Thermo Clone™ Putty

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

1.1. Product identifier

Product code : 4073
Product name : Thermo Clone™ Putty
Product description : Polyvinyl Siloxane Dental Impression 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]

: 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.

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)

Response : P305: IF IN EYES:
P351: Rinse cautiously with water for several minutes.
P337+P313: If eye irritation persists: Get medical advice/attention.
P301+P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

Storage : P273: Avoid release to the environment.


2.3. Other hazards

No risks worthy of mention.
Thermo Clone™ Putty

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 be mildly irritating to eyes.
Skin: None expected for this product.
Ingestion: None expected for this product.
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
Water spill: Do not empty into drains or the aquatic environment.
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

General procedures: Avoid contact with eyes, skin and clothing.
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: None Required.

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. Provide adequate ventilation.

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.
Odour: Odorless.
pH: Neutral.
Melting temperature: Not applicable.
Boiling temperature: Not applicable.
Density: 1.5 - 1.6 g/cm³ at 20°C.
Thermo Clone™ Putty

9.2. Other information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solubility in water</td>
<td>Insoluble</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not Explosive</td>
</tr>
<tr>
<td>Percent volatile</td>
<td>Not Volatile</td>
</tr>
</tbody>
</table>

SECTION 10: Stability and reactivity

10.1. Reactivity

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Stable</td>
</tr>
</tbody>
</table>

10.2. Chemical stability

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical stability</td>
<td>Stable when stored and handled under recommended conditions.</td>
</tr>
</tbody>
</table>

10.3. Possibility of hazardous reactions

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous polymerization</td>
<td>None</td>
</tr>
</tbody>
</table>

10.4. Conditions to avoid

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conditions to avoid</td>
<td>None by intended use.</td>
</tr>
</tbody>
</table>

10.5. Incompatible materials

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incompatible materials</td>
<td>None by intended use.</td>
</tr>
</tbody>
</table>

10.6. Hazardous decomposition products

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous decomposition products</td>
<td>None by intended use.</td>
</tr>
</tbody>
</table>

SECTION 11: Toxicological information

11.1. Information on toxicological effects

**Acute**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermal LD$_{50}$</td>
<td>Irritant effect on the skin: Not an irritant.</td>
</tr>
<tr>
<td>Oral LD$_{50}$</td>
<td>$&gt; 2000$ mg/kg (rat)</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>Irritant effect on the eye: Not an irritant.</td>
</tr>
<tr>
<td>Respiratory or skin sensitisation</td>
<td>No danger of sensitization.</td>
</tr>
<tr>
<td>Other information</td>
<td>Device is biocompatible when used as directed by dental professionals per ISO 10993-1.</td>
</tr>
</tbody>
</table>

SECTION 12: Ecological information

12.1. Toxicity

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity</td>
<td>Product has not been tested.</td>
</tr>
</tbody>
</table>

Aquatic toxicity (acute)

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic toxicity (acute)</td>
<td>Do not empty into drains or the aquatic environment.</td>
</tr>
<tr>
<td></td>
<td>1 ()</td>
</tr>
<tr>
<td></td>
<td>Doesn't get into the sewage water as long as the process is carried out according to regulations.</td>
</tr>
</tbody>
</table>

12.2. Persistence and degradability

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persistence and degradability</td>
<td>Not Available</td>
</tr>
</tbody>
</table>

12.3. Bioaccumulative potential
**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

**THermo Clone™ Putty**

**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 to enter sewers or drains that may lead to waterways.

**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

**Product disposal** : 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 man-made fibres; wastes containing silicones 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

**IATA - air** : Not Dangerous Goods
SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
Dental Use

Thermo Clone™ Putty

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

Transport in bulk : Not Dangerous Goods
Additional information : Not a hazardous material with respect to these transportation regulations.

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

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 2: EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. Section 5: EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, FIRE FIGHTING PROCEDURES, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. Section 6: Section 7: GENERAL PROCEDURES, HANDLING. Section 8: ENGINEERING CONTROLS, 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, ECOTOXICOLOGICAL INFORMATION, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), SECTION 12: Ecological information. 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.