

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010
Orthodontic Use

ULTRADENT
PRODUCTS, INC.

Date Issued : 01/21/2010
SDS No : 75-001.09
Date Revised : 03/12/2018
Revision No : 10

Opal® Bond™ Flow, Opal® Bond™ Flow Blue

SECTION 1 : Identification of the substance/preparation and of the company/undertaking

1.1. Product identifier

Product code : AZ/71161, BL/71050
Product name : Opal® Bond™ Flow, Opal® Bond™ Flow Blue
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

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.

Precautionary statement(s)

Prevention : P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response : P305: IF IN EYES:

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010
Orthodontic Use



Date Issued : 01/21/2010
SDS No : 75-001.09
Date Revised : 03/12/2018
Revision No : 10

Opal® Bond™ Flow, Opal® Bond™ Flow Blue

P351: Rinse cautiously with water for several minutes.
P315: Get immediate medical advice/attention.
P302+P352: IF ON SKIN: Wash with plenty of soap & water.
P332+P313: If skin irritation occurs: Get medical advice/attention.
P301: IF SWALLOWED:
P312: Call a POISON CENTER or doctor/physician if you feel unwell.
P330: Rinse mouth.
P331: Do NOT induce vomiting.

Storage : P273: Avoid release to the environment.
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	< 10	H315; H317; H319
Bis EMA	41637-38-1	NAP	< 15	Skin Irr.,Cat. 2; Skin Sens.,Cat. 1; Eye Irr.,Cat. 2; STOT SE,CAT 3; H315; H317; H319; H335
Triethylene glycol dimethacrylate	109-16-0	203-652-6	< 15	Not classified
Aluminum Oxide	1344-28-1	215-691-6	< 5	Not classified
Barium aluminosilicate glass powder	65997-17-3	NAP	< 43	Skin Irr.,Cat. 2; Eye Irr.,Cat. 2B; STOT SE,Cat. 3; H315; H319; H335

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes : Immediately flush eyes with plenty of water for at least 15 minutes. Get immediate medical attention.

Following skin : Remove contaminated clothing. Wash with soap and water. Get medical attention if irritation develops or persists.

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

SAFETY DATA SHEET
 according to Regulation (EC) No. 453/2010
 Orthodontic Use



Date Issued : 01/21/2010
 SDS No : 75-001.09
 Date Revised : 03/12/2018
 Revision No : 10

Opal® Bond™ Flow, Opal® Bond™ Flow Blue

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 : Contact may cause eye irritation.
Skin : May cause skin irritation.
Ingestion : None expected for this product.
Inhalation : None expected for this product.

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).

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

General procedures : Avoid contact with eyes, skin and clothing.

Handling : Use suitable protective equipment.

Storage : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

Shelf life : See product labeling

SAFETY DATA SHEET
 according to Regulation (EC) No. 453/2010
 Orthodontic Use



Date Issued : 01/21/2010
 SDS No : 75-001.09
 Date Revised : 03/12/2018
 Revision No : 10

Opal® Bond™ Flow, Opal® Bond™ Flow Blue

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

Barium aluminosilicate glass CAS 65997-17-3
 Maritime PEL: 15 mg/m³
 NIOSH REL 3 fibers/cm³ TWA (fibers with diameter < = 3.5 micrometers & length > = 10 micrometers) ; 5 mg/m³ TWA (total fibrous glass)

8.2. Exposure controls

Eye/face protection : Wear eye protection.
 Skin protection : Wear suitable protective clothing and gloves.
 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 : Resin paste
 Colour : Tan or blue
 Odour : Acrylic
 pH : NAP (non-aqueous)
 Specific gravity : Not determined

9.2. Other information

Additional information : No further information is 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

SAFETY DATA SHEET
 according to Regulation (EC) No. 453/2010
 Orthodontic Use



Date Issued : 01/21/2010
 SDS No : 75-001.09
 Date Revised : 03/12/2018
 Revision No : 10

Opal® Bond™ Flow, Opal® Bond™ Flow Blue

Hazardous polymerization : None

10.4. Conditions to avoid

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

Notes :

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

Carcinogenicity : None of the components are listed by IARC, NTP, or CA Prop 65 as carcinogens when used in the form in this mixture.

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.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

SAFETY DATA SHEET
 according to Regulation (EC) No. 453/2010
 Orthodontic Use



Date Issued : 01/21/2010
 SDS No : 75-001.09
 Date Revised : 03/12/2018
 Revision No : 10

Opal® Bond™ Flow, Opal® Bond™ Flow Blue

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 : This product is not considered dangerous for transportation.

SECTION 16: Other information

Relevant H-statements (number and full-text) : Eye Irr., Cat. 2B: Eye Irritation, Category 2B
 Eye Irr., Cat. 2: Eye Irritation, Category 2
 STOT SE, CAT 3: Target Organ Toxicity (Single exposure), Central Nervous System Category 3
 STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Respiratory Tract Category 3
 Skin Irr., Cat. 2: Skin Irritation, Category 2
 Skin Sens., Cat. 1: Skin Sensitization, Category 1
 H315: Causes skin irritation.
 H317: May cause an allergic skin reaction.

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Orthodontic Use



Date Issued : 01/21/2010

SDS No : 75-001.09

Date Revised : 03/12/2018

Revision No : 10

Opal® Bond™ Flow, Opal® Bond™ Flow Blue

H319: Causes serious eye irritation.
 H335: May cause respiratory irritation.

Prepared by

: Anu Kattoju

Revision summary

: This SDS replaces the 09/15/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 4:** NOTES TO PHYSICIAN. **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** . **Section 8:** . **Section 9:** COMMENTS, PERCENT VOLATILE, pH, SPECIFIC GRAVITY. **Section 11:** GENERAL COMMENTS, CARCINOGENICITY, GERM CELL MUTAGENICITY, REPRODUCTIVE TOXICITY. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION 12: Ecological information. **Section 14:** ROAD AND RAIL (ADR/RID), VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, UN number, Packing group, ADR - road, IMDG - sea, IATA - air. **Section 15:** COMMENTS, GENERAL COMMENTS, RoHS. **Section 16:** GENERAL STATEMENTS.

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.