

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/15/2006

SDS No : 87-001.6

Date Revised : 10/1/2014

Revision No : 5

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

: Not Applicable

2.2. Label elements

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

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

2.3. Other hazards

Immediate concerns : No Immediate Concerns

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

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Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC
Hectorite clay	12173-47-6	235-340-0	< 10	Xi; R36/37/38

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

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(CO₂)

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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

Eye/face protection : Not needed for normal use.

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 Determined

SECTION 10: Stability and reactivity

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10.1. Reactivity

Stable : Yes

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions : None Expected.

Hazardous polymerization : No

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

Dermal LD₅₀ : Not Determined

Oral LD₅₀ : Not Determined

Inhalation LC₅₀ : Not Determined

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute) : Not Applicable

96-hour LC₅₀ : Not Determined

48-hour EC₅₀ : Not Determined

96-hour EC₅₀ : 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 : Not Determined

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assessment

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 : Not Dangerous Goods

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

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 : Not Determined

Additional information : This product is not considered dangerous for transportation

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full) : R36/37/38: Irritating to eyes, respiratory system and skin.
R36: Irritating to eyes.

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Prepared by

: Anu Kattoju

Revision summary

: This SDS replaces the 2/24/2014 SDS. Revised: **Section 1:** Date-Revised.

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 MSDS(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.