

Safety data sheet

according to 1907/2006/EC, Article 31

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Printing date 31.03.2023

Revision: 31.03.2023

Version number 2

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

- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Product identifier**
- **Trade name: Simplee Silic A (betasil® VARIO LIGHT / LIGHT fast set / MEDIUM / HEAVY / IMPLANT)**
- **Application of the substance / the mixture** Dental impression material, medical device

- 1.3 Details of the supplier of the safety data sheet

- **Manufacturer**

Müller-Omicron GmbH & Co. KG
Schlosserstr. 1
D-51789 Lindlar
GERMANY
www.mueller-omicron.com

Supplier:

M+W Dental, Mueller & Weygandt GmbH
Reichardsweide 40
63654 Büdingen
GERMANY
www.mwdental.de

- **Further information obtainable from:**

Product safety department
sds@mueller-omicron.de

- **1.4 Emergency telephone number:**

Mon-Thu: +49 (0)2266 / 4742-0 (8 am - 5 pm CET)
Fri: +49 (0)2266 / 4742-0 (8 am - 1 pm CET)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- **2.2 Label elements**

- **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.

- **Hazard pictograms** Void

- **Signal word** Void

- **Hazard statements**

H412 Harmful to aquatic life with long lasting effects.

- **Precautionary statements**

P273 Avoid release to the environment.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Additional information:**

This Product contains a substance which is classified as STOT RE 1. Due to its physical form, exposure through inhalation is not expected (Regulation (EC) No 1272/2008 (CLP) - Annex I, 1.1.1.5).

- **2.3 Other hazards**

- **Results of PBT and vPvB assessment**

This substance/mixture does not contain components classified as either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **Determination of endocrine-disrupting properties**

Endocrine disrupting properties - human health: The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

Endocrine disrupting properties - Environment: The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

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Trade name: Simplee Silic A (betasil® VARIO LIGHT / LIGHT fast set / MEDIUM / HEAVY / IMPLANT)

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more.

SECTION 3: Composition/information on ingredients

- 3.2 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	25-50%
CAS: 556-67-2 EINECS: 209-136-7 Index number: 014-018-00-1	octamethylcyclotetrasiloxane Flam. Liq. 3, H226; Repr. 2, H361f; Aquatic Chronic 1, H410 (M=10) PBT; vPvB	≥0.025-<0.1%

- **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

- **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.

- 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:** Use fire extinguishing methods suitable to surrounding conditions.

- **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 product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

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).

Dispose contaminated material as waste according to item 13.

- 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 precautions are necessary if used correctly.

- **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.

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SECTION 8: Exposure controls/personal protection

- **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**
- **Appropriate engineering controls** No further data; see item 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Hand protection**
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.
- **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.
- **Eye/face protection** Goggles recommended during refilling

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Fluid
- **Colour:** according to product description
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Undetermined.
- **Boiling point or initial boiling point and boiling range** Undetermined.
- **Flammability** Not applicable.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** Not applicable.
- **Ignition temperature:** >400 °C
- **Decomposition temperature:** Not determined.
- **pH** Not determined.
- **Viscosity:**
- **Kinematic viscosity** Not determined.
- **Dynamic:** Not determined.
- **Solubility**
- **water:** Not miscible or difficult to mix.
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Vapour pressure at 20 °C:** 100 hPa
- **Density and/or relative density**
- **Density at 20 °C:** 1.4 g/cm³
- **Relative density** Not determined.
- **Vapour density** Not determined.

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Trade name: Simplee Silic A (betasil® VARIO LIGHT / LIGHT fast set / MEDIUM / HEAVY / IMPLANT)

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- 9.2 Other information	
- Appearance:	
- Form:	Pasty
- Important information on protection of health and environment, and on safety.	
- Auto-ignition temperature:	Product is not selfigniting.
- Explosive properties:	Product does not present an explosion hazard.
- Solvent content:	
- Organic solvents:	0 %
- VOC (EC)	0-<0.01 %
- Solids content:	60.0 %
- Change in condition	
- Evaporation rate	Not determined.
- Information with regard to physical hazard classes	
- Explosives	Void
- Flammable gases	Void
- Aerosols	Void
- Oxidising gases	Void
- Gases under pressure	Void
- Flammable liquids	Void
- Flammable solids	Void
- Self-reactive substances and mixtures	Void
- Pyrophoric liquids	Void
- Pyrophoric solids	Void
- Self-heating substances and mixtures	Void
- Substances and mixtures, which emit flammable gases in contact with water	Void
- Oxidising liquids	Void
- Oxidising solids	Void
- Organic peroxides	Void
- Corrosive to metals	Void
- Desensitised explosives	Void

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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **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.
- **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.

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Trade name: Simplee Silic A (betasil® VARIO LIGHT / LIGHT fast set / MEDIUM / HEAVY / IMPLANT)

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- 11.2 Information on other hazards

- Endocrine disrupting properties

Endocrine disrupting properties - human health: The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

None of the ingredients is listed.

*** 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.

- 12.5 Results of PBT and vPvB assessment

This substance/mixture does not contain components classified as either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

- PBT: Not applicable.

- vPvB: Not applicable.

- 12.6 Endocrine disrupting properties

Endocrine disrupting properties - Environment: The substance/mixture does not contain any components that exhibit endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Delegated Regulation (EU) 2018/605 in quantities of 0.1% or more.

- 12.7 Other adverse effects

- Remark: Harmful to fish

- 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.

Harmful to aquatic organisms

*** SECTION 13: Disposal considerations**

- 13.1 Waste treatment methods

- Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- Uncleaned packaging:

- Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

- 14.1 UN number or ID number

- ADR, IMDG, IATA Void

- 14.2 UN proper shipping name

- ADR, 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: Not applicable.

- 14.6 Special precautions for user Not applicable.

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| - 14.7 Maritime transport in bulk according to IMO instruments | Not applicable. |
| - UN "Model Regulation": | Void |

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Directive 2012/18/EU
- Named dangerous substances - ANNEX I None of the ingredients is listed.
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 70
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II
- None of the ingredients is listed.
- REGULATION (EU) 2019/1148
- Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))
- None of the ingredients is listed.
- Annex II - REPORTABLE EXPLOSIVES PRECURSORS
- None of the ingredients is listed.
- Regulation (EC) No 273/2004 on drug precursors
- None of the ingredients is listed.
- Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors
- None of the ingredients is listed.
- 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
- H226 Flammable liquid and vapour.
- H361f Suspected of damaging fertility.
- H372 Causes damage to organs through prolonged or repeated exposure.
- H410 Very toxic to aquatic life with long lasting effects.
- Contact: sds@mueller-omicron.de
- Date of previous version: 31.03.2023
- Abbreviations and acronyms:
 - ADR: Accord relatif au transport international 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
 - Flam. Liq. 3: Flammable liquids – Category 3
 - Repr. 2: Reproductive toxicity – Category 2
 - STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
 - Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
 - Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3
- Sources
- The data for the hazardous ingredients were taken respectively from the last version of Safety Data Sheets of suppliers.
- * Data compared to the previous version altered.