

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 28.10.2015

Version number 2

Revision: 28.10.2015

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

- **1.1 Product identifier**
- **Trade name:** *Aquasil Bite Catalyst*
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** *Dental impression material*
- **Uses advised against** *No further relevant information available.*
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
DENTSPLY DeTrey GmbH
De-Trey-Str. 1
D-78467 Konstanz
GERMANY
Tel.: +49-(0)7531-583-0
Fax: +49-(0)7531-583-104
email: KonstanzDEU.info-sdb@dentsply.com
- **Further information obtainable from:**
 - *Departement Research & Development for technical information*
 - *Departement Marketing & Sales for distribution of the safety data sheets*
- **1.4 Emergency telephone number:** *+49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)*


SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified according to the CLP regulation.
- **Additional information:**
Due to the physical form (paste) classification with H373 is not appropriate. An inhalation of the product is not possible (refer to section 11).
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** *Void*
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*
- **Additional information:**
Safety data sheet available on request.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

SECTION 3: Composition/information on ingredients

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

- **Dangerous components:**

CAS: 14464-46-1	cristobalite	 STOT RE 1, H372	2.5-<10%
EINECS: 238-455-4			

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

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information** *No special measures required.*
- **After inhalation** *Supply fresh air; consult doctor in case of complaints.*

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Trade name: Aquasil Bite Catalyst

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- **After skin contact**
Rinse with warm water.
Generally the product does not irritate the skin.
- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing** Do not induce vomiting; call for medical help immediately.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Information for doctor** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents** CO₂, powder or water spray. Fight larger fires with water spray.
- **For safety reasons unsuitable extinguishing agents** Water with full jet.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow product to reach sewage system or any water course.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Observe normal care for working with chemicals.
- **Handling** Product is intended for dental use only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Store in dry conditions.
- **Maximum storage temperature:** 28 °C
- **Minimum storage temperature** 2 °C
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 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.

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- **8.2 Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not necessary if room is well-ventilated.
- **Protection of hands:** Not required.
- **Material of gloves not applicable**
- **Penetration time of glove material not applicable**
- **Eye protection:** Not required.
- **Body protection:** Protective work clothing.

SECTION 9: Physical and chemical properties

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

- **General Information**

- **Appearance:**

· Form:	Pasty
· Colour:	White
· Odour:	Odourless
· Odour threshold:	Not determined.

- **pH-value:** Not determined.

- **Change in condition**

· Melting point/Melting range:	undetermined
· Boiling point/Boiling range:	Undetermined.

- **Flash point:** Not applicable

- **Flammability (solid, gaseous)** Not applicable.

- **Ignition temperature:** Not applicable

- **Decomposition temperature:** Not determined.

- **Self-igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

· Lower:	Not determined.
· Upper:	Not determined.

- **Vapour pressure:** Not determined.

· Density:	Not determined
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.

- **Solubility in / Miscibility with**

· **Water:** Insoluble

- **Partition coefficient (n-octanol/water):** Not determined.

- **Viscosity:**

· dynamic:	Not determined.
· kinematic:	Not determined.

- **Solvent content:**

· **Organic solvents:** 0.0 %

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· **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity**

· **LD/LC50 values relevant for classification:**

14464-46-1 cristobalite

Oral LD50 > 2000 mg/kg (rat) (OECD 401)

- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
EC regulation 1272/2008 annex 1, section 1.1.1.5: "For the purpose of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified."
- **CMR effects (carcinogenicity, mutagenicity and toxicity 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.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Not known to be hazardous to water.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

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SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.

- **European waste catalogue**

18 01 07	chemicals other than those mentioned in 18 01 06
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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, ADN, IMDG, IATA** Void

- **14.2 UN proper shipping name**
- **ADR, ADN, IMDG, IATA** Void

- **14.3 Transport hazard class(es)**
- **ADR, ADN, IMDG, IATA**
- **Class** Void

- **14.4 Packing group**
- **ADR, IMDG, IATA** Void

- **14.5 Environmental hazards:**
- **Marine pollutant:** No

- **14.6 Special precautions for user** Not applicable.

- **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.

- **UN "Model Regulation":** Void

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 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.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

- **Relevant phrases**
H372 Causes damage to organs through prolonged or repeated exposure.

