

**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 09/23/2021

Reviewed on 09/23/2021

**1 Identification**

- **Product identifier**
- **Trade name:** *Clone™ Bite - Catalyst*
- **Article number:** *SDS 426-001.01, 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**

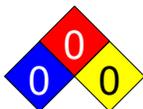
- **Classification of the substance or mixture**



*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*

(Contd. on page 2)

# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/23/2021

Reviewed on 09/23/2021

Trade name: Clone™ Bite - Catalyst

(Contd. of page 1)

· **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	≥1-<10%
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### 4 First-aid measures

- **Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** If skin irritation continues, consult a doctor.
- **After eye contact:**  
Remove contact lenses, if present. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Call a physician if irritation develops or persists.
- **After swallowing:** Do not induce vomiting; call for medical help immediately.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed** Information not available

### 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
Carbon dioxide  
Powder  
Foam  
Water spray  
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**  
Use water spray to cool fire exposed surfaces and protect personnel. Move containers from fire area if there isn't any risk.
- **Protective equipment:** Wear fully protective suit.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Ensure adequate ventilation  
Use respiratory protective device against the effects of fumes/dust/aerosol.  
Wear protective clothing.
- **Environmental precautions:** No special measures required.

(Contd. on page 3)

# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/23/2021

Reviewed on 09/23/2021

Trade name: Clone™ Bite - Catalyst

(Contd. of page 2)

- **Methods and material for containment and cleaning up:**  
Collect all contaminated wash water for proper disposal.  
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**  
Do not smoke.  
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:**  
Store receptacle in a well ventilated area.  
Protect from exposure to the light.  
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:**

### 14464-46-1 Cristobalite

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

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Do not eat, drink, smoke or sniff while working.

(Contd. on page 4)

# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/23/2021

Reviewed on 09/23/2021

Trade name: Clone™ Bite - Catalyst

(Contd. of page 3)

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:**

<b>Form:</b>	Fluid
<b>Color:</b>	White
<b>Odor:</b>	Odorless
<b>Odor threshold:</b>	Not available

· **pH-value:** Not applicable (non-aqueous)

· **Change in condition**

<b>Melting point/Melting range:</b>	Not available
<b>Boiling point/Boiling range:</b>	Not available

· **Flash point:** Not available

· **Flammability (solid, gaseous):** Not available

· **Decomposition temperature:** Not available

(Contd. on page 5)

# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/23/2021

Reviewed on 09/23/2021

Trade name: Clone™ Bite - Catalyst

(Contd. of page 4)

· <b>Auto igniting:</b>	Not available
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not available
<b>Upper:</b>	Not available
· <b>Vapor pressure:</b>	Not determined.
· <b>Density:</b>	Not available
· <b>Relative density</b>	Not available
· <b>Vapor density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with Water:</b>	Insoluble in water
· <b>Partition coefficient (n-octanol/water):</b>	Not applicable
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not available
<b>Kinematic:</b>	Not available
· <b>Solvent content:</b>	
<b>VOC content:</b>	0.00 %
	0.0 g/l / 0.00 lb/gal
<b>VOC (EC)</b>	0.00 %
<b>Solids content:</b>	>96.5-<103.5 %
· <b>Other information</b>	Information not available

## 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used and stored according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **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.
- **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:

(Contd. on page 6)

# Safety Data Sheet

## acc. to OSHA HCS

Printing date 09/23/2021

Reviewed on 09/23/2021

Trade name: Clone™ Bite - Catalyst

(Contd. of page 5)

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

All components have the value I.

- **NTP (National Toxicology Program)**

All components have the value 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:**  
At present there are no ecotoxicological assessments.  
Not hazardous for water.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** Information not 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

- |   |               |
|---|---------------|
| <ul style="list-style-type: none"> <li>· <b>UN-Number</b></li> <li>· <b>DOT, ADN, IMDG, IATA</b></li> </ul>               | Not Regulated |
| <ul style="list-style-type: none"> <li>· <b>UN proper shipping name</b></li> <li>· <b>DOT, ADN, IMDG, IATA</b></li> </ul> | Not Regulated |

(Contd. on page 7)

US

# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/23/2021

Reviewed on 09/23/2021

Trade name: Clone™ Bite - Catalyst

(Contd. of page 6)

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

## 15 Regulatory information

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

Directive 2012/18/EC: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

Product: None

Substances in Candidate List (Art. 59 REACH): None

Substances subject to authorisation (Annex XIV REACH): None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012: None

Substances subject to the Rotterdam Convention: None

Substances subject to the Stockholm Convention: None

Healthcare controls: Information not available

· **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:**

All ingredients are listed.

· **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.

(Contd. on page 8)

# Safety Data Sheet

acc. to OSHA HCS

Printing date 09/23/2021

Reviewed on 09/23/2021

**Trade name: Clone™ Bite - Catalyst**

(Contd. of page 7)

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

All components have the value A2.

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

All ingredients are listed.

· **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** 09/23/2021 / -

· **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