

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Orthodontic Use



Date Issued : 06/10/2011

SDS No : 219-001.06

Date Revised : 04/10/2018

Revision No : 5

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**

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 : Skin Sensitization, Category 1

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

Hazard pictogram(s) :



Exclamation
mark

Signal Word : WARNING

Hazard statement(s) : 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.

Response : P302+P352: IF ON SKIN: Wash with plenty of soap & water.

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Storage : P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
P363: Wash contaminated clothing before reuse.

Disposal : P273: Avoid release to the environment.
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]
TEGDMA	109-16-0	203-652-6	< 10	Skin Sens.,Cat. 1B; H317
Bis-GMA	1565-94-2	216-367-7	< 20	H315; H317; H319
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 : Flush eyes with water. Get medical attention if irritation develops or persists.

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 : Not needed for normal use.

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 : May cause 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 : NAP

SECTION 5: Fire fighting measures

5.1. Extinguishing media

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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 : 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 : Contains no substances with occupational exposure limit values.

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

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Appearance : Medium viscosity paste
Colour : Blue
Odour : Sweet
pH : NAP (non-aqueous)

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, 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

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

Dermal LD₅₀ : > 2300 mg/kg Rabbit/Rat/Mouse

Notes : ~80% of the mixture consists of components of unknown toxicity (Dermal)

Oral LD₅₀ : > 2600 mg/kg Rat OECD Test Guideline

Notes : ~79% of the mixture consists of components of unknown toxicity (Oral).

Inhalation LC₅₀ : > 34 mg/l/4H Rat/Guinea Pig

Notes : ~ 88% 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 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.

Other information : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

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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

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

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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 as potential carcinogens on the raw material SDS, IARC, and NTP.

SECTION 16: Other information

- Relevant H-statements (number and full-text)** : Skin Sens., Cat. 1B: Skin Sensitization, Category 1B
 H303: May be harmful if swallowed.
 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 09/11/2017 SDS. Revised: **Section 1**: MSDS No.
- General statements** : NAP = Not Applicable
 NE = Not Established
 TLV = Threshold Limit Value
 PEL = Permittable 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 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.