

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Orthodontic Use



Date Issued : 06/11/2011

SDS No : 221-001.06

Date Revised : 04/10/2018

Revision No : 5

Opal® Band™ Cement- Mixed**SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

Product code : RW/71100, RY/71101
Product name : Opal® Band™ Cement- Mixed
Product description : Orthodontic cement made up of equal parts of a base and catalyst.

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**

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 Damage, Category 1
 Skin Sensitization, Category 1

2.2. Label elements**Classification according to Regulation(EC) No 1272/2008 [CLP]**

Hazard pictogram(s) :  
 Exclamation mark Corrosive

Signal Word : DANGER

Hazard statement(s) : H319: Causes serious eye irritation.
 H317: May cause an allergic skin reaction.

Precautionary statement(s)

Prevention : P280: Wear protective gloves/protective clothing/eye protection/face protection.
 P261: Avoid breathing vapours.
 P272: Contaminated work clothing should not be allowed out of the workplace.

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



Date Issued : 06/11/2011
 SDS No : 221-001.06
 Date Revised : 04/10/2018
 Revision No : 5

Opal® Band™ Cement- Mixed

Response : P302+P352: IF ON SKIN: Wash with plenty of soap & water.
 P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
 P363: Wash contaminated clothing before reuse.
 P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes.
 Remove contact lenses, if present and easy to do. Continue rinsing.
 P310: Immediately call a POISON CENTER or doctor/physician.

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	< 20	H315; H317; H319
Poly(ethylene glycol) diacrylate	26570-48-9	607-960-5	< 10	Skin Irr.,Cat. 2; Skin Sens.,Cat. 1; EYE DMG.,Cat. 1; H315; H317; H318
TEGDMA	109-16-0	203-652-6	< 10	Skin Sens.,Cat. 1B; H317
Blue Spersastain	NAP	NAP	< 1	H315; H317; H335; H303

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes : Remove contact lenses, if present and easy to do. Flush eyes with plenty of water for at least 15 minutes, opening the eyelids fully. Seek immediate medical advice.

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

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.

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



Date Issued : 06/11/2011
 SDS No : 221-001.06
 Date Revised : 04/10/2018
 Revision No : 5

Opal® Band™ Cement- Mixed

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 : NAP

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media : Water spray, fog, or mist, foam, dry chemical, carbon dioxide (CO₂)

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.

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 : NAP

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling : Keep away from light, heat, and pressure

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 : Contains no substances with occupational exposure limit values.

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



Date Issued : 06/11/2011
 SDS No : 221-001.06
 Date Revised : 04/10/2018
 Revision No : 5

Opal® Band™ Cement- Mixed

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. In case of insufficient ventilation, wear suitable respiratory equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Paste
Colour : White to Beige
Odour : Acrylic

9.2. Other information

Additional information : No further relevant information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Polymerization occurs when exposed to amine catalysts, metals, pressure, light and 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 : Pressure, light, heat

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

Dermal LD₅₀ : > 3050 mg/kg Rabbit/Rat/Mouse
Notes : ~80% of the mixture consists of components of unknown toxicity (Dermal)
Oral LD₅₀ : > 3050 mg/kg Rat OECD Test Guideline
Notes : ~ 78% of the mixture consists of components of unknown toxicity. (Oral)
Inhalation LC₅₀ : > 17.0 mg/l/4H Rat/Guinea Pig
Notes : 93% of the mixture consists of components of unknown toxicity (inhalation)
Germ cell mutagenicity : The components in this product are not reported to produce mutagenic effects in

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



Date Issued : 06/11/2011
 SDS No : 221-001.06
 Date Revised : 04/10/2018
 Revision No : 5

Opal® Band™ Cement- Mixed

humans.

Carcinogenicity : WARNING! Spersastain Blue (Cobalt & Cobalt Compounds) are listed as potential carcinogens on the raw material SDS, IARC, and NTP.

Reproductive toxicity : The components in this product are not reported to cause reproductive effects in humans.

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)

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

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



Date Issued : 06/11/2011
 SDS No : 221-001.06
 Date Revised : 04/10/2018
 Revision No : 5

Opal® Band™ Cement- Mixed

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.
 All of the raw materials listed on the composition table are on the Canadian 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 : WARNING! Spersastain Blue (Cobalt & Cobalt Compounds) are listed on the raw material SDS, iARC, and NTP as potential carcinogens.

SECTION 16: Other information

Relevant H-statements (number and full-text) : EYE DMG., Cat. 1: Eye Damage, Category 1
 Skin Irr., Cat. 2: Skin Irritation, Category 2
 Skin Sens., Cat. 1B: Skin Sensitization, Category 1B
 Skin Sens., Cat. 1: Skin Sensitization, Category 1
 H303: May be harmful if swallowed.
 H315: Causes skin irritation.
 H317: May cause an allergic skin reaction.
 H318: Causes serious eye damage.
 H319: Causes serious eye irritation.
 H335: May cause respiratory irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 09/11/2017 SDS. Revised: **Section 1**: MSDS No.

General statements : NAP = Not Applicable
 NE = Not Established
 TLV = Threshold Limit Value
 PEL = Permissible 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

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



Date Issued : 06/11/2011
SDS No : 221-001.06
Date Revised : 04/10/2018
Revision No : 5

Opal® Band™ Cement- Mixed

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.