

SAFETY DATA SHEET

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



Date Issued : 08/28/2015
SDS No : 376-001.2
Date Revised : 06/08/2016
Revision No : 1

Thermo Clone™ Bite Registration

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

1.1. Product identifier

Product code : 4072
Product name : Thermo Clone™ Bite Registration
Product description : Bite registration 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)

Prevention : P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response : P305: IF IN EYES:
P351: Rinse cautiously with water for several minutes.
P337+P313: If eye irritation persists: Get medical advice/attention.
P301: IF SWALLOWED:
P314: Get medical advice/attention 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

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



Date Issued : 08/28/2015
SDS No : 376-001.2
Date Revised : 06/08/2016
Revision No : 1

Thermo Clone™ Bite Registration

Immediate concerns : No risks worthy of mention.

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 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

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



Date Issued : 08/28/2015
SDS No : 376-001.2
Date Revised : 06/08/2016
Revision No : 1

Thermo Clone™ Bite Registration

Water spill : Do not empty into drains or the aquatic environment.

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 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.

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

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



Date Issued : 08/28/2015
SDS No : 376-001.2
Date Revised : 06/08/2016
Revision No : 1

Thermo Clone™ Bite Registration

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 LD₅₀ : Irritant effect on the skin: Not an irritant.

Oral LD₅₀ : > 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.

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

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



Date Issued : 08/28/2015
SDS No : 376-001.2
Date Revised : 06/08/2016
Revision No : 1

Thermo Clone™ Bite Registration

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.
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 mad-made fibres; wastes containing silcones 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

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



Date Issued : 08/28/2015
SDS No : 376-001.2
Date Revised : 06/08/2016
Revision No : 1

Thermo Clone™ Bite Registration

IATA - air : Not Dangerous Goods

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

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

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 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.