

Safety Data Sheet according to WHS Regulations

Date of issue: 08.12.2025

Revision: 21.02.2025

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1 Identification

- **Other means of identification**
- **Trade name:** Thermo Clone™ Putty
- **Article number:** SDS 378-001.04R01, 4073
- **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:**
Manufactured by Kettensbach GmbH & Co. KG for:
Ultradent Products, Inc.
505 W. Ultradent Drive (10200 S)
South Jordan, UT 84095-3942
USA
onlineordersupport@ultradent.com
(800) 552-5512
- **Ultradent Australia Pty Ltd.**
Level 22/2 Market Street
Sydney NSW 2000
Australia
Email: info.anz@ultradent.com
Toll Free: 1-800-290929
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : +1 (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

3 Composition and 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)

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4 First Aid Measures

- **General information:**
In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). No known symptoms to date.
- **After inhalation:** Not Applicable
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse eyes thoroughly with water. If irritation persists, seek medical attention.
- **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

- **Suitable extinguishing agents:**
All standard extinguishing agents are suitable.
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.
- **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:** Pick up mechanically.
- **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.
- **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

8 Exposure controls and personal protection

- **Appropriate engineering controls** No further data; see section 7.
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.

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· Personal protective equipment:

· General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

· Respiratory protection: Not required under normal conditions.

· 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.

· Body protection: Protective work clothing

9 Physical and Chemical Properties

· General Information

· Appearance:

· Form: Not determined.

· Colour: Catalyst: white

Base: yellow

· Odour:

Not determined

· 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

Not applicable.

· Decomposition temperature:

Not determined.

· Ignition temperature:

Not determined.

· Explosive properties:

Product does not present an explosion hazard.

· Explosion limits:

· Lower: Not determined.

· Upper: Not determined.

· Vapour pressure: Not determined.

· Density at 20 °C: 1.5-1.6 g/cm³

· Relative density

Not determined.

· Vapour density

Not determined.

· Evaporation rate

Not determined.

· Solubility in / Miscibility with

· water: Insoluble.

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Not determined.

· Dynamic:

Not determined.

· Kinematic:

Not determined.

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· Other information	
· Particle characteristics	Not applicable.
· Physical state	Liquid

10 Stability and Reactivity

- **Reactivity** Stable
- **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.
- **Additional information:** Please pay attention to the Directions for Use.

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.
- **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.

Carcinogenicity (OSHA): Cristobalite (CAS 14464-46-1) is listed.

Carcinogenicity (IARC): Cristobalite (CAS 14464-46-1) is listed in group 1.

Carcinogenicity (NTP): Cristobalite (CAS 14464-46-1) is listed in group Known.

Based on available data, the classification criteria are not met.

- **Aspiration hazard** Based on available data, the classification criteria are not met.
- **Additional toxicological information:** Oral LD50 > 2,000 mg/kg Rat

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:**
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.

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- **vPvB:** Not applicable.

- **Other adverse effects**

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

13 Disposal considerations

- **Waste treatment methods**

- **Recommendation**

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

Dispose of contents/container in accordance with international, federal, state, and local regulations.

- **Uncleaned packaging:**

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

14 Transport information

· UN-Number	
· ADG, IMDG, IATA	<i>not regulated</i>
· UN proper shipping name	
· ADG, IMDG, IATA	<i>not regulated</i>
· Transport hazard class(es)	
· ADG, ADN, IMDG, IATA	
· Class	<i>not regulated</i>
· Packing group	
· ADG, IMDG, IATA	<i>not regulated</i>
· Environmental hazards:	<i>Not applicable.</i>
· Special precautions for user	<i>Not Applicable</i>
· Transport in bulk according to Annex II of Marpol and the IBC Code	<i>Not applicable.</i>
· UN "Model Regulation":	<i>not regulated</i>

15 Regulatory information

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

- **NIOSH-Ca (National Institute for Occupational Safety and Health)** Substance is not listed.

- **Australian Inventory of Industrial Chemicals** Substance is not listed.

- **Standard for the Uniform Scheduling of Medicines and Poisons** Substance is not listed.

- **Australia: Priority Existing Chemicals** Substance is not listed.

- **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

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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

· Abbreviations and acronyms:

ADR: Accord relatif au transport international 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

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

· * Data compared to the previous version altered.

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