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| <p>1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY/UNDERTAKING</p> <p>1.1 Product identifier Trade name Zirlux Transparent PMMA (Ref: 9793712 / 9793713 / 9793714 / 9793715/ 9793716)</p> <p>1.2 Relevant identifier uses of the substance or mixture and uses advised against Recommended use Fabrication of temporary crowns and bridges, splints, verification of bridge on the plaster model / mouth before the final ZrO₂ milling process.</p> <p>1.3 Details of the supplier of the Safety Data Sheet</p> <table><tr><td>Manufacturer:</td><td>Authorized EU Representative:</td><td>Contact :</td></tr><tr><td>Henry Schein Inc.</td><td>Henry Schein Services GmbH</td><td>cbdeurope@henryschein.com</td></tr><tr><td>135 Duryea Road</td><td>Monzastrasse 2a</td><td>www.henryscheinbrand.com</td></tr><tr><td>Melville, NY 11747 / USA</td><td>63225 Langen / Germany</td><td>Tel: +49 6103 757 5000</td></tr></table> <p>Information provided by Regulatory Affairs Europe - cbdeurope@henryschein.com</p> <p>1.4 Emergency telephone number INTERNATIONAL: +49 (0)6132 84463 - GBK GmbH (24h 7d/w - 365d/a)</p> | Manufacturer: | Authorized EU Representative: | Contact : | Henry Schein Inc. | Henry Schein Services GmbH | cbdeurope@henryschein.com | 135 Duryea Road | Monzastrasse 2a | www.henryscheinbrand.com | Melville, NY 11747 / USA | 63225 Langen / Germany | Tel: +49 6103 757 5000 | |
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| <p>2. HAZARDS IDENTIFICATION</p> <p>2.1 Classification of the substance or mixture Classification according to Regulation 1272/2008/EC: Not applicable</p> <p>2.2 Label elements Labelling according to Regulation 1272/2008/EC: Not applicable.</p> <p>2.3 Other hazards: None. Results of PBT and vPvB assessment PBT: Not applicable. vPvB: Not applicable.</p> | | | | | | | | | | | | | |
| <p>3. COMPOSITION/INFORMATION ON INGREDIENTS</p> <p>3.1 Chemical characterization: Mixtures Description Material on the base of polymethylmethacrylate, dimethacrylates and pigments. Hazardous ingredients according to Regulation 1272/2008/EC: Not applicable.</p> | | | | | | | | | | | | | |
| <p>4. FIRST AID MEASURES</p> <p>4.1 Description of first aid measures General information No special measures required. Inhalation Remove the casualty into fresh air. In case of complaints get medical advice. Skin contact Wash off with water and soap. Consult a physician if irritation persists. Eye contact Rinse eye with plenty of water if it is necessary seek medical attention: only mechanical effect.</p> | | | | | | | | | | | | | |

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| <p>Ingestion Wash out mouth with water and drink water. In case of complaints get medical advice.</p> <p>4.2 Most important symptoms and effects, both acute and delayed None known.</p> <p>4.3 Indication of any immediate medical attention and special treatment needed Treat symptomatically.</p> |
| <p>5. FIRE – FIGHTING MEASURES</p> <p>5.1 Extinguishing media Suitable extinguishing media Water, foam, dry powder, carbon dioxide. Unsuitable extinguishing media for safety reasons None.</p> <p>5.2 Special hazards arising from the substance or mixture May be released in case of fire: carbon monoxide, carbon dioxide, organic products of decomposition.</p> <p>5.3 Advice for firefighters Wear self-contained breathing apparatus.</p> |
| <p>6. ACCIDENTAL RELEASE MEASURES</p> <p>6.1 Personal precautions, protective equipment and emergency procedures Not required.</p> <p>6.2 Environmental precautions No special measures required.</p> <p>6.3 Methods and material for containment and cleaning up Pick up mechanically. Dispose of in accordance with regulations.</p> <p>6.4 Reference to other sections For information on safe handling see Section 7. For information on personal protection equipment see Section 8. For information on disposal information see section 13.</p> |
| <p>7. HANDLING AND STORAGE</p> <p>7.1 Precautions for safe handling Safe handling advice Only adequate trained persons may deal with product. For use in dentistry only. Keep away from children. Ensure the area is well ventilated. No eating, drinking or smoking during handling with product. Follow the usual good standards of occupational hygiene. Information on fire and explosion protection No special measures required.</p> |
| <p>7.2 Conditions for safe storage, including any incompatibilities Storage Requirements for storage areas Keep in dry storage.</p> |
| <p>7.3 Specific end use(s) None.</p> |
| <p>8. EXPOSURE CONTROLS /PERSONAL PROTECTION</p> <p>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.</p> <p>8.2 Exposure controls General protective measures Provide adequate ventilation. Hygiene measures Follow the usual good standards of occupational hygiene and dental practise.</p> |

