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. 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]
- Health: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.
  - Eye Irritation, Category 2
  - Skin Sensitization, Category 1
  - Skin Irritation, Category 2
  - Acute Toxicity (Oral), Category 4

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.
  - H319: Causes serious eye irritation.
  - H315: Causes skin irritation.

Precautionary statement(s)
Mosaic™ Universal Composite (all shades)

Prevention:
- P280: Wear protective gloves/protective clothing/eye protection/face protection.
- P264: Wash hands thoroughly after handling.
- P261: Avoid breathing dust/fumes/gas/mist/vapours/spray.
- P272: Contaminated work clothing should not be allowed out of the workplace.

Response:
- P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P337+P313: If eye irritation persists: Get medical advice/attention.
- P302+P352: IF ON SKIN: Wash with plenty of soap and water.
- P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
- P362: Take off contaminated clothing.
- P363: Wash contaminated clothing before reuse.

Disposal:

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS</th>
<th>EINECS No.</th>
<th>Wt.%</th>
<th>Classification according to Regulation(EC) No 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bis-GMA</td>
<td>1565-94-2</td>
<td>216-367-7</td>
<td>≤ 10</td>
<td>H315; H317; H319</td>
</tr>
<tr>
<td>Bis-PEGDDMA</td>
<td>41637-38-1</td>
<td>N/A</td>
<td>≤ 10</td>
<td>Skin Irr.,Cat. 2; Skin Sens.,Cat. 1; Eye Irr.,Cat. 2; STOT SE,Cat 3; H315; H317; H319; H335</td>
</tr>
<tr>
<td>TEGDMA</td>
<td>109-16-0</td>
<td>203-652-6</td>
<td>&lt; 5</td>
<td>Skin Sens.,Cat. 1B; H317</td>
</tr>
</tbody>
</table>

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. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

Following skin:
- Wash with soap and water. Get medical attention if irritation develops or persists.

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

**Mosaic™ Universal Composite (all shades)**

<table>
<thead>
<tr>
<th>Eyes</th>
<th>May cause eye irritation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin</td>
<td>May cause skin irritation and sensitization.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Ingestion of this material can cause abdominal pain, stomach upset, nausea, vomiting and diarrhea.</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Inhalation of this may cause cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.</td>
</tr>
</tbody>
</table>

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, fog or foam, dry chemical

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products : Carbon Monoxide and 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

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 : NAP

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

7.3. Specific end use(s)

Specific end use(s) : Professional Dental Restorative Material
# SAFETY DATA SHEET

Mosaic™ Universal Composite (all shades)

## SECTION 8: Exposure controls / personal protection

### 8.1. Control parameters

**Control parameters:** None

### 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

**Appearance:** High viscosity

**Colour:** Color dependent

**Odour:** Slight acrylic odor

**pH:** NAP (non-aqueous)

**Specific gravity:** 1.8 - 2.1

### 9.2. Other information

**Additional information:** No further relevant information available.

## 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**

**Dermal LD$_{50}$:** > 1800 mg/kg Mouse/Rat

**Notes:** 95% of the mixture consists of components of unknown toxicity (Dermal).
Mosaic™ Universal Composite (all shades)

Oral LD₉₀ : > 1200 mg/kg Rat

Notes : 95% of the mixture consists of components of unknown toxicity (Oral).

Inhalation LC₅₀ : Not able to calculate ATE mix (inhalation) due to lack of data on the components.

Germ cell mutagenicity : The components in this product are not reported to produce mutagenic effects in humans.

Carcinogenicity : None of the components of this material are listed by IARC, NTP, or CA Prop 65 as carcinogens.

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.

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute) : No specific hazards are encountered when product is used according to recommendations.

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


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

Mosaic™ Universal Composite (all shades)

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

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
General information : Substances of very high concern (SVHC) according to REACH, Article 57:
Contains no SVHC substances.

General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2. Chemical safety assessment
Chemical safety assessment : See Section 11
Additional information : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.
This product is not considered dangerous for transportation.

SECTION 16: Other information

Relevant H-statements (number and full text) : Eye Irr., Cat. 2: Eye Irritation, Category 2
STOT SE, Cat 3: Target Organ Toxicity (Single exposure), Category 3
Skin Irr., Cat. 2: Skin Irritation, Category 2
Skin Sens., Cat. 1B: Skin Sensitization, Category 1B
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 06/08/2015 SDS. Revised: Section 1: MSDS No. Section 2: EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. Section 4: EYES, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE - EYES SKIN. Section 5: EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. Section 6: . Section 8: . Section 9: APPEARANCE, COMMENTS,
SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
Dental Use

Date Issued : 08/25/2014
SDS No : 370-001.3
Date Revised : 03/27/2017
Revision No : 2

Mosaic™ Universal Composite (all shades)

PERCENT VOLATILE, pH, SPECIFIC GRAVITY. Section 11: ACUTE (DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat) ACUTE, GENERAL COMMENTS, CARCINOGENICITY, GERM CELL MUTAGENICITY, REPRODUCTIVE TOXICITY. Section 12: CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION 12: Ecological information. Section 14: ROAD AND RAIL (ADR/RID), VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, UN number, Packing group, ADR - road, IMDG - sea, IATA - air. Section 15: COMMENTS, GENERAL COMMENTS, RoHS. Section 16: Revision Summary, GENERAL STATEMENTS.

General statements
NAP = Not Applicable

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 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.