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

- **Product identifier**
  - **Trade name:** Thermo Clone™ Bite Registration
  - **Article number:** 4072
  - **Index number:** SDS 376-001.03
  - **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@utradent.com

  - **EC Responsible Person**
    Ultradent Products GmbH
    Am Westhover 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)

(Contd. on page 2)
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:
    - Carbon dioxide
    - Water fog
    - Foam
    - Use fire extinguishing methods suitable to surrounding conditions.
- Special hazards arising from the substance or mixture: No further relevant information available.
- Advice for firefighters:
  - 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:
  - 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: See product labelling.
  - Specific end use(s) Professional Dental Impression Material
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.
· Material of gloves
Polyethylene
Unsuitable material: NR (Natural rubber (Caoutchouc), Natural latex)
· 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: Not required.
· Body protection: Protective work clothing

9 Physical and chemical properties

· Information on basic physical and chemical properties
· General Information
· Appearance:
  Form: Paste
  Colour: White
  Green
· 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.
  Upper: Not determined.

· Vapour pressure:
  Not determined.

· Density at 20 °C:
  1.6-1.7 g/cm³
50.0.1 · 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: None by intended use.
  · Incompatible materials: None by intended use.
  · 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 (carcinogenity, 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.

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.
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.

Uncleaned packaging:
Recommendation: Disposal must be made according to official regulations.

14 Transport information

UN-Number
ADR, IMDG, IATA: not regulated

UN proper shipping name
ADR, IMDG, IATA: not regulated

Transport hazard class(es)
ADR, ADN, IMDG, IATA: not regulated

Class: not regulated

Packing group
ADR, IMDG, IATA: not regulated

Environmental hazards:
Not applicable.

Special precautions for user
Not applicable.

Transport in bulk according to Annex II of Marpol and the IBC Code
Not applicable.

UN "Model Regulation": not regulated

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.

National regulations:

Other regulations, limitations and prohibitive regulations
National regulatory information
Water contaminating class (D): 1-slightly water contaminating.
Trade name: Thermo Clone™ Bite Registration

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