

Safety Data Sheet

according to 29 CFR 1910.1200(g)

Thermo Clone™ Bite Registration

Revision date: 02/20/2025

Page 1 of 6

1. Identification

Product identifier

Thermo Clone™ Bite Registration

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

Further trade names Futar, Futar Fast

Article Number: SDS 376-001.04R01, 4072, 4079

Recommended use of the chemical and restrictions on

Use of the substance/mixture Extremely hard, addition-curing bite registration material based on polyvinyl-siloxane.
Medical device for use in dentistry, observe instructions for use.

Uses advised against

Use by untrained dental personnel and/or unapproved areas of application.

Details of the supplier of the safety data sheet

Company name: Kettenbach GmbH & Co. KG for Ultradent Products, Inc.
Street: 505 W. Ultradent Drive (10200 S)
Place: South Jordan, UT 84095-3942
USA
E-mail: onlineordersupport@ultradent.com
Telephone: (800) 552-5512

Emergency Telephone Number: CHEMTREC (NORTH AMERICA): +1 (800) 424-9300
(INTERNATIONAL): +(703) 527-3887

2. Hazard(s) identification

Classification of the chemical

29 CFR Part 1910.1200

This mixture is not classified as hazardous in accordance with Regulation 29 CFR 1910.1200(d).

Safety Information Sheet for Medical Devices The particulars given in the Safety Information Sheet only apply to the described product in connection with its appropriate utilization. These particulars are based on the latest state of our knowledge and information. In particular, they serve the purpose of describing our product under the aspect of hazards caused by such product and pertaining safety actions. They do not constitute any guarantee of product quality and/or quality features. The particulars given in this Safety Information Sheet are not required in accordance with FDA regulations. This product is classified as a medical device. Medical devices are exempt from the labelling provisions of GHS according to the Hazard Communication Standard (29 CFR § 1910.1200). They merely serve the purpose of providing sufficient information on the voluntary basis with a view to ensure the safe utilization of such substance/mixture/product.

Label elements

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 29 CFR 1910.1200(g))

4. First-aid measures

Safety Data Sheet

according to 29 CFR 1910.1200(g)

Revision date: 02/20/2025

Page 2 of 6

Description of first aid measures

General information

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

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.

After ingestion

Seek medical attention if problems persist.

Most important symptoms and effects, both acute and delayed

No data available

Indication of any immediate medical attention and special treatment needed

No data available

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media

All standard extinguishing agents are suitable.

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

No data available

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.

Safety Data Sheet

according to 29 CFR 1910.1200(g)

Revision date: 02/20/2025

Page 3 of 6

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.

8. Exposure controls/personal protection

Control parameters

Exposure limits

CAS No	Substance	ppm	mg/m ³	f/cc	Category	Origin
14464-46-1	Silica, crystalline cristobalite, respirable dust	(Z-3)	(Z-3)		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.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state:

Color:

Base paste: white. Hardener paste: green.

Melting point/freezing point:

not applicable

Boiling point or initial boiling point and boiling range:

not applicable

Water solubility:

insoluble

Density (at 20 °C):

1.6 - 1.7 g/cm³

10. Stability and reactivity

Safety Data Sheet

according to 29 CFR 1910.1200(g)

Revision date: 02/20/2025

Page 4 of 6

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.

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

Based on available data, the classification criteria are not met.

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

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.

Irritant effect on the skin non-irritant.

Irritant effect on the eye non-irritant.

Sensitizing effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects 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.

Specific target organ toxicity (STOT) - single exposure

Based on available data, the classification criteria are not met.

Specific target organ toxicity (STOT) - repeated exposure

Based on available data, the classification criteria are not met.

Carcinogenicity (OSHA):

Cristobalite (CAS 14464-46-1) is listed.

Carcinogenicity (IARC):

Cristobalite (CAS 14464-46-1) is listed in group 1.

Carcinogenicity (NTP):

Cristobalite (CAS 14464-46-1) is listed in group Known.

Aspiration hazard

Based on available data, the classification criteria are not met.

12. Ecological information

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.

Safety Data Sheet

according to 29 CFR 1910.1200(g)

Revision date: 02/20/2025

Page 5 of 6

Further information

Do not allow to enter into surface water or drains.
1 (slightly hazardous to water)

13. Disposal considerations

Waste treatment methods

14. Transport information

U.S. DOT 49 CFR 172.101

Proper shipping name:

No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

UN number or ID number:

No dangerous good in sense of this transport regulation.

UN proper shipping name:

No dangerous good in sense of this transport regulation.

Transport hazard class(es):

No dangerous good in sense of this transport regulation.

Packing group:

No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

UN number or ID number:

No dangerous good in sense of this transport regulation.

UN proper shipping name:

No dangerous good in sense of this transport regulation.

Transport hazard class(es):

No dangerous good in sense of this transport regulation.

Packing group:

No dangerous good in sense of this transport regulation.

Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

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

U.S. Regulations

State Regulations

Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65, State of California)

This product can not expose you to chemicals known to the State of California to cause cancer, birth defects or other reproductive harm.

16. Other information

Changes

Revision date: 02/20/2025

Revision No: 3,05

This data sheet contains changes from the previous version in section(s): 1,2,4,5,9,11,12,14,16.

Date of preparation / Revised on: 20/02/2025

Version number: 3,05

Replaces version number: 3,04 (08/09/2022)

Abbreviations and acronyms

ATE: Acute toxicity estimate. CAS: Chemical abstracts service. CFR: Code of Federal Regulations. DNEL:

Derived No Effect Level EC50: 50% of maximal effective concentration. FDA: Food and Drug Administration.

GHS: Globally Harmonised System. IATA: International air transport association. ICAO: Technical instructions

Safety Data Sheet

according to 29 CFR 1910.1200(g)

Revision date: 02/20/2025

Page 6 of 6

for the safe transport of dangerous goods by air. IMDG: International maritime dangerous goods. LC50: Lethal concentration to 50 % of a test population. LD50: Lethal dose to 50% of a test population (median lethal dose). NOAEL: No Observed Adverse Effect Level. PBT: Persistent, bioaccumulative and toxic substance. PEL: Permissible Exposure Limit. PNEC: Predicted No Effect Concentration. REL: Recommended exposure limit. STOT RE: Specific Target Organ Toxicity – Single Exposure. STOT SE: Specific Target Organ Toxicity – Repeated Exposure. TWA: 8-hour Time Weighted Averages (long-term exposure limit). US OSHA: US Occupational Safety and Health Administration. vPvB: Very persistent and very bioaccumulative.

Key literature references and sources for data

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

Other data

Training instructions: Use only by personnel trained in dentistry.

Disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions.

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