Thermo Clone™ Bite Registration

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

1.1. Product identifier

Product code: 4072
Product name: Thermo Clone™ Bite Registration
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 Regulation(EC) No 1272/2008 [CLP]:

- **Health**: Not Classified

2.2. Label elements

This material is not considered hazardous to the health according to Regulation(EC) No 1272/2008[CLP].

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.
P301: IF SWALLOWED:
P314: Get medical advice/attention if you feel unwell.

**Storage**: P273: Avoid release to the environment.


2.3. Other hazards
SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
Dental Use

Date Issued: 08/28/2015
SDS No.: 376-001.2
Date Revised: 06/08/2016
Revision No.: 1

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Immediate concerns: No risks worthy of mention.

SECTION 3: Composition / information on ingredients

3.1. Substances
Not Applicable

3.2. Mixtures

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS</th>
<th>EINECS No.</th>
<th>Wt.%</th>
<th>Classification according to Regulation(EC) No 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation of silicone polymers and fillers with platinum-catalyst (ppm range)</td>
<td>N/A</td>
<td>N/A</td>
<td>100</td>
<td>Not classified</td>
</tr>
</tbody>
</table>

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes: Flush eyes with water. Get medical attention if irritation develops or persists.
Following skin: No special measures required.
Following ingestion: Seek medical attention if you feel unwell.
Following inhalation: No specific treatment is necessary since this material is not likely to be hazardous by inhalation.

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

Eyes: May cause irritation.
Skin: None expected for this product.
Ingestion: May be harmful if swallowed.
Inhalation: None expected for this product.

4.3. Indication of any immediate medical attention and special treatment needed

Notes to physician: Not Applicable

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media: Water fog. Foam. Carbon Dioxide (CO2).

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products: None

5.3. Advice for firefighters

Fire fighting procedures: Extinguishing materials should be selected according to the surrounding area.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Special protective equipment: Not required

6.2. Environmental precautions
Thermo Clone™ Bite Registration

6.3. Methods and material for containment and cleaning up
Large Spill: Collect mechanically.

6.4. Reference to other sections
Reference to other sections: No release of hazardous substances.

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Handling: No special precautionary measures are necessary.
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 Dental Impression Material

SECTION 8: Exposure controls / personal protection

8.1. Control parameters
Control parameters: Not Available

8.2. Exposure controls
Engineering controls: Not Applicable
Eye/face protection: Not required.
Skin protection: Single-use gloves.
Suitable material: PE (polyethylene).
Unsuitable materials: NR (Natural rubber (Caoutchouc), Natural latex).
In the cases of special applications, it is recommended to check the chemical resistance with the manufacturer of the gloves.
Respiratory protection: With correct and proper use, and under normal conditions, breathing protection is not required.
Work hygienic practices: The usual precautions when handling chemicals have to be obtained.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
Physical state: Paste
Colour: Base paste: white. Hardener paste: green
Odour: Odorless
pH: Neutral
Melting temperature: Not applicable
Boiling temperature: Not applicable
Density: 1.6 - 1.7 g/cm³
Thermo Clone™ Bite Registration

Solubility in water : Insoluble
Explosive properties : Not Explosive

9.2. Other information
Percent volatile : Not Volatile

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 : None by intended use.

10.5. Incompatible materials
Incompatible materials : None by intended use

10.6. Hazardous decomposition products
Hazardous decomposition products : None by intended use.

SECTION 11: Toxicological information

11.1. Information on toxicological effects
Acute
Dermal LD₅₀ : Irritant effect on the skin: Not an irritant.
Oral LD₅₀ : > 2000 mg/kg (rat)
Serious eye damage/irritation : Irritant effect on the eye: Not an irritant.
Respiratory or skin sensitisation : No danger of sensitization.
Other information : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity
Toxicity : Product has not been tested.
Aquatic toxicity (acute) : Do not empty into drains or the aquatic environment.

12.2. Persistence and degradability
Persistence and degradability : Not Available

12.3. Bioaccumulative potential
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Bioaccumulative potential : Not Available

12.4. Mobility in soil
Mobility in soil : Not Available

12.5. Results of PBT and vPvB assessment
Results of PBT and vPvB assessment : Not Available

12.6. Other adverse effects
Environmental data : Do not allow undiluted product or large quantities to reach ground water, water ways or sewage system.

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Disposal method : Advice on disposal
Remove according to the regulations.
Additional information:
Waste disposal number of waste from residues/unused products
070217 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of plastics, synthetic rubber and mad-made fibres; wastes containing silcones other than those mentioned in 07 02 16
Waste disposal number of used product
200399 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; other municipal wastes; municipal wastes not otherwise specified
Contaminated packaging
Completely emptied packings can be re-cycled.

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 : Not Dangerous Goods
RID - rail : Not Dangerous Goods
IMDG - sea : Not Dangerous Goods
**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use

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**Thermo Clone™ Bite Registration**

**IATA - air**: Not Dangerous Goods

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

**Transport in bulk**: Not Dangerous Goods

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**SECTION 15: Regulatory information**

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

**RoHS**: Please refer to Medical Devices Directive 93/42/EEC

**15.2. Chemical safety assessment**

**Chemical safety assessment**: See Section 11

**Additional information**: National regulatory information

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

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**SECTION 16: Other information**

**Prepared by**: Anu Kattoju

**Revision summary**: This SDS replaces the 08/28/2015 SDS. Revised: **Section 1**: Date-Revised, MSDS No. **Section 5**: EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, FIRE FIGHTING PROCEDURES, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6**: GENERAL PROCEDURES, LARGE SPILL, SPECIAL PROTECTIVE EQUIPMENT, WATER SPILL. **Section 7**: HANDLING. **Section 8**: PERSONAL PROTECTIVE EQUIPMENT (RESPIRATORY), WORK HYGIENIC PRACTICES. **Section 9**: BOILING POINT, DENSITY, MELTING POINT, ODOR. **Section 11**: ACUTE, GENERAL COMMENTS. **Section 12**: CHEMICAL FATE INFORMATION, DISTRIBUTION, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), SECTION 12: Ecological information. **Section 13**: DISPOSAL METHOD. **Section 14**: ROAD AND RAIL (ADR/RID), VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 UN number, Packing group. **Section 15**: COMMENTS. **Section 16**: Revision Summary, GENERAL STATEMENTS.

**General statements**: NAP = 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.