

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

Hazard pictogram(s)


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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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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SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute)

96-hour LC₅₀ : Not Determined48-hour EC₅₀ : Not Determined96-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.