

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Orthodontic Use



Date Issued : 07/18/2014

SDS No : 369-001.04

Date Revised : 04/10/2018

Revision No : 3

Opal® Bond™**SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

Product code : BY/15079
 Product name : Opal® Bond™
 Product description : Light-Cured Bonding Adhesive

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

Relevant identified uses : Professional Orthodontic Adhesive

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

Ultradent Products, Inc.
 505 W. Ultradent Drive (10200 South)
 South Jordan, UT 84095

EC Responsible Person

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

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Health : Eye Irritation, Category 2
 Skin Irritation, Category 2
 Skin Sensitization, Category 1
 Target Organ Toxicity (Single exposure), Respiratory Tract Category 3
 Acute Toxicity (Inhalation), Category 4

2.2. Label elements**Classification according to Regulation(EC) No 1272/2008 [CLP]**

Hazard pictogram(s) :



Exclamation
 mark

Signal Word : WARNING

Hazard statement(s) : H319: Causes serious eye irritation.
 H315: Causes skin irritation.
 H317: May cause an allergic skin reaction.

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H333: May be harmful if inhaled.

Precautionary statement(s)

Prevention

: P280: Wear protective gloves/protective clothing/eye protection/face protection.
P264: Wash hands thoroughly after handling.
P261: Avoid breathing vapours.
P272: Contaminated work clothing should not be allowed out of the workplace.

Response

: P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313: If eye irritation persists: Get medical advice/attention.
P302+P352: IF ON SKIN: Wash with plenty of soap & water.
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
P363: Wash contaminated clothing before reuse.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312: Call a POISON CENTER or doctor/physician if you feel unwell.

Storage

: P273: Avoid release to the environment.
P403+P235: Store in a well-ventilated place. Keep cool.
P405: Store locked up.

Disposal

: P501: Dispose of in compliance with governmental regulation. (EC1975L0442-20/11/2003)

2.3. Other hazards

Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

| Chemical Name | CAS | EINECS No. | Wt. % | Classification according to Regulation(EC) No 1272/2008 [CLP] |
|-----------------------------------|------------|------------|-------|--|
| Bis-GMA | 1565-94-2 | 216-367-7 | < 20 | H315; H317; H319 |
| Ethoxylatebisphenoldimethacrylate | 41637-38-1 | NAP | < 10 | Skin Irr.,Cat. 2; Eye Irr.,Cat. 2; Skin Sens.,Cat. 1; STOT SE,Cat. 3; H315; H317; H319; H335 |
| TEGDMA | 109-16-0 | 203-652-6 | < 5 | Skin Sens.,Cat. 1B; H317 |
| Aluminum Oxide | 1344-28-1 | 215-691-6 | < 10 | Not Classified |

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes

: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical

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advice.

- Following skin** : Wash off with soap and plenty of water. Get medical attention if irritation or sensitization develops and persists. Remove contaminated clothing.
- Following ingestion** : If swallowed in small quantity the product is harmless, otherwise consult a doctor.
- Following inhalation** : Rest in the fresh air and seek medical advice if necessary.

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

- Eyes** : Contact may cause eye irritation.
- Skin** : May cause skin irritation and sensitization.
- Ingestion** : Maybe harmful if swallowed in large quantities.
- Inhalation** : May be harmful if inhaled.

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

- Notes to physician** : NAP

SECTION 5: Fire fighting measures

5.1. Extinguishing media

- Extinguishing media** : Foam, dry chemical, carbon dioxide (CO₂).
Unsuitable Extinguishing Media: Water

5.2. Special hazards arising from the substance or mixture

- Hazardous combustion products** : 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.

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** : Do not allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up

- Small Spill** : Pick up wash liquid with additional absorbent and place in a disposable container.
- Large Spill** : Collect in tightly closed containers.

6.4. Reference to other sections

- Reference to other sections** : NAP

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Handling** : Use suitable protective equipment.

