

# SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010  
Dental Use



Date Issued : 08/28/2015  
SDS No : 378-001.2  
Date Revised : 06/08/2016  
Revision No : 1

## 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.

**Disposal** : P501: Dispose of in compliance with governmental regulation.(EC1975L0442-20/11/2003)

#### 2.3. Other hazards

No risks worthy of mention.

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**SECTION 3: Composition / information on ingredients**

**3.1. Substances**

Not Applicable

**3.2. Mixtures**

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

**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 (CO<sub>2</sub>).

**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.

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**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  
Colour : Base Paste: White. Catalyst: Light Gray  
Odour : odorless  
pH : neutral  
Melting temperature : not applicable  
Boiling temperature : not applicable  
Density : 1.5 - 1.6 g/cm<sup>3</sup> at 20°C

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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 LD<sub>50</sub> : Irritant effect on the skin: Not an irritant.

Oral LD<sub>50</sub> : > 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.

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Doesn't get into the sewage water as long as the process is carried out according to regulations.

**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 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

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**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.