

Safety Data Sheet

Thermo Clone™ VPS (Medium Body)

Revision date: 09/21/2022

Page 1 of 5

1. Identification

Product identifier

Thermo Clone™ VPS (Medium Body)

Further trade names: Panasil monophase

Article Number: SDS 61-001.01R01, 4058, 4066, 4068, 4070

Recommended use of the chemical and restrictions on use

Use of the substance/mixture: Medium viscosity, addition-curing, elastomeric monophase impression material based on polyvinyl siloxane.
Medical device for use in dentistry, observe instructions for use.

Details of the supplier of the safety data sheet

Company name: Street: Kettenbach GmbH & Co. for Ultradent Products, Inc.
Place: 505 W. Ultradent Drive (10200 S)
Telephone: South Jordan, UT 84095-3942
E-mail: USA
(800) 552-5512
onlineordersupport@ultradent.com
Emergency Telephone Number: CHEMTREC (NORTH AMERICA): +1 (800) 424-9300
(INTERNATIONAL): +(703) 527-3887

2. Hazard(s) identification

Classification of the chemical

Regulation (EC) No 1272/2008

This mixture is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

Label elements

Regulation (EC) No 1272/2008

Precautionary statements

P501 Dispose of contents/container to Disposal of the contents/container in accordance with local/regional/national international regulations..
P305+P354+P338 IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P280 Wear protective gloves.

Hazards not otherwise classified

No risks worthy of mention.

3. Composition/information on ingredients

Mixtures

Chemical characterization

Mixture of silicone polymers and fillers with platinum-catalyst (ppm-range).

Hazardous components

none (according to Regulation (EC) No 1907/2006 (REACH))

4. First-aid measures

Description of first aid measures

General information

No known symptoms to date.

Safety Data Sheet

Revision date: 09/21/2022

Page 2 of 5

After inhalation

not applicable

After contact with skin

In general the product is not skin irritative.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

5. Fire-fighting measures

Extinguishing media

Specific hazards arising from the chemical

Not applicable.

Special protective equipment and precautions for fire-fighters

Co-ordinate fire-fighting measures to the fire surroundings.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

General advice

Not required.

Environmental precautions

Do not allow to enter into surface water or drains.

Methods and material for containment and cleaning up

Other information

Take up mechanically.

Reference to other sections

No release of hazardous substances.

7. Handling and storage

Precautions for safe handling

Advice on safe handling

No special precautionary measures are necessary.

Advice on protection against fire and explosion

No special precautionary measures are necessary.

Advice on general occupational hygiene

The usual precautions when handling chemicals have to be obtained.

Avoid contact with skin, eyes and clothes.

Further information on handling

No special precautionary measures are necessary.

Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

No special requirements.

Hints on joint storage

Not required.

Further information on storage conditions

No special requirements.

Specific end use(s)

Not required.

Safety Data Sheet

Revision date: 09/21/2022

Page 3 of 5

8. Exposure controls/personal protection

Control parameters

Exposure limits

CAS No	Substance	ppm	mg/m ³	f/cc	Category	Origin
56-81-5	Glycerin (mist) Respirable fraction	-	5		TWA (8 h)	PEL

Exposure controls

Appropriate engineering controls

not applicable

Individual protection measures, such as personal protective equipment

Eye/face protection

Not required.

Hand protection

Single-use gloves.

Suitable material: PE (polyethylene).

Unsuitable material: NR (Natural rubber (Caoutchouc), Natural latex).

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Skin protection

Not required.

Respiratory protection

Respiratory protection is not required when used properly and under normal conditions.

Environmental exposure controls

Not required.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state:

Color:

Catalyst: white. Base: blue.

Melting point/freezing point:

not applicable

Boiling point or initial boiling point and boiling range:

not applicable

Water solubility:

insoluble

Vapor pressure:

not applicable

Density (at 20 °C):

ca. 1,5 g/cm³

10. Stability and reactivity

Reactivity

None by intended use.

Chemical stability

None by intended use.

Possibility of hazardous reactions

None by intended use.

Conditions to avoid

None by intended use.

Safety Data Sheet

Revision date: 09/21/2022

Page 4 of 5

Incompatible materials

None by intended use.

Hazardous decomposition products

None by intended use.

Further information

Please pay attention to the Directions for Use.

11. Toxicological information

Information on toxicological effects

Acute toxicity

LD50: > 2000 mg/kg Rat

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

Irritation and corrosivity

non-irritant.

non-irritant.

Information on other hazards

Other information

None by intended use.

12. Ecological information

Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

Further information

Do not allow to enter into surface water or drains.

1 (slightly hazardous to water)

13. Disposal considerations

Waste treatment methods

List of Wastes Code - 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

14. Transport information

Land transport (ADR/RID)

UN number or ID number: N/A

UN proper shipping name: N/A

Transport hazard class(es): N/A

Packing group: N/A

Inland waterways transport (ADN)

UN number or ID number: N/A

UN proper shipping name: N/A

Transport hazard class(es): N/A

Safety Data Sheet

Revision date: 09/21/2022

Page 5 of 5

Packing group: N/A

Marine transport (IMDG)

UN number or ID number: N/A

UN proper shipping name: N/A

Transport hazard class(es): N/A

Packing group: N/A

Segregation group: 4 - chlorates

Air transport (ICAO-TI/IATA-DGR)

UN number or ID number: N/A

UN proper shipping name: N/A

Transport hazard class(es): N/A

Packing group: N/A

Danger releasing substance: N/A

Special precautions for user

N/A

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

N/A

Other applicable information

No dangerous good in sense of these transport regulations.

15. Regulatory information

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

National regulatory information

Water hazard class (D): 1 - slightly hazardous to water

Chemical Safety Assessment

For this substance a chemical safety assessment is not required.

16. Other information

Changes

Update 2022-09-21

Other data

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights.

The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the relevant ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)