

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 07/26/2012

SDS No : 257-001.2

Date Revised : 07/14/2015

Revision No : 1

Clone™ Bite**SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

Product code : Catalog Part#7600
Product name : Clone™ Bite
Product description : Bite registration material

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

Relevant identified uses : Professional Dental Impression 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.
 This material is not considered hazardous to health.

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

Health : Not Classified

2.2. Label elements**Classification according to Regulation (EC) No 1272/2008 [CLP]**

Hazard statement(s) : 8768US4H: This Material Is Not Considered To Be Hazardous To Health.

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 and water.
 P332+P313: If skin irritation occurs: Get medical advice/attention.
 P304: IF INHALED:

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Storage : P312: Call a POISON CENTER/doctor if you feel unwell.
P340: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

Disposal : P273: Avoid release to the environment.
P501: Dispose of in compliance with governmental regulation.(EC 1975L0442-10/11/2003)

2.3. Other hazards

Immediate concerns : None

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

| Chemical Name | CAS | EINECS No. | Wt. % | Classification according to Directive 67/548/EEC | Classification according to Regulation (EC) No 1272/2008 [CLP] |
|-----------------------------|------------|------------|-------|--|--|
| Silica, Cristobalite | 14464-46-1 | 238-455-4 | ≤ 15 | Xn; R48/20 | STOT RE,Cat 1; H372 |
| Methylhydrogenopolysiloxane | 68988-57-8 | 273-531-0 | ≤ 2 | F; R10 | Flam. Liq.,CAT 3; H226 |

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 : Immediately flush eyes with plenty of water. Get medical attention, if irritation persists.

Following skin : Flush skin with large amounts of water. Seek medical attention if irritation develops and persists.

Following ingestion : No specific hazards are encountered under normal product use.

Following inhalation : Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

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

Eyes : Mildly irritating to eyes.

Skin : Non-irritating to the skin.

Ingestion : None expected for this product.

Inhalation : Prolonged inhalation may be harmful to health.

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Control parameters : Not Determined

8.2. Exposure controls

Eye/face protection : Wear eye protection

Skin protection : Wear suitable protective clothing and gloves.

Respiratory protection : Use only in well-ventilated areas.

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

Physical state : Gel

Colour : Orange

Odour : Bubblegum

Solubility in water : Insoluble

9.2. Other information

Percent volatile : Not Determined

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

Reactivity : Stable

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 : Not Determined

10.5. Incompatible materials

Incompatible materials : Not Determined

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

SECTION 11: Toxicological information**11.1. Information on toxicological effects****Acute**Dermal LD₅₀ : Not Determined

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Oral LD₅₀ : Not Determined
Inhalation LC₅₀ : Not Determined

SECTION 12: Ecological information

12.1. Toxicity

Toxicity : Information not available
Aquatic toxicity (acute) : Do not allow to enter sewers or drains that may lead to waterways.
96-hour LC₅₀ : Not Determined
48-hour EC₅₀ : Not Determined
96-hour EC₅₀ : Not Determined

12.2. Persistence and degradability

Persistence and degradability : Cristobalite
 Not rapidly biodegradable

12.3. Bioaccumulative potential

Bioaccumulative potential : Information not available

12.4. Mobility in soil

Mobility in soil : Information not available

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0.1%.

12.6. Other adverse effects

Environmental data : Not 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 : 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

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Relevant R-phrases and/or H-statements (number and full text) : R10: Flammable.
 R48/20: Harmful : danger of serious damage to health by prolonged exposure through inhalation.
 Flam. Liq., CAT 3: Flammable Liquids, Category 3
 STOT RE, Cat 1: Target Organ Toxicity (Repeated exposure), lungs, Category 1
 H226: Flammable liquid and vapour.
 H372: Causes damage to lungs.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 07/26/2012 SDS. Revised: **Section 1:** GENERAL USE, PREPARED BY. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **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, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** GENERAL PROCEDURES, . **Section 7:** HANDLING, SHELF LIFE, STORAGE, . **Section 8:** PERSONAL PROTECTIVE EQUIPMENT (EYES AND FACE), . **Section 9:** COLOR, ODOR, PERCENT VOLATILE, PHYSICAL STATE. **Section 10:** CONDITIONS TO AVOID, HAZARDOUS DECOMPOSITION PRODUCTS, HAZARDOUS POLYMERIZATION, INCOMPATIBLE MATERIALS, STABLE. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat)), COMMENTS. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ECOTOXICOLOGICAL

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INFORMATION, 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) (ROAD AND RAIL (ADR/RID), 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 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 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.