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

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

R&S statement(s) : R36/38: Irritating to eyes and skin.
Opal® Band™ Cement - Base

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**

**2.3. Other hazards**

Immediate concerns:
- None

**SECTION 3: Composition / information on ingredients**

3.1. Substances

Not Applicable

3.2. Mixtures

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS</th>
<th>EINECS No.</th>
<th>Wt.%</th>
<th>Classification according to Directive 67/548/EEC</th>
<th>Classification according to Regulation(EC) No 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triethylene Glycol Dimethacrylate</td>
<td>109-16-0</td>
<td>203-652-6</td>
<td>&lt; 10</td>
<td>Xi; R43</td>
<td>Not classified</td>
</tr>
<tr>
<td>Bis-GMA</td>
<td>1565-94-2</td>
<td>216-367-7</td>
<td>&lt; 20</td>
<td>Xi; R36/37/38; R22</td>
<td>H315; H319; H317</td>
</tr>
</tbody>
</table>

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 : 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 firefighting. 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.
### Opal® Band™ Cement - Base

**6.4. Reference to other sections**

Reference to other sections : Not Applicable

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

<table>
<thead>
<tr>
<th>Handling</th>
<th>Stable when stored and handled under recommended conditions.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage</td>
<td>See product labeling.</td>
</tr>
</tbody>
</table>

#### 7.2. Conditions for safe storage, including any incompatibilities

<table>
<thead>
<tr>
<th>Shelf life</th>
<th>See product labeling</th>
</tr>
</thead>
</table>

#### 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

<table>
<thead>
<tr>
<th>Eye/face protection</th>
<th>Wear eye protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin protection</td>
<td>Wear suitable protective clothing and gloves.</td>
</tr>
<tr>
<td>Respiratory protection</td>
<td>Good general ventilation should be sufficient to control airborne levels.</td>
</tr>
</tbody>
</table>

### SECTION 9: Physical and chemical properties

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

<table>
<thead>
<tr>
<th>Physical state</th>
<th>Paste</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>Blue</td>
</tr>
<tr>
<td>Odour</td>
<td>Sweet</td>
</tr>
</tbody>
</table>

#### 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 LC_{50} : Not Determined
48-hour EC_{50} : Not Determined
96-hour EC_{50} : 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
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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
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 LD\textsubscript{50} (rat)), INHALATION LC\textsubscript{50} (rat) 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.