

## **SAFETY DATA SHEETS**

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

077639461

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

077639453 077639479

**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/15/2006

SDS No : 87-001.7

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Revision No : 6

**OraSeal® Caulk, Oraseal® Putty****SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

**Product code** : OC/10321, OP/10322  
**Product name** : OraSeal® Caulk, Oraseal® Putty  
**Product description** : Dental caulking and sealing material

**1.2. Relevant identified uses of the substance or mixture and uses advised against**

**Relevant identified uses** : Professional Dental Caulking & Sealing Materials

**1.3. Details of the supplier of the safety data sheet****Manufacturer**

Ultradent Products, Inc.  
 505 W. 10200 S.  
 South Jordan, UT 84095

**Distributor**

Ultradent Products GmbH  
 Am Westhover Berg 30  
 51149 Cologne Germany  
 Email: infoDE@ultradent.com  
**Emergency Phone** : +49(0)2203-35-92-0

**1.4. Emergency telephone number**

**CHEMTREC (NORTH AMERICA)** :(800) 424 - 9300  
**(INTERNATIONAL)** :+1(703) 527 - 3887

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Classification according to Directive 1999/45/EC**

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.  
 This material is not considered hazardous to health.

**Classification according to Regulation (EC) No 1272/2008 [CLP]**

**Health** : None

**2.2. Label elements**

**Classification according to Directive 1999/45/EC** : This material is not considered to be hazardous for the health.

**Classification according to Regulation (EC) No 1272/2008 [CLP]**

**Hazard statement(s)** : 9502HLMN: This Material is not considered to be hazardous for the health.

**Precautionary statement(s)**

**Prevention** : P280: Wear protective gloves/protective clothing/eye protection/face protection.  
**Response** : P305: IF IN EYES:.  
 P351: Rinse cautiously with water for several minutes.  
 P313: Get medical advice/attention.

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**Storage** : P391: Collect spillage.  
**Disposal** : P501: Dispose of in compliance with governmental regulation(EC 1975L0442-20/11/2003)

**2.3. Other hazards**

**Immediate concerns** : None

**SECTION 3: Composition / information on ingredients**

**3.1. Substances**

Not Applicable

**3.2. Mixtures**

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Hectorite clay	12173-47-6	235-340-0	< 10	Xi; R36/37/38	Eye Irr., Cat. 2; H319

For full text of H-statements and R-phrases: see SECTION 16.

**SECTION 4: First aid measures**

**4.1. Description of first aid measures**

**Following eyes** : No special measures required.  
**Following skin** : No special measures required.  
**Following ingestion** : If swallowed in small quantity the product is harmless, otherwise consult a doctor.  
**Following inhalation** : No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

**4.2. Most important symptoms and effects, both acute and delayed**

**Eyes** : None expected for this product.  
**Skin** : None expected for this product.  
**Ingestion** : May be harmful if swallowed in large quantities.  
**Inhalation** : None expected for this product.

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

**Notes to physician** : Not Applicable

**SECTION 5: Fire fighting measures**

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**5.1. Extinguishing media**

**Extinguishing media** : Please see Fire Fighting Equipment under Section 5.3.

**5.2. Special hazards arising from the substance or mixture**

**Explosion hazards** : Not Determined

**Fire explosion** : Not Determined

**Sensitive to static discharge** : Not Determined

**Sensitivity to impact** : Not Determined

**5.3. Advice for firefighters**

**Fire fighting procedures** : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.

**Fire fighting equipment** : Water spray, fog, or mist, foam, dry chemical, carbon dioxide(CO<sub>2</sub>)

**SECTION 6: Accidental release measures**

**6.1. Personal precautions, protective equipment and emergency procedures**

**General procedures** : Refer to Section 8 for Personal Protective Equipment.

**6.2. Environmental precautions**

**Water spill** : No special measures required.

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

**Small spill** : Wipe up with cloth, soap and water.

**Large spill** : After removal, flush contaminated area thoroughly with water.

**6.4. Reference to other sections**

**Reference to other sections** : Not Applicable

**SECTION 7: Handling and storage**

**7.1. Precautions for safe handling**

**Handling** : Not needed for normal use.

**Storage** : See product labeling.

**7.2. Conditions for safe storage, including any incompatibilities**

**Shelf life** : See product labeling

**7.3. Specific end use(s)**

**Specific end use(s)** : Professional Dental Caulking & Sealing Materials

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

**8.1. Control parameters**

**Control parameters** : Not Determined

**8.2. Exposure controls**

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**Eye/face protection** : Wear eye protection.  
**Skin protection** : Not needed for normal use.  
**Respiratory protection** : Good general ventilation should be sufficient to control airborne levels.

