

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



Date Issued : 06/10/2011
SDS No : 219-001.4
Date Revised : 11/12/2015
Revision No : 3

Opal® Band™ Cement - Base

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

1.1. Product identifier

Product code : RW/71100
Product name : Opal® Band™ Cement - Base
Product description : Base 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 : R36/38

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

Health : Eye Irritation
 Skin Irritation

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)

: H315: Causes skin irritation.
 H319: Causes serious eye 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.
 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

: 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]
Triethylene Glycol Dimethacrylate	109-16-0	203-652-6	< 10	Xi; R43	Not classified
Bis-GMA	1565-94-2	216-367-7	< 20	Xi; R36/37/38; R22	H315; H319; H317

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

SECTION 4: First aid measures

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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** : 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.

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

- Eyes** : Causes eye irritation.
- Skin** : May cause skin irritation and sensitization.
- Ingestion** : Maybe 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

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** : 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(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** : Not Applicable

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.

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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 : 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 : Blue

Odour : Sweet

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Polymerization occurs when exposed to amine catalysts, metals, or pressure.

10.2. Chemical stability

Chemical stability : Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization : None

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10.4. Conditions to avoid

Conditions to avoid : Pressure

10.5. Incompatible materials

Incompatible materials : Amine catalysts, metals

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

Toxicity : Not Determined

Aquatic toxicity (acute)

96-hour LC₅₀ : Not Determined

48-hour EC₅₀ : Not Determined

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 defined

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

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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

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.
 H315: Causes skin irritation.
 H317: May cause an allergic skin reaction.
 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, SIGNS AND SYMPTOMS OF

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OVEREXPOSURE - INGESTION. **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 LD₅₀ (rat), INHALATION LC₅₀ (rat) ACUTE. **Section 14:** VESSEL (IMO/IMDG) - MARINE POLLUTANT #1. **Section 15:** COMMENTS, SECTION 15: Regulatory information. **Section 16:** GENERAL STATEMENTS.

General statements

Manufacturer disclaimer

: N/A= Not Applicable

: 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.