

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



Date Issued : 07/18/2014
SDS No : 368-001.2
Date Revised : 09/24/2015
Revision No : 1

Opal® Bond™ MV

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

1.1. Product identifier

Product code : OV/71025
Product name : Opal® Bond™ MV
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

Opal® Orthodontics
 505 W 10200 S
 South Jordan, UT 84095

Distributor

MPG Service GmbH
 Gereonstrasse 34-36
 D-50670 Cologne, Germany
 Email: mpgservicekoeln@googlemail.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.

Danger symbols : Xi

R phrases : R36/38

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

Health : Eye Irritation, Category 2
 Skin Irritation, Category 2

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : Xi



Irritant

R&S statement(s) : R36/38: Irritating to eyes and skin.

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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:
 P351: Rinse cautiously with water for several minutes.
 P313: Get medical advice/attention.
 P306+P360: IF ON CLOTHING: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.
 P332+P313: If skin irritation occurs: Get medical advice/attention.
 P363: Wash contaminated clothing before reuse.
 P301: IF SWALLOWED:
 P331: Do NOT induce vomiting.
 P330: Rinse mouth.
 P312: Call a POISON CENTER or doctor/physician if you feel unwell.

Storage

: P273: Avoid release to the environment.

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

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Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Directive 67/548/EEC	Classification according to Regulation(EC) No 1272/2008 [CLP]
Bis-GMA	1565-94-2	216-367-7	< 35	Xi; R36/37/38; R22	H315; H319; H317
Bis EMA	41637-38-1	N/A	< 15	Xi; R36/37/38; R43	Skin Irr.,Cat. 2; Skin Sens.,Cat. 1; Eye Irr.,Cat. 2; STOT SE,CAT 3; H315; H317; H319; H335
Acetoacetoxyethyl Methacrylate	21282-97-3	244-311-1	< 20	Xi; R36/37/38; R43	Not classified
Aluminum Oxide	1344-28-1	215-691-6	< 10	Xi; R36/37	Not Classified

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** : Flush eye with water for 15 minutes. Get medical attention.
- Following skin** : Wash immediately with plenty of water. Remove contaminated clothing. If irritation persists seek medical attention. Wash contaminated clothing before using them.
- Following ingestion** : If swallowed Don't induce vomiting. Rinse mouth and seek medical advice if necessary.
- Following inhalation** : No specific treatment is necessary since this material is not likely to be hazardous by inhalation.

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

- Eyes** : Causes eye irritation.
- Skin** : Causes skin irritation.
- Ingestion** : May be harmful if swallowed.
- 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

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.

Fire fighting equipment : 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 : 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 : Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling : Use suitable protective equipment.

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 : Not Determined

8.2. Exposure controls

Eye/face protection : Wear eye protection.

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Skin protection : Wear suitable protective clothing and gloves.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Paste
Colour : White with slight to no yellowish tint

9.2. Other information

Percent volatile : Not Determined

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 : Heat, flames, ignition sources, direct light.

10.5. Incompatible materials

Incompatible materials : None known.

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

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) : Do not allow to enter sewers or drains that may lead to waterways.
96-hour LC₅₀ : Not Determined
48-hour EC₅₀ : Not Determined
96-hour EC₅₀ : Not Determined

12.2. Persistence and degradability

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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 : Do not flush to sewer.

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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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

Additional information : This product is not considered dangerous for transportation

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R22: Harmful if swallowed.
 R36/37/38: Irritating to eyes, respiratory system and skin.
 R36/37: Irritating to eyes and respiratory system.
 R43: May cause sensitization by skin contact.
 Eye Irr., Cat. 2: Eye Irritation, Category 2
 Not Classified, : Not Classified,
 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.
 H319: Causes serious eye irritation.
 H335: May cause respiratory irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 07/18/2014 SDS. Revised: **Section 1:** . **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 4:** INGESTION, SIGNS AND SYMPTOMS OF OVEREXPOSURE - INGESTION. **Section 5:** EXPLOSION HAZARDS, FIRE EXPLOSION, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 10:** HAZARDOUS DECOMPOSITION PRODUCTS, HAZARDOUS POLYMERIZATION, INCOMPATIBLE MATERIALS, STABLE, POSSIBILITY OF HAZARDOUS REACTIONS. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat) ACUTE. **Section 12:** AQUATIC TOXICITY (ACUTE). **Section 14:** ROAD AND RAIL (ADR/RID) - PROPER SHIPPING NAME ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, ADR - road, IMDG - sea, IATA - air. **Section 15:** COMMENTS, SECTION 15: Regulatory information. **Section 16:** Revision Summary, GENERAL STATEMENTS.

General statements : N/A= Not Applicable

Additional SDS information : Revision #:1

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

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