- **Department issuing MSDS:** Research & Development
- **Contact:** HotLine for urgent technical support: +49-7531-583-350

- **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)

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*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)**LC50: Lethal concentration, 50 percent**LD50: Lethal dose, 50 percent**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**STOT RE 1: Specific target organ toxicity - Repeated exposure, Hazard Category 1***· * Data compared to the previous version altered.**

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

- **1.1 Product identifier**
- **Trade name:** *Aquasil Bite Base*
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** *Dental impression material*
- **Uses advised against** *No further relevant information available.*
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
DENTSPLY DeTrey GmbH
De-Trey-Str. 1
D-78467 Konstanz
GERMANY
Tel.: +49-(0)7531-583-0
Fax: +49-(0)7531-583-104
email: KonstanzDEU.info-sdb@dentsply.com
- **Further information obtainable from:**
 - *Departement Research & Development for technical information*
 - *Departement Marketing & Sales for distribution of the safety data sheets*
- **1.4 Emergency telephone number:** *+49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)*


SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified according to the CLP regulation.
- **Additional information:**
Due to the physical form (paste) classification with H372 is not appropriate. An inhalation of the product is not possible (refer to section 11).
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** *Void*
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*
- **Additional information:**
Safety data sheet available on request.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

SECTION 3: Composition/information on ingredients

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

- **Dangerous components:**

CAS: 14464-46-1	crystalite	 STOT RE 1, H372	10-<25%
EINECS: 238-455-4			

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

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information** *No special measures required.*
- **After inhalation** *Supply fresh air; consult doctor in case of complaints.*

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Trade name: Aquasil Bite Base

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- **After skin contact**
Rinse with warm water.
Generally the product does not irritate the skin.
- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing** Do not induce vomiting; call for medical help immediately.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Information for doctor** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents** Water with full jet.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow product to reach sewage system or any water course.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Observe normal care for working with chemicals.
- **Handling** Product is intended for dental use only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Store in dry conditions.
- **Maximum storage temperature:** 28 °C
- **Minimum storage temperature** 2 °C
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 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.

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Trade name: Aquasil Bite Base

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- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not necessary if room is well-ventilated.
- **Protection of hands:** Not required.
- **Material of gloves** not applicable
- **Penetration time of glove material** not applicable
- **Eye protection:** Not required.
- **Body protection:** Protective work clothing.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

· Form:	Pasty
· Colour:	Violet
· Odour:	Odourless
· Odour threshold:	Not determined.

· **pH-value:** Not determined.

· Change in condition

· Melting point/Melting range:	undetermined
· Boiling point/Boiling range:	Undetermined.

· **Flash point:** Not applicable

· **Flammability (solid, gaseous)** Not applicable.

· **Ignition temperature:** Not applicable

· **Decomposition temperature:** Not determined.

· **Self-igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· Explosion limits:

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapour pressure:** Not determined.

· Density:	Not determined
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.

· Solubility in / Miscibility with

· **Water:** Insoluble

· **Partition coefficient (n-octanol/water):** Not determined.

· Viscosity:

· dynamic:	Not determined.
· kinematic:	Not determined.

· Solvent content:

· **Organic solvents:** 0.0 %

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· **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity**

· **LD/LC50 values relevant for classification:**

14464-46-1 cristobalite

Oral LD50 > 2000 mg/kg (rat) (OECD 401)

- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
EC regulation 1272/2008 annex 1, section 1.1.1.5: "For the purpose of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified."
- **CMR effects (carcinogenicity, mutagenicity and toxicity 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.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Not known to be hazardous to water.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

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SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.

- **European waste catalogue**

18 01 07	chemicals other than those mentioned in 18 01 06
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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, ADN, IMDG, IATA** Void

- **14.2 UN proper shipping name**
- **ADR, ADN, IMDG, IATA** Void

- **14.3 Transport hazard class(es)**
- **ADR, ADN, IMDG, IATA**
- **Class** Void

- **14.4 Packing group**
- **ADR, IMDG, IATA** Void

- **14.5 Environmental hazards:**
- **Marine pollutant:** No

- **14.6 Special precautions for user** Not applicable.

- **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code** Not applicable.

- **UN "Model Regulation":** Void

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 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.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

- **Relevant phrases**
H372 Causes damage to organs through prolonged or repeated exposure.

- **Department issuing MSDS:** Research & Development
- **Contact:** HotLine for urgent technical support: +49-7531-583-350

- **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)

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*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)**LC50: Lethal concentration, 50 percent**LD50: Lethal dose, 50 percent**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**STOT RE 1: Specific target organ toxicity - Repeated exposure, Hazard Category 1***· * Data compared to the previous version altered.**

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