

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)**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]**

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Health : 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)

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Mosaic™ Universal Composite (all shades)

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| 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 | : P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-21/11/2003) |

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 | ≤ 10 | H315; H317; H319 |
| Bis-PEGDDMA | 41637-38-1 | N/A | ≤ 10 | Skin Irr.,Cat. 2; Skin Sens.,Cat. 1; Eye Irr.,Cat. 2; STOT SE,Cat 3; H315; H317; H319; H335 |
| TEGDMA | 109-16-0 | 203-652-6 | < 5 | Skin Sens.,Cat. 1B; H317 |

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



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 SDS No : 370-001.3
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 Revision No : 2

Mosaic™ Universal Composite (all shades)

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| Eyes | : May cause eye irritation. |
| 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, headache, hoarseness, and nose and throat pain. |

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
 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)

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 LD₅₀ : > 1800 mg/kg Mouse/Rat

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

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)

| | |
|-----------------------------------|--|
| Oral LD₅₀ | : > 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

| | |
|------------------------|---|
| 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)

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)

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
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 Dental Use



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 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.