

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

Date Revised : 04/16/2015

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(CO₂)

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 LC₅₀ : Not Determined
48-hour EC₅₀ : Not Determined

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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 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 LD₅₀ (rat), INHALATION LC₅₀ (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.