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

Thermo Clone™ Bite Registration

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

<table>
<thead>
<tr>
<th>1.1. Product identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product code</strong></td>
</tr>
<tr>
<td><strong>Product name</strong></td>
</tr>
<tr>
<td><strong>Product description</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1.2. Relevant identified uses of the substance or mixture and uses advised against</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Relevant identified uses</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1.3. Details of the supplier of the safety data sheet</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufacturer</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Distributor</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Email</strong></td>
</tr>
<tr>
<td><strong>Emergency Phone</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1.4. Emergency telephone number</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHEMTREC (NORTH AMERICA)</td>
</tr>
<tr>
<td>(INTERNATIONAL)</td>
</tr>
</tbody>
</table>

### SECTION 2: Hazards identification

<table>
<thead>
<tr>
<th>2.1. Classification of the substance or mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification according to Regulation(EC) No 1272/2008 [CLP]</td>
</tr>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

#### Health
| Not Classified |

<table>
<thead>
<tr>
<th>2.2. Label elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention</td>
</tr>
<tr>
<td>P280: Wear protective gloves/protective clothing/eye protection/face protection.</td>
</tr>
<tr>
<td>P351: Rinse cautiously with water for several minutes.</td>
</tr>
<tr>
<td>P337+P313: If eye irritation persists: Get medical advice/attention.</td>
</tr>
<tr>
<td>P301: IF SWALLOWED:</td>
</tr>
<tr>
<td>P314: Get medical advice/attention if you feel unwell.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>P273: Avoid release to the environment.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Disposal</th>
</tr>
</thead>
</table>
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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
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 materials: 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
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<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>
</tbody>
</table>

9.2. Other information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent volatile</td>
<td>Not Volatile</td>
</tr>
</tbody>
</table>

**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.

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**SECTION 11: Toxicological information**

11.1. Information on toxicological effects

**Acute**

- Dermal LD$_{50}$: Irritant effect on the skin: Not an irritant.
- Oral LD$_{50}$: $> 2000$ 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.

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**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.

1 () 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 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.

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

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IATA - air : Not Dangerous Goods

Transport in bulk : Not Dangerous Goods

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

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 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.