

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 08/28/2015

SDS No : 379-001.1

Thermoclon™ 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 : Thermoclon™ 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

: 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.

Classification according to Regulation(EC) No 1272/2008 [CLP]

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. (EC

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1975L0442-20/11/2003)

2.3. Other hazards

Immediate concerns : None

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 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 : Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

- Explosion hazards** : None known.
- Fire explosion** : None
- Sensitive to static discharge** : None
- Sensitivity to impact** : None

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5.3. Advice for firefighters

- Fire fighting procedures** : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.
- Fire fighting equipment** : Water fog, Foam, Carbon Dioxide (CO2)

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 allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up

- Large spill** : Collect mechanically

6.4. Reference to other sections

- Reference to other sections** : Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Handling** : Avoid contact with eyes, skin, and clothing.
- 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 Determined

8.2. Exposure controls

- Eye/face protection** : Not required.
- Skin protection** : Wear suitable gloves.
- Respiratory protection** : Good general ventilation should be sufficient to control airborne levels.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

- Physical state** : Paste
- Colour** : Color dependent
- Odour** : Odorless or no characteristic odor
- pH** : Neutral

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Density : 1,4 - 1,6 g/cm³
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

Eyes : Irritant effect on the eye: Not an irritant.
Dermal LD₅₀ : Irritant effect on the skin: Not an irritant.
Oral LD₅₀ : > 2000 mg/kg (rat)
Notes : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.
Sensitisation : No danger of sensitization.

SECTION 12: Ecological information

12.1. Toxicity

Toxicity : Product has not been tested.
Aquatic toxicity (acute) : Do not allow to enter sewers or drains that may lead to waterways.

12.2. Persistence and degradability

Persistence and degradability : Not Determined

12.3. Bioaccumulative potential

Bioaccumulative potential : Not Determined

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12.4. Mobility in soil

Mobility in soil : Not Determined

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Not Determined

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 : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

SECTION 14: Transport information

14.1. UN number

UN number : N/A

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : N/A

14.4. Packing group

Packing group : N/A

14.5. Environmental hazards

Marine pollutant #1 : N/A

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

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 : This product is not considered dangerous for transportation

SECTION 16: Other information

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Prepared by	: Anu Kattoju
General statements	: N/A= Not Applicable
Additional SDS information	: This is the first SDS.
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.