

SAFETY DATA SHEET

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



Date Issued : 04/27/2010
SDS No : 305-001.04
Date Revised : 05/07/2018
Revision No : 3

Emiluma™ Transparent Silicone

SECTION 1 : Identification of the substance/preparation and of the company/undertaking

1.1. Product identifier

Product code : 61500
Product name : Emiluma™ Transparent Silicone
Product description : Transparent Silicone

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Professional Orthodontic Indirect Bonding System, Part 2 of 2

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]

: This mixture is not classified as hazardous according to Regulation(EC) No 1272/2008 [CLP].

Health : Not Classified

2.2. Label elements

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

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.
P302+P352: IF ON SKIN: Wash with plenty of soap & water.
P332+P313: If skin irritation occurs: Get medical advice/attention.

Storage : P103: Read label before use.

Disposal : P501: Dispose of in compliance with governmental regulation. (EC1975L0442-20/11/2003)

2.3. Other hazards

Immediate concerns : None

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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]
Silicone	NAP	N/AP	100	Not classified

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes : Flush eye with water for 15 minutes. Get medical attention.
Following skin : Wash with soap and water.
Following ingestion : Do not try to vomit. Drink one cup of water.
Following inhalation : Remove to fresh air and seek medical assistance.

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

Eyes : Irritating to eyes.
Skin : May cause skin irritation.
Ingestion : May be harmful if swallowed.
Inhalation : May be harmful if inhaled.

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 : Foam, CO₂, or Fire Extinguishing Powder

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products : None known.

5.3. Advice for firefighters

Fire fighting procedures : As in any fire, wear self-contained breathing apparatus pressure-demand, (MSHA/NIOSH approved or equivalent) and full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General procedures : Refer to Section 8 for Personal Protective Equipment.
Special protective equipment : Do not enter the treatment area, if protective outer wear is not worn.

6.2. Environmental precautions

Water spill : Avoid going into the drain sewer system.

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6.3. Methods and material for containment and cleaning up

Large Spill : Dispose following local regulations.

6.4. Reference to other sections

Additional information : Secondary prevention measures : Avoid fire.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

General procedures : Caution: No smoking. Wear eye mask, and gloves.
Handling : Make sure that there is proper air ventilation space and eye wash station.
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 Indirect Bonding System, Part 2 of 2

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Not yet known

8.2. Exposure controls

Eye/face protection : Not required.
Skin protection : Gloves : No Data
 Skin Protection: Gown and boots are needed in case of large spills.
Respiratory protection : NAP

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Translucent
Colour : Colorless
Odour : Faint odor
Solubility in water : Insoluble
Auto-ignition temperature : 450°C
Viscosity : NAP

9.2. Other information

Additional information : Ignition Temperature: 300° C

SECTION 10: Stability and reactivity

10.1. Reactivity

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Reactivity : Stable

10.2. Chemical stability

Chemical stability : Substantially stable but on contact with a strong acid or alkali the substance polymerizes or decomposes.

10.3. Possibility of hazardous reactions

Hazardous polymerization : None

10.4. Conditions to avoid

Conditions to avoid : Heat, fire

10.5. Incompatible materials

Incompatible materials : Strong acids or Strong alkalis

10.6. Hazardous decomposition products

Hazardous decomposition products : Dangerous degradation products
 CO, CO₂, SiO₂
 If the temperature is more than 150° C, formaldehyde appears.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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

SECTION 12: Ecological information

12.1. Toxicity

Toxicity : Water environment harmful effect
 Fish (Acute) : NAP
 Water Invertebrates: NAP
 Fish: NAP
 Water invertebrates: NAP
 Water toxicity: NAP

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

12.2. Persistence and degradability

Persistence and degradability : NAP

12.3. Bioaccumulative potential

Bioaccumulative potential : Not classified

12.4. Mobility in soil

Mobility in soil : Sandbag migratory potential: NAP

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Conclusion(I) The substance does not fulfill the PBT and vPvB criteria for screening assessment there is no indications of P or B properties.

12.6. Other adverse effects

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Environmental data : Harmful effect to Ozone Layer: NAP
 Others: NAP

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

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

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

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : Registration condition
 AICS: Registered
 EU: Registered
 ENCS: Registered
 IECSC: Registered
 KECl: Registered
 DSL: Not Registered
 ND SL: Not Registered

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PICCS: Registered
 TSCA: Registered
 Taiwan: Not Registered
 This product is not considered dangerous for transportation.

SECTION 16: Other information

- Prepared by** : Anu Kattoju
- Revision summary** : This SDS replaces the 07/08/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** . **Section 3:** Wt.%. **Section 4:** EYES, INGESTION, INHALATION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE (INGESTION, INHALATION, SKIN), SKIN. **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** COMMENTS, LARGE SPILL, SMALL SPILL, SPECIAL PROTECTIVE EQUIPMENT, WATER SPILL, . **Section 7:** GENERAL PROCEDURES, HANDLING. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT (EYES AND FACE, RESPIRATORY), . **Section 9:** COMMENTS, FLASHPOINT AND METHOD, PERCENT VOLATILE, PHYSICAL STATE, VISCOSITY. **Section 10:** CONDITIONS TO AVOID, HAZARDOUS DECOMPOSITION PRODUCTS. **Section 11:** ACUTE, GENERAL COMMENTS. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, 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 16:** GENERAL STATEMENTS.
- General statements** : NAP = Not Applicable
- 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.