

**Safety data sheet (GB)**  
according to 1907/2006/EC, Article 31

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Printing date 27.10.2016  
Revision: 27.10.2016  
Version number 3

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

- **Product identifier**
- **Trade name: Aqium® 3D bite**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture**  
Dental impression material,  
medical device
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Müller-Omicron GmbH & Co. KG  
Schlosserstr. 1  
51789 Lindlar / Köln  
GERMANY  
www.mueller-omicron.de
- **Further information obtainable from:**  
Product safety department  
sds@mueller-omicron.de
- **1.4 Emergency telephone number:**  
During normal opening times (08:00 a.m. - 05:00 p.m.): +49 (0) 2771 / 3304 - 23

**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.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **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:**

EINECS: 238-455-4 Cristobalite (CAS 14464-46-1)	 STOT RE 1, H372	50 - < 70%
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- **Additional information:** For the wording of the listed hazard 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.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.

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- **4.2 Most important symptoms and effects, both acute and delayed**  
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:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

## SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **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**  
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** No special measures required.
- **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:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **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.
- **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 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 the 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.  
Not required.

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**- Penetration time of glove material**

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

Not required.

**- Eye protection:** Goggles recommended during refilling

**SECTION 9: Physical and chemical properties**

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

**- General Information**

**- Appearance:**

**Form:** Pasty  
**Colour:** according to product description  
base: yellow  
catalyst: white

**- Odour:** Characteristic  
base: mint  
catalyst: characteristic

**- 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:** >290 °C

**- 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 at 20 °C:** 1 hPa

**- Density:** Not determined.

**- Relative density at 20 °C** 1.4

**- Vapour density** Not determined.

**- Evaporation rate** Not determined.

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

Not miscible or difficult to mix.

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

**- Viscosity:**

**Dynamic:** Not determined.

**Kinematic:** Not determined.

**- Solvent content:**

**VOC (EC)** 0.00 %

**Solids content:** 70.0 %

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

**SECTION 10: Stability and reactivity**

**- 10.1 Reactivity** No further relevant information available.

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

### - LD/LC50 values relevant for classification:

#### Siliziumdioxid

Oral	LD50	> 5000 mg/kg (rat)
Dermal	LD50	> 5000 mg/kg (rabbit)
Inhalative	LC50/4 h	0.139 mg/l (rat)

- **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.
- **CMR effects (carcinogenity, 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:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

## SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

## SECTION 14: Transport information

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

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- 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 - Stowage Category	Not applicable. A
- 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.*

- **Relevant phrases**  
H372 Causes damage to organs through prolonged or repeated exposure.
- **Department issuing SDS:** Product safety department
- **Contact:** sds@mueller-omicron.de
- **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)  
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) – Category 1
- **Sources**  
The data for the hazardous ingredients were taken respectively from the last version of Safety Data Sheets of suppliers.  
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- \* **Data compared to the previous version altered.**