

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 08/25/2014

SDS No : 370-001.2

Date Revised : 06/08/2015

Revision No : 1

Mosaic™ Universal Composite(all shades)**SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier****Product code** : 4760-4779, 4780-4799, 4801, S4801, 4802, S4802, 4803**Product name** : Mosaic™ Universal Composite(all shades)**Product description** : Dental Composite**1.2. Relevant identified uses of the substance or mixture and uses advised against****Relevant identified uses** : Professional Dental Restorative Material**1.3. Details of the supplier of the safety data sheet****Manufacturer**Ultradent Products, Inc.
505 W. 10200 S.
South Jordan, UT 84095**Distributor**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 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,R43**Classification according to Regulation (EC) No 1272/2008 [CLP]****Health** : Eye Irritation
Skin Irritation
Skin Sensitization**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.
R43: May cause sensitization by skin contact.

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:

Exclamation
mark**Signal Word**

: WARNING

Hazard statement(s)

: H316: Causes mild skin irritation.
 H317: May cause an allergic skin reaction.
 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.
 P303+P361+P353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
 P315: Get immediate medical advice/attention.
 P363: Wash contaminated clothing before reuse.
 P301: IF SWALLOWED:
 P331: Do NOT induce vomiting.
 P304: IF INHALED:
 P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
 P340: Remove person to fresh air and keep comfortable for breathing.

Storage

: P103: Read label before use.

Disposal

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

2.3. Other hazards**Immediate concerns**

: Not Applicable

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	≤ 10	Xi; R36/37/38; R22	H315; H319; H317
Bis-PEGDDMA	41637-38-1	N/A	≤ 10	Xi; R36/37/38; R43	Skin Irr.,Cat. 2; Skin Sens.,Cat. 1; Eye Irr.,Cat. 2; STOT SE,Cat 3; H315; H317; H319; H335
PEGDMA	25852-47-5	N/A	< 5	Xi; R37/38; R41	Not classified
TEGDMA	109-16-0	203-652-6	< 5	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** : Flush eyes with water. Get medical attention if irritation develops or persists.
- Following skin** : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately. Thoroughly wash or discard clothing and shoes before reuse.
- Following ingestion** : DO NOT induce vomiting unless directed to do so by medical personnel. Give victim two glasses of water. Never give anything by mouth to an unconscious person.
- Following inhalation** : If inhaled, remove to fresh air. If breathing becomes difficult, call a physician.

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

- Eyes** : Moderately irritating to the eyes.
- Skin** : May cause skin irritation and sensitization.
- Ingestion** : Ingestion of this material can cause abdominal pain, stomach upset, nausea, vomiting and diarrhea.
- Inhalation** : Inhalation of this may cause cough, sneezing, nasal discharge,

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headache, hoarseness, and nose and throat pain.

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 Monoxide and Carbon Dioxide**Explosion hazards** : Not Determined**Fire explosion** : Not Determined**Sensitive to static discharge** : Not Determined**Sensitivity to impact** : Not Determined**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, fog or foam, dry chemical**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****Land spill** : Place in an appropriate container for disposal. Dispose collected material as soon as possible.**6.3. Methods and material for containment and cleaning up****Large spill** : Eliminate all sources of ignition. Evacuate unprotected and untrained personnel from hazard area. Ventilate area with fresh air. Collect in approved disposal container.**6.4. Reference to other sections****Reference to other sections** : Not Applicable**SECTION 7: Handling and storage****7.1. Precautions for safe handling****Handling** : Keep away from heat and flame.**Storage** : See product labeling.**7.2. Conditions for safe storage, including any incompatibilities****Shelf life** : See product labeling

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Mosaic™ Universal Composite(all shades)**7.3. Specific end use(s)**

Specific end use(s) : Professional Dental Restorative Material

SECTION 8: Exposure controls / personal protection**8.1. Control parameters**

Control parameters : Not Determined

8.2. Exposure controls

Eye/face protection : Wear safety glasses with side shields

Skin protection : Wear suitable protective clothing and gloves.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state : Paste

Colour : Color dependent

Odour : Slight acrylic odor

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity**10.1. Reactivity**

Reactivity : Light exposure initiates polymerization

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 : Light

10.5. Incompatible materials

Incompatible materials : None known.

10.6. Hazardous decomposition products

Hazardous decomposition products : Carbon Monoxide and 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.

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Mosaic™ Universal Composite(all shades)**SECTION 12: Ecological information****12.1. Toxicity****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)**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

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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.
 R37/38: Irritating to respiratory system and skin.
 R41: Risk of serious damage to eyes.
 R43: May cause sensitization by skin contact.
 Eye Irr., Cat. 2: Eye Irritation, Category 2
 STOT SE, Cat 3: Target Organ Toxicity (Single exposure), respiratory tract, Category 3
 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.
 H319: Causes serious eye irritation.
 H335: May cause respiratory irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 08/25/2014 SDS. Revised: **Section 1:** PRODUCT CODE/ PART #. **Section 2:** . **Section 3:** Wt.%. **Section 7:** HANDLING. **Section 10:** HAZARDOUS POLYMERIZATION, STABLE. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat) ACUTE. **Section 14:** . **Section 15:** COMMENTS, SECTION 15: Regulatory information. **Section 16:** Revision Summary, GENERAL STATEMENTS.

General statements : N/A= Not Applicable

Additional SDS information : Revision #:1

Manufacturer disclaimer : FOR DENTAL 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

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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.