Thermo Clone™ VPS; Regular and Fast Set; Light/SuperLight, Medium, and Heavy

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

1.1. Product identifier

Product code: 4057, 4058, 4059, 4060, 4065, 4066, 4067, 4068, 4069, 4070

Product name: Thermo Clone™ VPS; Regular and Fast Set; Light/SuperLight, Medium, and Heavy

Product description: Polyvinyl Siloxane Dental Impression 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)


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.

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2.3. Other hazards

Immediate concerns : None

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</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 eye 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

Explosion hazards : None known.

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

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

General procedures
Avoid contact with eyes, skin and clothing.

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 Required

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
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
Color dependent

Odour
odorless

pH
neutral

Melting temperature
not applicable

Boiling temperature
not applicable

Density
1.4-1.6 g/cm³
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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 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.

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 to enter sewers or drains that may lead to waterways.

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 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
IATA - air : Not Dangerous Goods
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14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk : Not Dangerous Goods
Additional information : Not a hazardous material with respect to these transportation regulations.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

RoHS General Information : 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: EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, FIRE FIGHTING PROCEDURES, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. Section 6: WATER SPILL, . Section 7: GENERAL PROCEDURES, HANDLING. Section 8: ENGINEERING CONTROLS, PERSONAL PROTECTIVE EQUIPMENT ( RESPIRATORY ). 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: COMMENTS, 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.