

01. Identification of the substance / preparation and of the company

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| Product: | betasil® VARIO MEDIUM / LIGHT/ betasil® LIGHT fast set; betasil® VARIO IMPLANT base / catalyst |
| Registration number: | not applicable |
| Use / Method of operation: | see product information / instructions for use |
| Identified use: | Medical device, dental impression material |
| Company: | Müller-Omicron GmbH & Co. KG Schlosserstraße 1 51789 Lindlar / GERMANY |
| Phone : | 0049 (0) 2266-4742-0 |
| Fax : | 0049 (0) 2266-3417 |
| eMail : | info@mueller-omicron.de |
| Homepage : | www.mueller-omicron.de |
| Emergency phone: | 0049 (0) 2266-4742-0 (8:00 – 17:00) |
| Responsible: | vsahr@omicron-dental.de |

02. Hazards identification

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|----------------------------------|-----------------------------|
| Physico-chemical hazards: | No particular hazard known. |
| Human health dangers: | No particular hazard known. |
| Environmental hazards: | No particular hazard known. |
| Other hazards: | none |
| Hazard symbols : | none |
| R-phrases : | none |

03. Composition / Information on ingredients

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| Description: | Two-part polyvinylsiloxane-based dental impression material, comprising a base-component and matching catalyst-component. |
| Hazardous Ingredients: | not applicable |

04. First aid measures

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| General information: | none |
| Inhalation: | not applicable |
| Skin contact: | When in contact with the skin, clean with soap and water. Consult a doctor if skin irritation persists. |
| Eye contact: | In case of contact with eyes rinse thoroughly with plenty of water and seek medical advice. |
| Ingestion: | Supply with medical care. Rinse out mouth and give plenty of water to drink. |
| Advice to doctor: | Treat symptomatically. |

05. Fire-fighting measures

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| Suitable extinguishing media: | Dry powder. Foam. Water spray jet. Carbon dioxide. |
| Extinguishing media that must not be used: | Full water jet. |

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| Special exposure hazards arising from the substance or preparation itself or combustion products: | Unknown risk of formation of toxic pyrolysis products. |
| Special protective equipment for firefighters: | Use self-contained breathing apparatus. |
| Additional information: | Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations. |

06. Accidental release measures

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| Personal precautions: | Forms slippery surfaces with water |
| Environmental precautions: | Do not discharge into the drains / surface waters / groundwater. Prevent spread over a wide area (e.g. by containment or oil barriers). |
| Methods for cleaning up: | Take up mechanically. Dispose of absorbed material in accordance within the regulations. |

07. Handling and storage

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| Advice on safe handling: | No special measures necessary if used correctly. |
| Advice on protection against fire and explosion: | No special measures necessary. |
| Requirements for storage rooms and vessels: | Keep only in original container. |
| Advice on storage compatibility: | No special measures necessary. |
| Further information on storage conditions: | Keep container tightly closed. |

08. Exposure controls / personal protection

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| Additional advice on system design: | not applicable |
| Ingredients with occupational exposure limits to be monitored: | not applicable |
| Respiratory protection: | not applicable |
| Hand protection: | butyl rubber, > 120 min (EN 374) |
| Eye protection: | not applicable |
| Skin protection: | none |
| General protective measures: | Avoid contact with eyes. |
| Hygiene measures: | Wash hands before breaks and after work. Use barrier skin cream. |
| Delimitation and monitoring of the environment exposition: | not determined |

09. Physical and chemical properties

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|----------------------------|----------------|--------------------------------|----------------|
| Appearance: | pasty | Density at 23°C [g/ml]: | 1,35 – 1,55 |
| Color: | different | Evaporation speed: | not determined |
| Odor: | characteristic | Vapour pressure [kPa]: | not determined |
| pH-value: | not applicable | Viscosity [mPas]: | not determined |
| Boiling point [°C]: | not determined | Solubility in water: | immiscible |
| Flash point [°C]: | not determined | Oxidizing properties: | no |
| Flammability: | not determined | Melting point [°C]: | not determined |

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| | | | |
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| Upper explosion limit: | not applicable | Autoignition temperature: | not determined |
| Lower explosion limit: | not applicable | Decomposition temperature: | not determined |

10. Stability and reactivity

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| Hazardous reactions: | No hazardous reactions known. |
| Hazardous decomposition products: | No hazardous decomposition products known. |

11. Toxicological information

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| Acute toxicity oral / dermal / inhalational: | not determined |
| Irritant effect on eye: | not determined |
| Irritant effect on skin : | not determined |
| Sensitization: | not determined |
| Subacute / Chronic toxicity: | not determined |
| CMR-activity | not determined |
| Experiences made in practice: | none. |
| General remarks: | Toxicological data are not available. No classification on the basis of the calculation procedure of the preparation directive. |

12. Ecological information

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| Fish / Daphnia / Bacteria toxicity: | not determined |
| Behaviour in environment compartments: | not determined |
| Behaviour in sewage plant: | not determined |
| Biological degradability: | not determined |
| Chemical (COD) / Biochemical (BOD 5) oxygen demand: | not determined |
| AOX-advice: | No dangerous components. |
| 2006/11/EC: | not determined |
| General information: | Ecological data are not available. No classification on the basis of the calculation procedure of the preparation directive. |

13. Disposal considerations

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| Product: | For recycling, consult manufacturer. Coordinate disposal with the authorities if necessary. |
| Contaminated packaging: | Uncontaminated packaging may be taken for recycling. Packaging that cannot be cleaned should be disposed of as for product. |
| Waste no. (recommended): | 070799 |

14. Transport information

Classification according to ADR:

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| Classification according to ADR: | no dangerous goods |
| - Classification Code: | - |
| - Label: | - |
| - ADR LQ | - |

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|----------------------|---|
| - ADR 1.1.3.6 (8.6): | Transport category (tunnel restriction code): - |
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Classification according to IMDG:

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| Classification according to IMDG: | not classified as « Dangerous Goods » |
| - EMS: | - |
| - Label: | - |
| IMDG LQ: | - |

Classification according to IATA:

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|--|---------------------------------------|
| Classification according to IATA: | not classified as « Dangerous Goods » |
| - Label: | - |

15. Regulatory information

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| Exposure scenario: | not determined |
| Chemical safety report: | not determined |
| Labelling: | The product does not require a hazard warning label in accordance with EC-directives. |
| Hazard symbols: | none |
| R-phrases: | none |
| S-phrases: | none |
| Special labelling: | Safety data sheet available for professional user on request. |
| Authorisation, TITEL VII: | not applicable |
| Restrictions, TITEL VIII: | not applicable |
| EEC-REGULATIONS: | 1967/548 (2008/58, 30. ATP/ 31. ATP); 1991/689 (2001/118); 1999/13; 2004/42; 648/2004; 1907/2006. |
| TRANSPORT- REGULATIONS: | DOT-Classification, ADR (2009); IMDG-Code (34. Amdt.); IATA-DGR (2009). |
| NATIONAL REGULATIONS: | EH40/2005 Workplace exposure limits with amendments October 2007 |

16. Other informations

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| R-phrases (Chapter 03): | not applicable |
| Observe employment restrictions for people: | not applicable |
| VOC (1999/13/CE): | not determined |
| Customs tariff: | not determined |

Disclaimer: 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.