

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 25.09.2019

Revision: 12.11.2018

**1 Identification of the substance/mixture and of the company/undertaking**

- **Product identifier**
- **Trade name:** Clone™ Bite - Base
- **Article number:** 7600
- **Index number:** SDS 257-001.03
- **Relevant identified uses of the substance or mixture and uses advised against**  
Professional Dental Impression Material
- **Application of the substance / the mixture** Professional Dental Impression Material
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ultradent Products Inc.  
505 W. Ultradent Drive (10200 S)  
South Jordan, UT 84095-3942  
USA  
onlineordersupport@ultradent.com
  
- **EC Responsible Person**  
Ultradent Products GmbH  
Am Westhoyer Berg 30  
51149 Cologne Germany  
Email: infoDe@ultradent.com  
Emergency Phone: +49(0)2203-35-92-0
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**  
CHEMTREC (NORTH AMERICA) : (800) 424-9300  
(INTERNATIONAL) : +(703) 527-3887

**2 Hazards identification**

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product is not classified, according to the CLP regulation.

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- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The Regulation EC 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5(d). Therefore, the product is exempted from the CLP labelling requirements, and no SDS is required by Regulation 1907/2006, Art 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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### 3 Composition/information on ingredients

- **Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 14464-46-1	Cristobalite	<20%
EINECS: 238-455-4	⚠ STOT RE 1, H372	
CAS: 68391-04-8	Amines, C12-18-Alkyldimethyl	<0.2%
EINECS: 269-923-6	⚠ Skin Corr. 1B, H314; ⚠ Eye Dam. 1, H318; ⚠ Aquatic Acute 1, H400; ⚠ Acute Tox. 4, H302	
CAS: 123-92-2	Isopentyl Acetate	<0.2%
EINECS: 204-662-3	⚠ Flam. Liq. 3, H226	

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 4 First aid measures

- **Description of first aid measures**
- **After inhalation:**  
Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.
- **After skin contact:**  
Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.
- **After eye contact:**  
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.
- **After swallowing:**  
Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**  
Specific information on symptoms and effects caused by the product are unknown.
- **Indication of any immediate medical attention and special treatment needed** Information not available

### 5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
Fire-extinguishing powder  
Water  
Foam  
Carbon dioxide
- **Special hazards arising from the substance or mixture** Do not breathe combustion products.
- **Advice for firefighters:**
- **Protective equipment:**  
Wear self-contained respiratory protective device.  
Wear fully protective suit.  
Mouth respiratory protective device.
- **Additional information**  
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.  
Collect contaminated fire fighting water separately. It must not enter the sewage system.

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Cool endangered receptacles with water spray.

## 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.  
Dispose of the material collected according to regulations.  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

## 7 Handling and storage

- **Handling:**
- **Precautions for safe handling:**  
Avoid release to the environment  
Keep away from heat and direct sunlight.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**  
Provide ventilation for receptacles.  
Store only in the original receptacle.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:**  
Protect from exposure to the light.  
Store receptacle in a well ventilated area.  
See product labelling.
- **Specific end use(s)** Professional Dental Impression Material

## 8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Observe good industrial hygiene practices.  
Do not eat, drink, smoke or sniff while working.  
The usual precautionary measures are to be adhered to when handling chemicals.

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· **Respiratory protection:** Use suitable respiratory protective device in case of insufficient ventilation.

· **Protection of hands:**



Protective gloves

· **Material of gloves**

The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The determined penetration times according to EN 374 part III are not performed under practical conditions. Therefore a maximum wearing time, which corresponds to 50% of the penetration time, is recommended.

· **Eye protection:**



Tightly sealed goggles

· **Body protection:**

Boots

Protective work clothing

## 9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

<b>Form:</b>	Fluid
<b>Colour:</b>	Orange
<b>Odour:</b>	Bubble Gum
<b>Odour threshold:</b>	Not determined.

