

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

Printing date 03.12.2019

Revision: 14.11.2019

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

- **Product identifier**
- **Trade name:** Thermo Clone™ Putty
- **Article number:** 4073
- **Index number:** SDS 378-001.03
- **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)

GB2

(Contd. on page 2)

Safety data sheet

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Printing date 03.12.2019

Revision: 14.11.2019

Trade name: **Thermo Clone™ Putty**

(Contd. of page 1)

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:**
Foam
Carbon dioxide
Water fog
Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters:** Use fire extinguishing methods suitable to surrounding conditions.

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:** None.
- **Specific end use(s)** Professional Dental Impression Material

GB2

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

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Revision: 14.11.2019

Trade name: **Thermo Clone™ Putty**

(Contd. of page 2)

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.
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 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 |
| Colour: | According to product specification |
| · Odour: | Odourless |
| · Odour threshold: | Not determined. |
| · pH-value: | Not applicable (non-aqueous) |
| · Change in condition | |
| Melting point/freezing point: | Not applicable |
| Initial boiling point and boiling range: | 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: | |
| Lower: | Not determined. |

(Contd. on page 4)

Safety data sheet
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Printing date 03.12.2019

Revision: 14.11.2019

Trade name: **Thermo Clone™ Putty**

(Contd. of page 3)

Upper:	Not determined.
· Vapour pressure:	Not determined.
· Density at 20 °C:	1.5-1.6 g/cm ³
· Relative density	Not determined.
· Vapour 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.
· Solvent content:	
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:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **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.

GB2

(Contd. on page 5)

Safety data sheet

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Revision: 14.11.2019

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(Contd. of page 4)

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.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Doesn't get into the sewage water as long as the process is carried out according to regulations.
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.
Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

<ul style="list-style-type: none"> · UN-Number · ADR, IMDG, IATA 	<i>not regulated</i>
<ul style="list-style-type: none"> · UN proper shipping name · ADR, IMDG, IATA 	<i>not regulated</i>
<ul style="list-style-type: none"> · Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class 	<i>not regulated</i>
<ul style="list-style-type: none"> · Packing group · ADR, IMDG, IATA 	<i>not regulated</i>
<ul style="list-style-type: none"> · Environmental hazards: 	<i>Not applicable.</i>
<ul style="list-style-type: none"> · Special precautions for user 	<i>Not applicable.</i>
<ul style="list-style-type: none"> · Transport in bulk according to Annex II of Marpol and the IBC Code 	<i>Not applicable.</i>
<ul style="list-style-type: none"> · UN "Model Regulation": 	<i>not regulated</i>

GB2

(Contd. on page 6)

Safety data sheet
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(Contd. of page 5)

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.
- **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

GB2