


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

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| Product: | Paste Hardener Catalyst for C-Silicone Impression Materials |
| Registration number: | not applicable |
| Use / Method of operation: | see product information / instructions for use |
| Identified use: | Medical device, dental impression material (base-component) |
| Company: | President Dental GmbH Zehenstadelweg 7 81247 Munchen / GERMANY |
| Phone: | 0049 89 127 660 240 |
| Fax: | 0049 89 127 660 269 |
| eMail: | info@presidentdental.de |
| Homepage: | www.presidentdental.de |
| Emergency phone: | 0049 89 127 660 268 (8:00 – 17:00) |
| Responsible: | support@presidentdental.de |

02. Hazards identification

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| Physico-chemical hazards: | See chapter 10 |
| Human health dangers: | See chapter 11 |
| Environmental hazards: | See chapter 12. |
| Other hazards: | none |
| Hazard symbols : |  Harmful Contains: organo tin compounds |
| R-phrases: | R38 Irritating to skin. R43 May cause sensitization by skin contact. R48/22 Harmful: danger of serious damage to health by prolonged exposure if swallowed. R62 Possible risk of impaired fertility R63 Possible risk of harm to the unborn child. |

03. Composition / Information on ingredients

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| Tetraalkylsilicate | 20 - < 50 % |
| Xi, R38 CAS: -, EINECS/ELINCS: -, EU-INDEX: -, ECBnr:- | |
| Diorganotin-dicarboxylate | 1 - < 10 % |
| Xn, R48/22-53 CAS: -, EINECS/ELINCS: -, EU-INDEX: -, ECBnr:- | |
| Tetraorganotin compound | 1 - < 10 % |
| Xn, R48/22-62-63-43-52/53 CAS: -, EINECS/ELINCS: -, EU-INDEX: -, ECBnr:- | |
| Description: | Mixture: hardener for the base-component of dental impression materials based on condensation-curing 2-part silicones. |
| Hazardous Ingredients: | For the wording of the listed risk phrases refer to section 16. |

04. First aid measures

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| General information: | Change soaked clothing. |
| Inhalation: | Ensure supply of fresh air. In the event of symptoms seek for medical treatment. |
| Skin contact: | In case of contact with skin wash off immediately with soap and water. |

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| Eye contact: | In case of contact with eyes rinse thoroughly with plenty of water and seek medical advice. |
| Ingestion: | Rinse out mouth and give plenty of water to drink. Do not induce vomiting. Seek medical advice. |
| Advice to doctor: | Treat symptomatically. |

05. Fire-fighting measures

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| Suitable extinguishing media: | Foam. Dry powder. Water spray jet. Carbon dioxide. |
| 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. |
| 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

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| Personal precautions: | High risk of slipping due to leakage/spillage of product. Ensure adequate ventilation. |
| Environmental precautions: | Do not discharge into the drains / surface waters / groundwater. |
| Methods for cleaning up: | Take up mechanically. Take up residues with absorbent material (e.g. sand, sawdust, generalpurpose binder, diatomaceous earth). Dispose of absorbed material in accordance within the regulations. |

07. Handling and storage

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| Advice on safe handling: | Use only in well-ventilated areas. |
| Advice on protection against fire and explosion: | Keep away from all sources of ignition - Refrain from smoking. |
| Requirements for storage rooms and vessels: | Keep only in original container. Prevent penetration into the ground. |
| Advice on storage compatibility: | Do not store together with oxidizing agents. |
| Further information on storage conditions: | Keep container tightly closed. Keep container in a well-ventilated place. Keep in a cool place. |

08. Exposure controls / personal protection

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| Additional advice on system design: | Ensure adequate ventilation on workstation. |
| Ingredients with occupational exposure limits to be monitored: | not applicable |
| Respiratory protection: | Breathing apparatus in the event of high concentrations. Short term: filter apparatus, filter A. |
| Hand protection: | butyl rubber, > 120 min (EN 374) |
| Eye protection: | safety glasses |
| Skin protection: | Light protective clothing. |
| General protective measures: | Avoid contact with eyes and skin. Do not inhale gases/vapours. |
| Hygiene measures: | Do not eat, drink, smoke or take drugs at work. Wash hands before breaks and after work. Use barrier skin cream. |

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| Delimitation and monitoring of the environment exposition: | not determined |
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09. Physical and chemical properties

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| Appearance: | pasty | Density at 23°C [g/ml]: | approx. 0,98 |
| Color: | red | Evaporation speed: | not determined |
| Odor: | characteristic | Vapour pressure [kPa]: | not determined |
| pH-value: | not determined | Viscosity [mPas]: | not applicable |
| Boiling point [°C]: | not determined | Solubility in water: | immiscible |
| Flash point [°C]: | not applicable | Oxidizing properties: | no |
| Flammability: | not determined | Melting point [°C]: | not determined |
| Upper explosion limit: | not applicable | Autoignition temperature: | not applicable |
| Lower explosion limit: | not applicable | Decomposition temperature: | not applicable |

10. Stability and reactivity

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| Hazardous reactions: | Reactions with oxidizing agents. |
| 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. The product was classified 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: | not applicable |
| 2006/11/EC: | not applicable |
| General information: | Ecological data are not available. Do not discharge product unmonitored into the environment or into the drainage. |

13. Disposal considerations

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| Product: | Dispose of as hazardous waste. For recycling, consult manufacturer. |
| Waste no. (recommended): | 070608* |
| Contaminated packaging: | Uncontaminated packaging may be taken for recycling. Packaging that cannot be cleaned should be disposed of as for product. |
| Waste no. (recommended): | 150110* |

14. Transport information

Classification according to ADR:

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| 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:

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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 is classified and labelled in accordance within EC-directives. This preparation is excluded as medical device from the regulation 1999/45/EEC and TITEL IV of 1907/2006/EEC (REACH). |
| Special labelling: | not applicable |
| Authorisation, TITEL VII: | not applicable |
| Restrictions, TITEL VIII: | not applicable |
| EEC-REGULATIONS: | 1967/548 (1999/45); 1991/689 (2001/118); 1999/13; 2004/42; 648/2004; 1907/2006 (Reach); 1272/2008; 75/324/EC (2008/47/EC); 453/2010/EC |
| TRANSPORT- REGULATIONS: | DOT-Classification, ADR (2011); IMDG-Code (2011, 35. Amdt.); IATA-DGR (2011). |
| NATIONAL REGULATIONS: | EH40/2005 Workplace exposure limits with amendments October 2007 |

16. Other informations

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| R-phrases (Chapter 03): | R 48/22 Harmful: danger of serious damage to health by prolonged exposure if swallowed. |
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Material Safety Data Sheet

Paste Hardener

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| | R 53 May cause long-term adverse effects in the aquatic environment. R 62 Possible risk of impaired fertility R 63 Possible risk of harm to the unborn child. R 43 May cause sensitization by skin contact. R 52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R 38 Irritating to skin. |
| Observe employment restrictions for people: | yes |
| 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.