

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/16/2021

Reviewed on 09/16/2021

1 Identification

- **Product identifier**
- **Trade name:** *Clone™ Bite - Base*
- **Article number:** *SDS 257-001.03, 7600*
- **Application of the substance / the mixture** *Professional Dental Impression Material*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
*Ultradent Products Inc.
505 W. Ultradent Drive (10200 S)
South Jordan, UT 84095-3942
USA
onlineordersupport@ultradent.com*
- **Information department:** *Customer Service*
- **Emergency telephone number:**
*CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887*

2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS08 Health hazard

Carc. 1A H350 May cause cancer.

- **Label elements**
- **GHS label elements** *Void*
- **Hazard pictograms** *GHS08*
- **Signal word** *Danger*
- **Health Hazard-determining components of labeling:**
Cristobalite
- **Hazard statements**
May cause cancer.
- **Precautionary statements**
*P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.*
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



*Health = 0
Fire = 0
Reactivity = 0*

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· **HMIS-ratings (scale 0 - 4)**

HEALTH	*0	Health = *0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

14464-46-1	Cristobalite	 Carc. 1A, H350; STOT RE 1, H372	>10-≤25%
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4 First-aid measures

- **Description of first aid measures**
- **After inhalation:**
Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.
- **After skin contact:**
Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.
- **After eye contact:**
Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.
- **After swallowing:**
Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**
Specific information on symptoms and effects caused by the product are unknown.
- **Indication of any immediate medical attention and special treatment needed** Information not available

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
Fire-extinguishing powder
Water
Foam
Carbon dioxide
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** Do not breathe combustion products.
- **Advice for firefighters**
- **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.
- **Additional information**
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.
Collect contaminated fire fighting water separately. It must not enter the sewage system.

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Cool endangered receptacles with water spray.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Avoid release to the environment
Keep away from heat and direct sunlight.
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
- **Information about protection against explosions and fires:** Keep respiratory protective device available.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Provide ventilation for receptacles.
Store only in the original receptacle.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:**
Protect from exposure to the light.
Store receptacle in a well ventilated area.
See product labelling.
Keep receptacle tightly sealed.
- **Specific end use(s)** Professional Dental Impression Material

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

- **Components with limit values that require monitoring at the workplace:**

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PEL	Long-term value: 0.05* mg/m ³ *resp. dust; ½ value from resp.dust formulae Quartz
REL	Long-term value: 0.05* mg/m ³ *respirable dust; See Pocket Guide App. A
TLV	Long-term value: 0.025* mg/m ³ *as respirable fraction

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· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Observe good industrial hygiene practices.

Do not eat, drink, smoke or sniff while working.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Store protective clothing separately.

· **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material is based on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The determined penetration times according to EN 16523-1:2015 are not performed under practical conditions.

Therefore a maximum wearing time, which corresponds to 50% of the penetration time, is recommended.

The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles

· **Body protection:** Boots

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Fluid

Color: Orange

· **Odor:** Bubble Gum

· **Odor threshold:** Not determined.

· **pH-value:** Not available

· **Change in condition**

Melting point/Melting range: Not available

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Boiling point/Boiling range:	Not available
· Flash point:	Not available
· Flammability (solid, gaseous):	Not available
· Decomposition temperature:	Not available
· Auto igniting:	Not available
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not available
Upper:	Not available
· Vapor pressure:	Not available
· Density:	Not available
· Relative density	Not available
· Vapor density	Not available
· Evaporation rate	Not available
· Solubility in / Miscibility with	
Water:	Insoluble in water
· Partition coefficient (n-octanol/water):	Not available
· Viscosity:	
Dynamic:	Not available
Kinematic:	Not available
· Solvent content:	
Organic solvents:	<0.2 %
VOC content:	<0.20 %
	<2.0 g/l / <0.02 lb/gal
VOC (EC)	<0.20 %
Solids content:	>89.6-<110 %
· Other information	Information not available

10 Stability and reactivity

- **Reactivity** Stable when stored and handled under recommended conditions.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** None by intended use.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** Does not meet the classification criteria for this hazard class.

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- **on the eye:** Does not meet the classification criteria for this hazard class.
 - **Sensitization:** Does not meet the classification criteria for this hazard class.
 - **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
 - **Carcinogenic categories**
- | | | |
|--|--------------|---|
| · IARC (International Agency for Research on Cancer) | | |
| 14464-46-1 | Cristobalite | I |
| · NTP (National Toxicology Program) | | |
| 14464-46-1 | Cristobalite | K |
| · OSHA-Ca (Occupational Safety & Health Administration) | | |
| None of the ingredients is listed. | | |
- **Germ cell mutagenicity** Does not meet the classification criteria for this hazard class.
 - **Carcinogenicity** Does not meet the classification criteria for this hazard class.
 - **Reproductive toxicity** Does not meet the classification criteria for this hazard class.
 - **Specific target organ toxicity - single exposure** Does not meet the classification criteria for this hazard class.
 - **Specific target organ toxicity - repeated exposure** Does not meet the classification criteria for this hazard class.
 - **Aspiration hazard** Does not meet the classification criteria for this hazard class.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** Not easily biodegradable
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Not hazardous for water.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Disposal should be in accordance with applicable regional, national and local laws and regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|----------------------------------|---------------|
| · UN-Number | |
| · DOT, ADN, IMDG, IATA | Not Regulated |
| · UN proper shipping name | |
| · DOT, ADN, IMDG, IATA | Not Regulated |

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· Transport hazard class(es)	
· DOT, ADN, IMDG, IATA	
· Class	Not Regulated
· Packing group	
· DOT, IMDG, IATA	Not Regulated
· Environmental hazards:	Not Applicable.
· Special precautions for user	Not Applicable
· Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not Applicable.
· UN "Model Regulation":	Not Regulated

15 Regulatory information

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

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

- **TSCA (Toxic Substances Control Act):**

All components have the value ACTIVE.

- **Hazardous Air Pollutants**

None of the ingredients is listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

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- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

- **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

- **ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)**

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A2

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

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· **National regulations:**

· **Information about limitation of use:**

Workers are not allowed to be exposed to the hazardous carcinogenic materials contained in this preparation. Exceptions can be made by the authorities in certain cases.

· **Chemical safety assessment:** *A chemical safety assessment has not been carried out.*

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing SDS:** *Environmental, Health, and Safety*

· **Contact:** *Customer Service*

· **Date of preparation / last revision** 09/16/2021 / -

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Carc. 1A: Carcinogenicity – Category 1A

STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

US