

**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 <sup>3</sup> , 150* ppm *vapour&particulates; **particulates only
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#### 13463-67-7 Titanium Dioxide

WES	Long-term value: 10 mg/m <sup>3</sup> 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:

&gt;35 °C

#### · Flash point:

&gt;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/cm<sup>3</sup>

#### · Relative density

Not determined.

#### · Vapour density

Not determined.

#### · Evaporation rate

Not determined.

#### · Solubility in / Miscibility with

#### · water:

Not miscible or difficult to mix.

#### · Partition coefficient: n-octanol/water:

Not determined.

#### · Viscosity:

#### · Dynamic:

Not determined.

#### · Kinematic:

Not determined.

#### · 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

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

### 15 Regulatory information

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