· **pH-value:** Not available

· **Change in condition**

<b>Melting point/freezing point:</b>	Not available
<b>Initial boiling point and boiling range:</b>	Not available

· **Flash point:** Not available

· **Flammability (solid, gas):** Not available

· **Decomposition temperature:** Not available

· **Auto-ignition temperature:** Not available

· **Explosive properties:** Not available

· **Explosion limits:**

<b>Lower:</b>	Not available
<b>Upper:</b>	Not available

· **Vapour pressure:** Not available

· **Density:** Not available

· **Relative density:** Not available

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· Vapour density	Not available
· Evaporation rate	Not available
· Solubility in / Miscibility with water:	Insoluble in water
· Partition coefficient: n-octanol/water:	Not available
· Viscosity:	
Dynamic:	Not available
Kinematic:	Not available
· Solvent content:	
Organic solvents:	<0.2
VOC (EC)	<0.20 %
· Solids content:	>89.6-<110 %
· Other information	Information not available

### 10 Stability and reactivity

- **Reactivity** Stable when stored and handled under recommended conditions.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** None by intended use.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation** Does not meet the classification criteria for this hazard class.
- **Serious eye damage/irritation** Does not meet the classification criteria for this hazard class.
- **Respiratory or skin sensitisation** Does not meet the classification criteria for this hazard class.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Does not meet the classification criteria for this hazard class.
- **Carcinogenicity** Does not meet the classification criteria for this hazard class.
- **Reproductive toxicity** Does not meet the classification criteria for this hazard class.
- **STOT-single exposure** Does not meet the classification criteria for this hazard class.
- **STOT-repeated exposure** Does not meet the classification criteria for this hazard class.
- **Aspiration hazard** Does not meet the classification criteria for this hazard class.

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** Not easily biodegradable
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Not hazardous for water.

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- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Disposal should be in accordance with applicable regional, national and local laws and regulations.

- **European waste catalogue**

HP 5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |   |                 |
|---|-----------------|
| · <b>UN-Number</b>  |                 |
| · <b>ADR, ADN, IMDG, IATA</b>   | not regulated   |
| · <b>UN proper shipping name</b>  |                 |
| · <b>ADR, ADN, IMDG, IATA</b>   | not regulated   |
| · <b>Transport hazard class(es)</b>   |                 |
| · <b>ADR, ADN, IMDG, IATA</b>   |                 |
| · <b>Class</b>  | not regulated   |
| · <b>Packing group</b>  |                 |
| · <b>ADR, IMDG, IATA</b>  | not regulated   |
| · <b>Environmental hazards:</b>   | Not applicable. |
| · <b>Special precautions for user</b>                                       | Not applicable. |
| · <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>   | not regulated   |

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I**  
Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.  
Product: None  
Contained substance: None  
Substances in Candidate List (Art. 59 REACH): None.  
Substances subject to authorisation (Annex XIV REACH): None  
Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012: None  
Substances subject to the Rotterdam Convention: None  
Substances subject to the Stockholm Convention: None  
Healthcare controls: Information not available.

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· **Chemical safety assessment:** A chemical safety assessment has not been carried out.

## 16 Other information

*This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*

· **Relevant phrases**

*H226 Flammable liquid and vapour.*

*H302 Harmful if swallowed.*

*H314 Causes severe skin burns and eye damage.*

*H318 Causes serious eye damage.*

*H372 Causes damage to organs through prolonged or repeated exposure.*

*H400 Very toxic to aquatic life.*

· **Department issuing SDS:** Regulatory Affairs

· **Contact:** Customer Service

· **Abbreviations and acronyms:**

*ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)*

*IMDG: International Maritime Code for Dangerous Goods*

*IATA: International Air Transport Association*

*GHS: Globally Harmonised System of Classification and Labelling of Chemicals*

*EINECS: European Inventory of Existing Commercial Chemical Substances*

*ELINCS: European List of Notified Chemical Substances*

*CAS: Chemical Abstracts Service (division of the American Chemical Society)*

*VOC: Volatile Organic Compounds (USA, EU)*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*

*Flam. Liq. 3: Flammable liquids – Category 3*

*Acute Tox. 4: Acute toxicity – Category 4*

*Skin Corr. 1B: Skin corrosion/irritation – Category 1B*

*Eye Dam. 1: Serious eye damage/eye irritation – Category 1*

*STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1*

*Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1*

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