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| <p>Respiratory protection Avoid contact with powder generated by final working. Wear respiratory protective device in case of dust formation.</p> <p>Hand protection Not required.</p> <p>Eye protection Wear safety goggles during mechanical processing.</p> |
| <p>9. PHYSICAL AND CHEMICAL PROPERTIES</p> <p>9.1 Information on basic physical and chemical properties</p> <p>Appearance: Form: firm disc Colour: different colours Odour: odourless Changes in condition: / Melting point: Undetermined Boiling point: Undetermined Flash point: >250°C Ignition temperature: not applicable Lower explosion limit: not determined Upper explosion limit: not determined Vapour pressure: not applicable Density: 1,17 g/cm³ Viscosity (dynamic): not applicable Solubility in water: insoluble pH – value: not applicable</p> <p>9.2 Other information None.</p> |
| <p>10. STABILITY AND REACTIVITY</p> <p>10.1 Reactivity No relevant information available.</p> <p>10.2 Chemical stability The product is stable under normal handling and storage conditions.</p> <p>10.3 Possibility of hazardous reactions No hazardous reactions known.</p> <p>10.4 Conditions to avoid Decompositions begins at appr. 250°C.</p> <p>10.5 Incompatible materials No relevant information available.</p> <p>10.6 Hazardous decomposition products None when used as prescribed. May be released in case of fire: carbon monoxide, carbon dioxide, organic products of decomposition</p> |
| <p>11. TOXICOLOGICAL INFORMATION</p> <p>11.1 Information on toxicological effects</p> <p>Acute oral toxicity The similar product has been tested according to EN ISO 10993-5 (2009): Tests for in vitro cytotoxicity. The test article extract met the requirements of the EN ISO 10993-5 (2009).</p> <p>Irritation The similar product has been tested according to EN ISO 10993-10 (2010): Tests for irritation and skin sensitization. An intracutaneous irritation test by intradermal injection in the rabbit has been performed and the test article extract met the requirements of the ISO 10993-10 (2010).</p> <p>Sensitization The similar product has been tested according to EN ISO 10993-10 (2010): Tests for irritation and skin sensitization. According to the EN ISO 10993-10 (2010) the product did not induce delayed sensitization.</p> |

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| <p>12. ECOLOGICAL INFORMATION</p> <p>12.1 Toxicity Hazardous to the aquatic environment: No further relevant information available, no evidence for hazardous properties</p> <p>12.2 Persistence and degradability: No further relevant information available, no evidence for hazardous properties</p> <p>12.3 Bioaccumulative potential: No further relevant information available, no evidence for hazardous properties</p> <p>12.4 Mobility in soil: No further relevant information available, no evidence for hazardous properties</p> <p>12.5 Results of PBT and vPvB assessment PBT: Not applicable. vPvB: Not applicable.</p> <p>12.6 Other adverse effects: No further relevant information available.</p> |
| <p>13. DISPOSAL CONSIDERATIONS</p> <p>13.1 Waste treatment methods Product: Disposal should be made in accordance with local, state and national legislation. Uncleaned packaging: Disposal should be made in accordance with local, state and national legislation. Code of waste EWC: 18 01 07</p> |
| <p>14. TRANSPORT INFORMATION</p> <p>14.1 UN Number: see section 14.2</p> <p>14.2 UN proper shipping name Land transport ADR: Not dangerous according to transport regulations. Land transport RID: Not dangerous according to transport regulations. Inland waterway transport ADN: Not dangerous according to transport regulations. Shipment by sea IMDG: Not dangerous according to transport regulations. Air transport ICAO/IATA: Not dangerous according to transport regulations.</p> <p>14.3 Transport hazard class(es): see section 14.2</p> <p>14.4 Packing group: see section 14.2</p> <p>14.5 Environmental hazards: None.</p> <p>14.6 Special precautions for user: see section 14.2</p> <p>14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: None.</p> |
| <p>15. REGULATORY INFORMATION</p> <p>15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture National regulations Other regulations, limitations and prohibitive regulations The product is Class IIa medical device according to the EC Directive 93/42/EEC.</p> <p>15.2 Chemical Safety Assessment A chemical safety assessment has not been carried out for this mixture.</p> |
| <p>16. OTHER INFORMATION</p> <p>This information is based on our present knowledge and experience. They are intended as a description of the products safety requirements and are not to be seen as a guarantee of certain product's features.</p> <p>New versions of Safety Data Sheet will be <i>laying printed</i> for the data compared to the previous version altered.</p> |