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according to 1907/2006/EC, Article 31

Printing date 27.10.2016 Version number 3 Revision: 27.10.2016

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

- **Product identifier**

- **Trade name: Smartdent Bissregistrierung**
- **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**
bite registration material,
medical device

- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Omnident Dental-Handelsgesellschaft mbH
Gutenbergring 7 - 9
D - 63110 Rodgau
Phone: +49 (0) 6106 / 874 - 0
Fax: +49 (0) 6106 / 874 - 265
Homepage: www.smartdent.com
E-Mail: info@smartdent.de

- **Further information obtainable from:**
info@omnident.de
info@smartdent.com
- **1.4 Emergency telephone number:**
+49 (0) 6106 / 874 - 0 (Mo - Fri 8:00 am - 5:00 pm)
+49 (0) 6106 - 874 - 0 (Mo - Fr 8:00 a.m. - 5:00 p.m.)

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%

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

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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.
- **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:**
CO2, 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.

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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 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.
- **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

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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

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- **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.
- **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.

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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
- **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.
- **Stowage Category**	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.

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- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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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:**
info@omnident.de
info@smartdent.com
- **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.
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.**