

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/22/2021

Reviewed on 09/22/2021

1 Identification

- **Product identifier**
- **Trade name:** *Thermo Clone™ Bite Registration*
- **Article number:** *SDS 376-001.03, 4072*
- **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*
- **Information department:** *Customer Service*
- **Emergency telephone number:**
*CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887*

2 Hazard(s) identification

- **Classification of the substance or mixture**
The substance is not classified, according to the Globally Harmonized System (GHS).
- **Label elements**
- **GHS label elements** *Void*
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

3 Composition/information on ingredients

- **Chemical characterization:** *Substances*
- **CAS No. Description**
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 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
Carbon dioxide
Water fog
Foam
Use fire fighting measures that suit the environment.
- **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 protection against explosions and fires:** 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 systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material is based on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
Polyethylene
Unsuitable material: NR (Natural rubber (Caoutchouc), Natural latex)
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **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:** Goggles recommended during refilling.
- **Body protection:** Protective work clothing

9 Physical and chemical properties

- | | |
|--|---|
| · Information on basic physical and chemical properties | |
| · General Information | |
| · Appearance: | |
| Form: | Paste |
| Color: | According to product specification |
| · Odor: | Odorless |
| · Odor threshold: | Not determined. |
| · pH-value: | Not applicable (non-aqueous) |
| · Change in condition | |
| Melting point/Melting range: | Not applicable |
| Boiling point/Boiling range: | Not applicable |
| · Flash point: | Not applicable |
| · Flammability (solid, gaseous): | Not applicable. |
| · Decomposition temperature: | Not determined. |
| · Auto igniting: | Not determined. |
| · Danger of explosion: | Product does not present an explosion hazard. |

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· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not determined.
· Density at 20 °C:	1.6-1.7 g/cm ³
· Relative density	Not determined
· Vapor density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Not miscible or difficult to mix.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined
VOC content:	0.00 %
	0.0 g/l / 0.00 lb/gal
VOC (EC)	0.00 %
Solids content:	0.0 %
· Other information	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:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
- Oral LD50 > 2,000 mg/kg Rat
- When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
- The substance is not subject to classification.
- **Carcinogenic categories**
- **IARC (International Agency for Research on Cancer)**
- Substance is not listed.

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· **NTP (National Toxicology Program)**

Substance is not listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

Substance is not listed.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:** No further relevant information available.

· **Persistence and degradability** No further relevant information available.

· **Behavior in environmental systems:**

· **Bioaccumulative potential** No further relevant information available.

· **Mobility in soil** No further relevant information available.

· **Additional ecological information:**

· **General notes:**

Water hazard class 1 (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:**

Disposal should be in accordance with applicable regional, national and local laws and regulations.

· **Uncleaned packagings:**

· **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· **UN-Number**

· **DOT, IMDG, IATA**

Not Regulated

· **UN proper shipping name**

· **DOT, IMDG, IATA**

Not Regulated

· **Transport hazard class(es)**

· **DOT, ADN, IMDG, IATA**

· **Class**

Not Regulated

· **Packing group**

· **DOT, IMDG, IATA**

Not Regulated

· **Environmental hazards:**

Not Applicable.

· **Special precautions for user**

Not Applicable

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not Applicable.

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· **UN "Model Regulation":** Not Regulated

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
 · **Sara**

· **Section 355 (extremely hazardous substances):**

Substance is not listed.

· **Section 313 (Specific toxic chemical listings):**

Substance is not listed.

· **TSCA (Toxic Substances Control Act):**

Substance is not listed.

· **Hazardous Air Pollutants**

Substance is not listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

Substance is not listed.

· **Chemicals known to cause reproductive toxicity for females:**

Substance is not listed.

· **Chemicals known to cause reproductive toxicity for males:**

Substance is not listed.

· **Chemicals known to cause developmental toxicity:**

Substance is not listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

Substance is not listed.

· **ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)**

Substance is not listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

Substance is not listed.

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

National regulatory information

Water contaminating class (D): 1-slightly water contaminating.

· **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:** Environmental, Health, and Safety

· **Contact:** Customer Service

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· Date of preparation / last revision 09/22/2021 / -**· Abbreviations and acronyms:***IMDG: International Maritime Code for Dangerous Goods**DOT: US Department of Transportation**IATA: International Air Transport Association**CAS: Chemical Abstracts Service (division of the American Chemical Society)**NFPA: National Fire Protection Association (USA)**HMIS: Hazardous Materials Identification System (USA)**VOC: Volatile Organic Compounds (USA, EU)**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**NIOSH: National Institute for Occupational Safety**OSHA: Occupational Safety & Health**TLV: Threshold Limit Value**PEL: Permissible Exposure Limit**REL: Recommended Exposure Limit*

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