 22/2 Market Street
Sydney NSW 2000
Australia
Email: info.anz@ultradent.com
Toll Free: 1-800-290929*
- **Further information obtainable from:**
*Customer Service
None*
- **Emergency telephone number:**
*CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887*

2 Hazard(s) Identification

- **Classification of the substance or mixture**

*health hazard**Carc. 2 H351 Suspected of causing cancer. Route of exposure: Inhalation.*

- **Label elements**
- **GHS label elements** *Void*
- **Hazard pictograms** *GHS08*
- **Signal word** *Warning*
- **Hazard-determining components of labelling:**
Titanium Dioxide
- **Hazard statements**
H351 Suspected of causing cancer. Route of exposure: Inhalation.
- **Precautionary statements**
*P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.
P103 Read label before use.*

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- P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P308+P313 IF exposed or concerned: Get medical advice/attention.
 P405 Store locked up.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

3 Composition and Information on Ingredients

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

- **Dangerous components:**

57-55-6	Propylene Glycol		30-60%
13463-67-7	Titanium Dioxide	☠ Carc. 2, H351	≥0.1-<10%
	Dimethicone	☠ Repr. 2, H361f; STOT RE 2, H373	<3%

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

4 First Aid Measures

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **Suitable extinguishing agents:**
Water spray, fog, or mist, foam, dry chemical, carbon dioxide
Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** No special measures required.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to item 13.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

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7 Handling and Storage

- **Handling:**
- **Precautions for safe handling:**
See product labeling.
Open and handle receptacle with care.
- **Information about fire - and explosion protection:** Keep respiratory protective device available.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
See product labelling.
Keep container tightly sealed.
- **Specific end use(s)** Professional Dental Caulking & Sealing Materials

8 Exposure controls and personal protection

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

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

57-55-6 Propylene Glycol

WES	Long-term value: 474* 10** mg/m ³ , 150* ppm *vapour&particulates; **particulates only
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13463-67-7 Titanium Dioxide

WES	Long-term value: 10 mg/m ³ inhalable dust
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- **Additional information:** The lists valid during the making were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
Store protective clothing separately.
- **Respiratory protection:** Not required.
- **Protection of hands:**



Protective gloves

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

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

- **Material of gloves**

The selection of 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 breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:** Goggles recommended during refilling

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· **Body protection:** Protective work clothing

9 Physical and Chemical Properties

· General Information

· Appearance:

· Form:

Paste

· Colour:

Purple

· Odour:

Odourless

· Odour threshold:

Not determined.

· pH-value:

Not applicable (non-aqueous)

· Change in condition

· Melting point/freezing point:

Undetermined.

· Initial boiling point and boiling range:

>35 °C

· Flash point:

>121 °C

· Flammability (solid, gas):

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:

1-1.3 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.

· Other information

No further relevant information available.

10 Stability and Reactivity

· Reactivity Stable

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

· **Possibility of hazardous reactions:** No dangerous reactions known.

· **Conditions to avoid:** No further relevant information available.

· **Incompatible materials:** No further relevant information available.

· **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological Information

· Information on toxicological effects

· **Acute toxicity** Based on available data, the classification criteria are not met.

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

57-55-6 Propylene Glycol

Oral	LD50	18,000 mg/kg (rabbit)
	LC50 Fish	>5,000 mg/l (Fish)
Dermal	LD50	20,800 mg/kg (rabbit)

13463-67-7 Titanium Dioxide

Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Suspected of causing cancer. Route of exposure: Inhalation.
- **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.

12 Ecological Information

· **Toxicity**

· **Aquatic toxicity:**

57-55-6 Propylene Glycol

EC50	18,100 mg/kg (Algae)
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13463-67-7 Titanium Dioxide

EC50	>100 mg/kg (Algae)
	>1,000 mg/kg (Fish)

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

13 Disposal considerations

· **Waste treatment methods**

· **Recommendation**

Dispose of contents/container in accordance with international, federal, state, and local regulations.

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

14 Transport information

· UN-Number	
· ADG, ADN, IMDG, IATA	not regulated
· UN proper shipping name	
· ADG, ADN, IMDG, IATA	not regulated
· Transport hazard class(es)	
· ADG, ADN, IMDG, IATA	
· Class	not regulated
· Packing group	
· ADG, IMDG, IATA	not regulated
· Environmental hazards:	Not applicable.
· Special precautions for user	Not Applicable
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	not regulated

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture	
· Australian Inventory of Industrial Chemicals	
57-55-6	Propylene Glycol
63148-62-9	Dimethyl siloxane
12173-47-6	Hectorite
13463-67-7	Titanium Dioxide
· Standard for the Uniform Scheduling of Medicines and Poisons	
None of the ingredients is listed.	
· Australia: Priority Existing Chemicals	
None of the ingredients is listed.	
· Directive 2012/18/EU	
· Named dangerous substances - ANNEX I None of the ingredients is listed.	
· Chemical safety assessment:	
Device is biocompatible when used as directed by dental professionals per ISO 10993-1	

16 Other information

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

- **Relevant phrases from Section 3**
- H351 Suspected of causing cancer.

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H361f Suspected of damaging fertility.

H373 May cause damage to organs through prolonged or repeated exposure.

· **Department issuing SDS:** Environmental, Health, and Safety

· **Contact:** Customer Service

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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

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

Carc. 2: Carcinogenicity – Category 2

Repr. 2: Reproductive toxicity – Category 2

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

· *** Data compared to the previous version altered.**

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