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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 Orthodontic Adhesive

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Aluminum Oxide CAS: 1344-28-1

| Control Parameters | Exposure Limits |
|------------------------------|----------------------|
| OSHA PEL Respirable fraction | 5 mg/m ³ |
| OSHA PEL Total Dust | 15 mg/m ³ |
| OSHA TWA Total Dust | 10 mg/m ³ |
| OSHA TWA Respirable Fraction | 5 mg/m ³ |
| OSHA TWA Respirable Fraction | 1 mg/m ³ |

8.2. Exposure controls

Eye/face protection : Wear eye protection.

Skin protection : Wear suitable protective clothing and gloves.

Respiratory protection : If inhaled, remove to fresh air. If feeling unwell get medical attention.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Paste

Appearance : Clear

Colour : White with slight to no yellowish tint

Odour : Acrylic

pH : NAP (non-aqueous)

9.2. Other information

Additional information : No relevant additional information available.

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

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Conditions to avoid : Heat, flames, ignition sources, direct light.

10.5. Incompatible materials

Incompatible materials : Not determined

10.6. Hazardous decomposition products

Hazardous decomposition products : Not determined

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD₅₀ : > 10500 mg/kg Mouse/Rabbit

Notes : ~ 92% of the mixture consists of components of unknown toxicity (Dermal).

Oral LD₅₀ : > 4900 mg/kg Rat/Mouse

Notes : ~87% of the mixture consists of components of unknown toxicity (Oral).

Inhalation LC₅₀ : > 1.5 mg/L/4H Rat

Notes : ~95% of the mixture consists of components of unknown toxicity (Inhalation)

Germ cell mutagenicity : The components in this product are not reported to produce mutagenic effects in humans.

Carcinogenicity : None of the components of this material are listed by IARC, NTP, or CA Prop 65 as carcinogens.

Reproductive toxicity : The components in this product are not reported to cause reproductive effects in humans.

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

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute) : Do not allow to enter sewers or drains that may lead to waterways.

12.2. Persistence and degradability

Persistence and degradability : Not classified

12.3. Bioaccumulative potential

Bioaccumulative potential : Not classified

12.4. Mobility in soil

Mobility in soil : Not available

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

12.6. Other adverse effects

Environmental data : No further relevant information available.

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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 : NAP

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : NAP

14.4. Packing group

Packing group : NAP

14.5. Environmental hazards

Marine pollutant #1 : NAP

14.6. Special precautions for user

ADR - road : NAP

RID - rail : NAP

IMDG - sea : NAP

IATA - air : NAP

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

Transport in bulk : NAP

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

General information : European Substances of very high concern (SVHC) according to REACH, Article 57: Contains no SVHC Substances.
CAN: All of the raw materials listed in Section 3 are on the Candian DSL list.

General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.
This product is not considered dangerous for transportation.

SECTION 16: Other information

Relevant H-statements (number and full-text) : Eye Irr., Cat. 2: Eye Irritation, Category 2
Not Classified, : Not Classified,

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STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Respiratory Tract Category 3
 Skin Irr., Cat. 2: Skin Irritation, Category 2
 Skin Sens., Cat. 1B: Skin Sensitization, Category 1B
 Skin Sens., Cat. 1: Skin Sensitization, Category 1
 H315: Causes skin irritation.
 H317: May cause an allergic skin reaction.
 H319: Causes serious eye irritation.
 H335: May cause respiratory irritation.

Prepared by

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Revision summary

: This SDS replaces the 09/06/2017 SDS. Revised: **Section 1**: MSDS No.

General statements

: NAP = Not Applicable
 NE = Not Established
 TLV = Threshold Limit Value
 PEL = Permittable exposure limits
 MAK = Maximum Workplace Concentration
 STEL = Short-term exposure limit
 STEV = Short-term exposure value
 TWA = Time Weighted Average
 PPE = Personal Protective Equipment

Manufacturer disclaimer

: FOR ORTHO 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.