

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



**Date Issued :** 06/10/2011  
**SDS No :** 220-001.4  
**Date Revised :** 11/12/2015  
**Revision No :** 3

**Opal® Band™ Cement - Catalyst**

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

**1.1. Product identifier**

**Product code** : RY/71101  
**Product name** : Opal® Band™ Cement - Catalyst  
**Product description** : Catalyst for orthodontic cement

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

**Relevant identified uses** : Professional Orthodontic Cement

**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** : R36/37/38

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

**Health** : Eye Damage, Category 1  
 Skin Irritation, Category 2

**2.2. Label elements**

**Classification according to Directive 1999/45/EC**

**Hazard pictogram(s)** : Xi



Irritant

**R&S statement(s)** : R36/37/38: Irritating to eyes, respiratory system and skin.

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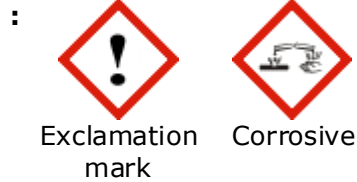


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**Classification according to Regulation(EC) No 1272/2008 [CLP]**

**Hazard pictogram(s)**



**Signal Word**

: DANGER

**Hazard statement(s)**

: H315: Causes skin irritation.  
 H318: Causes serious eye damage.

**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.  
 P337+P313: If eye irritation persists: Get medical advice/attention.  
 P302+P352: IF ON SKIN: Wash with plenty of soap and water.  
 P332+P313: If skin irritation occurs: Get medical advice/attention.

**Storage**

: P273: Avoid release to the environment.

**Disposal**

: P501: Dispose of in compliance with governmental regulations (EC 1975L0442-20/11/2003).

**2.3. Other hazards**

**Immediate concerns**

: May cause severe eye irritation.

**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	< 20	Xi; R36/37/38; R22	H315; H319; H317
Poly(ethylene glycol) diacrylate	26570-48-9	N/A	< 15	Xi; R36/37/38; R22; R43	Skin Irr.,Cat. 2; Skin Sens.,Cat. 1; EYE DMG.,Cat. 1; H315; H317; H318
Triethylene Glycol Dimethacrylate	109-16-0	203-652-6	< 10	Xi; R43	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** : Immediately flush eyes with plenty of water. Get medical attention, if irritation persists.
- Following skin** : Wash with soap and water. Get medical attention if irritation develops or persists.
- Following ingestion** : No special measures required.
- 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** : May cause skin irritation and sensitization.
- 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** : May cause severe eye irritation.

**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**

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**Hazardous combustion products :** Carbon Dioxide

**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(CO<sub>2</sub>)

**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 :** Wipe up with cloth, soap and water.

**Large spill :** Absorb with inert, damp non-combustible material, then flush area 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 :** Stable when stored and handled under recommended conditions.

**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 Cement

**SECTION 8: Exposure controls / personal protection**

**8.1. Control parameters**

**Control parameters :** Not Determined

**8.2. Exposure controls**

**Eye/face protection :** Wear eye protection

**Skin protection :** Wear suitable protective clothing and gloves.

**Respiratory protection :** In case of insufficient ventilation, wear suitable respiratory equipment.

**SECTION 9: Physical and chemical properties**

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**9.1. Information on basic physical and chemical properties**

**Physical state** : Liquid  
**Colour** : Yellow  
**Odour** : Acrylic

**9.2. Other information**

**Percent volatile** : Not Determined

**SECTION 10: Stability and reactivity**

**10.1. Reactivity**

**Reactivity** : Polymerization occurs when exposed to visible light, ultraviolet light or extreme heat.

**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** : Visible light, ultraviolet light, and extreme heat

**10.5. Incompatible materials**

**Incompatible materials** : None known.

**10.6. Hazardous decomposition products**

**Hazardous decomposition products** : Carbon Dioxide

**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 LC<sub>50</sub>** : Not Determined  
**48-hour EC<sub>50</sub>** : Not Determined  
**96-hour EC<sub>50</sub>** : 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** : Not defined

**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.  
 R43: May cause sensitization by skin contact.  
 EYE DMG., Cat. 1: Eye Damage, Category 1  
 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.  
 H318: Causes serious eye damage.  
 H319: Causes serious eye irritation.

**Prepared by** : Anu Kattoju

**Revision summary** : This SDS replaces the 12/17/2014 SDS. Revised: **Section 1:** . **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 4:** INGESTION, INHALATION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE ( INHALATION ). **Section 5:** EXPLOSION HAZARDS, FIRE EXPLOSION, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 10:** CONDITIONS TO AVOID, HAZARDOUS POLYMERIZATION, INCOMPATIBLE MATERIALS, STABLE, POSSIBILITY OF HAZARDOUS REACTIONS. **Section 11:** ACUTE ( ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat) ACUTE. **Section 12:** AQUATIC TOXICITY (ACUTE). **Section 14:** VESSEL (IMO/IMDG) - MARINE POLLUTANT #1. **Section 15:** COMMENTS, SECTION 15: Regulatory information. **Section 16:** GENERAL STATEMENTS.

**General statements** : N/A= Not Applicable

**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.