**SECTION 9: Physical and chemical properties**

**9.1. Information on basic physical and chemical properties**

**Physical state** : Paste  
**Colour** : Ivory or light purple  
**Odour** : Odorless or no characteristic odor

**9.2. Other information**

**Percent volatile** : Not Volatile

**SECTION 10: Stability and reactivity**

**10.1. Reactivity**

**Reactivity** : Stable

**10.2. Chemical stability**

**Chemical stability** : Stable when stored and handled under recommended conditions.

**10.3. Possibility of hazardous reactions**

**Hazardous polymerization** : None

**10.4. Conditions to avoid**

**Conditions to avoid** : Not Determined

**10.5. Incompatible materials**

**Incompatible materials** : None

**10.6. Hazardous decomposition products**

**Hazardous decomposition products** : None

**SECTION 11: Toxicological information**

**11.1. Information on toxicological effects**

**Acute**

**Notes** : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

**SECTION 12: Ecological information**

**12.1. Toxicity**

**Aquatic toxicity (acute)** : Not Applicable  
**96-hour LC<sub>50</sub>** : Not Determined  
**48-hour EC<sub>50</sub>** : Not Determined

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96-hour EC<sub>50</sub> : Not Determined

**12.2. Persistence and degradability**

Persistence and degradability : Not Determined

**12.3. Bioaccumulative potential**

Bioaccumulative potential : Not Determined

**12.4. Mobility in soil**

Mobility in soil : Not Determined

**12.5. Results of PBT and vPvB assessment**

Results of PBT and vPvB assessment : Not Determined

**12.6. Other adverse effects**

Environmental data : Not Available

**SECTION 13: Disposal considerations****13.1. Waste treatment methods**

Disposal method : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

**SECTION 14: Transport information****14.1. UN number**

UN number : N/A

**14.2. UN proper shipping name**

UN proper shipping name : Not Dangerous Goods

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

Hazard classification : N/A

**14.4. Packing group**

Packing group : N/A

**14.5. Environmental hazards**

Marine pollutant #1 : N/A

**14.6. Special precautions for user**

ADR - road : Not Dangerous Goods

RID - rail : Not Dangerous Goods

IMDG - sea : Not Dangerous Goods

IATA - air : Not Dangerous Goods

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Transport in bulk : Not Dangerous Goods

**SECTION 15: Regulatory information**

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**OraSeal® Caulk, Oraseal® Putty****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****RoHS** : Please refer to Medical Devices Directive 93/42/EEC**15.2. Chemical safety assessment****Chemical safety assessment** : See Section 11**SECTION 16: Other information**

**Relevant R-phrases and/or H-statements (number and full text)** : R36/37/38: Irritating to eyes, respiratory system and skin. Eye Irr., Cat. 2: Eye Irritation, Category 2  
H319: Causes serious eye irritation.

**Prepared by** : Anu Kattoju

**Revision summary** : This SDS replaces the 10/01/2014 SDS. Revised: **Section 1:** . **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - EYES AND FACE. **Section 9:** PERCENT VOLATILE. **Section 10:** HAZARDOUS POLYMERIZATION, STABLE, POSSIBILITY OF HAZARDOUS REACTIONS. **Section 11:** ACUTE ( ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat) ACUTE. **Section 14:** VESSEL (IMO/IMDG) - MARINE POLLUTANT #1. **Section 15:** COMMENTS, SECTION 15: Regulatory information.

**General statements** : N/A= Not Applicable

**Manufacturer disclaimer** : FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.