Safety Data Sheet 1907/2006/EC (GB)

Bite registration material

Müller-Omicron GmbH & Co. KG

Date printed: 08.03.2011, Revision: 08.10.2009



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

Bite registration material base / catalyst

Product: Granit perfect D45; Granit perfect 3D;

Topas perfect A85; Kristall perfect A50; Kristall perfect A70;

Registration number: not applicable

Use / Method of operation: see product information / instructions for use

Identified use: Medical device, dental impression material for bite-registration

Company: Müller-Omicron GmbH & Co. KG

Schlosserstraße 1

51789 Lindlar / GERMANY 0049 (0) 2266-4742-0

Phone: 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: vsohr@omicron-dental.de

02. Hazards identification

| 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

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

04. First aid measures

| 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

| Suitable extinguishing media: | Water spray jet. Foam. Carbon dioxide. Dry powder. | |
|---|--|--|
| Extinguishing media that must not be used: | Full water jet. | |
| Special exposure hazards arising from the substance or preparation itself or combustion products: | Unknown risk of formation of toxic pyrolysis products. | |

Safety Data Sheet 1907/2006/EC (GB) Bite registration material



Date printed: 08.03.2011, Revision: 08.10.2009



| Special protective equipment for firefighters: | Use self-contained breathing apparatus. |
|--|---|
| Additional information: | Fire residues and contaminated firefighting water must be disposed of in accordance within the local regulations. |

06. Accidental release measures

| Personal precautions: | Forms slippery surfaces with water. | |
|----------------------------|--|--|
| Environmental precautions: | Do not discharge into the drains / surface waters / groundwater. | |
| Methods for cleaning up: | Take up mechanically. Dispose of absorbed material in accordance with the regulations. | |

07. Handling and storage

| 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: | none | |
| Further information on storage conditions: | Prevent drying-out. | |

08. Exposure controls / personal protection

| Additional advice on system design: | No special measures necessary. |
|--|--|
| 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: | not applicable |
| 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

| Appearance: | pasty | Density at 23°C [g/ml]: | 1,05 - 1,65 |
|------------------------|--|----------------------------|----------------|
| Color: | Base: different Catalyst: light grey / transparent | Evaporation speed: | not determined |
| Odor: | Base: mint aroma Catalyst: characteristic | Vapour pressure [kPa]: | not determined |
| pH-value: | not determined | 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 |
| Upper explosion limit: | not applicable | Autoignition temperature: | not determined |
| Lower explosion limit: | not applicable | Decomposition temperature: | not determined |

Safety Data Sheet 1907/2006/EC (GB) Bite registration material Müller-Omicron GmbH & Co. KG



Date printed: 08.03.2011, Revision: 08.10.2009

10. Stability and reactivity

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

11. Toxicological information

| 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

| 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

| 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:

| Classification according to 712111 | |
|------------------------------------|---|
| Classification according to ADR: | no dangerous goods |
| - Classification Code: | - |
| - Label: | - |
| - ADR LQ | - |
| - ADR 1.1.3.6 (8.6): | Transport category (tunnel restriction code): - |

Classification according to IMDG:

| Classification according to | not alocaified as « Dangarous Coods » |
|-----------------------------|---------------------------------------|
| IMDG: | not classified as « Dangerous Goods » |

Safety Data Sheet 1907/2006/EC (GB) Bite registration material

Müller-Omicron GmbH & Co. KG

Date printed: 08.03.2011, Revision: 08.10.2009

| müller- |
|---------|
| omicron |

| - EMS: | - |
|----------|---|
| - Label: | - |
| IMDG LQ: | - |

Classification according to IATA:

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

15. Regulatory information

| 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

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