

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

Printing date 10.12.2019

Revision: 05.11.2019

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

- **Product identifier**
- **Trade name:** Thermo Clone™ Bite Registration
- **Article number:** 4072
- **Index number:** SDS 376-001.03
- **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 substance is not classified, according to the CLP regulation.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

**3 Composition/information on ingredients**

- **Chemical characterisation:** Mixtures
- **Description:** Mixture of substances listed below with nonhazardous additions.  
Preparation of Silicone Polymers and Fillers with Platinum Catalyst (ppm range)

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## 4 First aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** This product is a thick paste, therefore inhalation is extremely unlikely.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

## 5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
Carbon dioxide  
Water fog  
Foam  
Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters:**
- **Protective equipment:** No special measures required.

## 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **Reference to other sections**  
No dangerous substances are released.  
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:** No special measures required.
- **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:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** See product labelling.
- **Specific end use(s)** Professional Dental Impression Material

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### 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:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:**  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
- **Material of gloves**  
Polyethylene  
Unsuitable material: NR (Natural rubber (Caoutchouc), Natural latex)
- **Penetration time of glove material**  
The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Not required.
- **Body protection:** Protective work clothing

### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

<b>Form:</b>	Paste
<b>Colour:</b>	White Green
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **pH-value:** Not applicable (non-aqueous)
- **Change in condition**

<b>Melting point/freezing point:</b>	Not applicable
<b>Initial boiling point and boiling range:</b>	Not applicable
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.
- **Decomposition temperature:** Not determined.
- **Auto-ignition temperature:** Not determined.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**

<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
- **Vapour pressure:** Not determined.
- **Density at 20 °C:** 1.6-1.7 g/cm<sup>3</sup>

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· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water:</b>	Not miscible or difficult to mix.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
· <b>Solvent content:</b>	
<b>VOC (EC)</b>	0.00 %
<b>Solids content:</b>	0.0 %
· <b>Other information</b>	No further relevant information available.

## 10 Stability and reactivity

- **Reactivity Stable**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** None by intended use.
- **Incompatible materials:** None by intended use.
- **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** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Additional toxicological information:** Oral LD50 > 2,000 mg/kg Rat
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

## 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.

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- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **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** Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

· <b>UN-Number</b> · <b>ADR, IMDG, IATA</b>	not regulated
· <b>UN proper shipping name</b> · <b>ADR, 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** Substance is not listed.
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
National regulatory information  
Water contaminating class (D): 1-slightly water contaminating.

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**· Chemical safety assessment:***Device is biocompatible when used as directed by dental professionals per ISO 10993-1***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.*

**· 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*

*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*

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