

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 27.09.2019

Revision: 14.11.2018

1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** Clone™ Bite - Catalyst
- **Article number:** 7600
- **Index number:** SDS 426-001.01
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Impression Material
- **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

- **EC Responsible Person**
Ultradent Products GmbH
Am Westhoyer Berg 30
51149 Cologne Germany
Email: infoDe@ultradent.com
Emergency Phone: +49(0)2203-35-92-0
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified, according to the CLP regulation.

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The Regulation EC 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5(d). Therefore, the product is exempted from the CLP labelling requirements, and no SDS is required by Regulation 1907/2006, Art 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

GB2

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 27.09.2019

Revision: 14.11.2018

Trade name: Clone™ Bite - Catalyst

(Contd. of page 1)

3 Composition/information on ingredients

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

- **Dangerous components:**

CAS: 14464-46-1	Cristobalite	 STOT RE 1, H372	<10%
EINECS: 238-455-4			

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- **Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:**
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
- **After skin contact:**
Immediately rinse with water.
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 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
Carbon dioxide
Powder
Foam
Water spray
Use fire extinguishing methods suitable to surrounding conditions.
- **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:** Do not allow product to reach sewage system or any water course.
- **Methods and material for containment and cleaning up:**
Ensure adequate ventilation.

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 27.09.2019

Revision: 14.11.2018

Trade name: Clone™ Bite - Catalyst

(Contd. of page 2)

- Collect all contaminated wash water for proper disposal.
- Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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.
- **Information about fire - and explosion protection:** Protect from heat.
- **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 heat and direct sunlight.
- Store receptacle in a well ventilated area.
- Protect from exposure to the light.
- See product labelling.
- **Specific end use(s)** Professional Dental Impression Material

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
- The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
- Immediately remove all soiled and contaminated clothing.
- Do not eat, drink, smoke or sniff while working.
- **Respiratory protection:** Not required.
- **Protection of hands:**
- 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 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.

(Contd. on page 4)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 27.09.2019

Revision: 14.11.2018

Trade name: Clone™ Bite - Catalyst

(Contd. of page 3)

- **Penetration time of glove material**

The determined penetration times according to EN 374 part III 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:** Goggles recommended during refilling

- **Body protection:** Boots

9 Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form: Fluid

Colour: White

- **Odour:** Odourless

- **Odour threshold:** Not available

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

- **Change in condition**

Melting point/freezing point: Not available

Initial boiling point and boiling range: Not available

- **Flash point:** Not available

- **Flammability (solid, gas):** Not available

- **Decomposition temperature:** Not available

- **Auto-ignition temperature:** Not available

- **Explosive properties:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower: Not available

Upper: Not available

- **Vapour pressure:** Not determined.

- **Density:** Not available

- **Relative density** Not available

- **Vapour density** Not determined.

- **Evaporation rate** Not determined.

- **Solubility in / Miscibility with water:**

Insoluble in water

- **Partition coefficient: n-octanol/water:** Not applicable

- **Viscosity:**

Dynamic: Not available

Kinematic: Not available

- **Solvent content:**

VOC (EC) 0.00 %

Solids content: ≤100 %

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 27.09.2019

Revision: 14.11.2018

Trade name: Clone™ Bite - Catalyst

(Contd. of page 4)

· **Other information** 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** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation** Does not meet the classification criteria for this hazard class.
- **Serious eye damage/irritation** Does not meet the classification criteria for this hazard class.
- **Respiratory or skin sensitisation** Does not meet the classification criteria for this hazard class.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.
- **STOT-single exposure** Does not meet the classification criteria for this hazard class.
- **STOT-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
- **Behaviour 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

GB2

(Contd. on page 6)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 27.09.2019

Revision: 14.11.2018

Trade name: Clone™ Bite - Catalyst

(Contd. of page 5)

13 Disposal considerations· **Waste treatment methods**· **Recommendation**

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Smaller quantities can be disposed of with household waste.

· **European waste catalogue**

HP5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

· **Uncleaned packaging:**· **Recommendation:** Disposal must be made according to official regulations.**14 Transport information**· **UN-Number**· **ADR, ADN, IMDG, IATA** not regulated· **UN proper shipping name**· **ADR, ADN, IMDG, IATA** not regulated· **Transport hazard class(es)**· **ADR, ADN, IMDG, IATA**· **Class** not regulated· **Packing group**· **ADR, IMDG, IATA** not regulated· **Environmental hazards:**

Not applicable.

· **Special precautions for user**

Not applicable.

· **Transport in bulk according to Annex II of Marpol 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**

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

· **Directive 2012/18/EU**· **Named dangerous substances - ANNEX I** None of the ingredients is listed.· **Chemical safety assessment:** A chemical safety assessment has not been carried out.

GB2

(Contd. on page 7)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 27.09.2019

Revision: 14.11.2018

Trade name: Clone™ Bite - Catalyst

(Contd. of page 6)

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.

· Relevant phrases

H372 Causes damage to organs through prolonged or repeated exposure.

· Department issuing SDS: Regulatory Affairs

· Contact: Customer Service

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

VOC: Volatile Organic Compounds (USA, EU)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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

GB2