

Safety Data Sheet

according to 1907/2006/EC, Article 31

Revision Date: 07.10.2015

Version: 1

Date of Print: 15.04.2016

1. <u>Product identification/preparation/company undertaking</u>
Product details Trade name: Harvard PremiumSil Heavy Maximix Use or preparation: Dental product Manufacturer/supplier: Harvard Dental International GmbH, Margaretenstraße 2-4, 15366 Hoppegarten, Germany info@harvard-dental-international.de Emergency telephone number: + 49 (0) 30 99 28 978-0 (Quality Management)
2. <u>Hazards identification</u>
Classification of the substance or mixture Classification according to Regulation (EC) 1272/2008: void Information concerning particular hazards for human and environment: The product does not have to be labeled due to the calculation procedure of the „General classification guideline for preparations of the EU“ in the latest valid version. Label elements: Labeling according to Regulation (EC) 1272/2008: void Labeling according to EU guidelines: Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body; are exempted from the provisions of Regulation (EC) No. 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user. Other hazards Results of PBT and vPvB assessment PBT: not applicable vPvB: not applicable
3. <u>Composition/Information of Ingredients</u>
Chemical characterization: Description: mixture of polydimethyl polymethyl vinyl siloxane, polydimethyl polymethyl hydrogen siloxane and silica Hazardous components: none
4. <u>First-aid measures:</u>
General information: no special measures required after skin contact: wash with plenty of water and soap after eye contact: rinse with plenty of water and consult a doctor after swallowing: If symptoms persist consult a doctor
5. <u>Fire fighting measures</u>
Extinguishing media: CO ₂ , water Protective equipment: no special measures required

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6. Accidental release measures			
Personal precautions: not required			
Environmental precautions: no special measures required			
Methods for cleaning up: pick up mechanically			
Additional information: none			
7. Handling and storage			
Handling:			
Information for safe handling: For dental use only. No special measures required.			
Recommendation for fire and explosion protection: No special measures required			
Storage:			
Requirements at storerooms and containers: No special measures required			
Requirements for storage with other products: not required			
Further information on storage conditions: none			
8. Exposure controls/personal protection			
Components with limits of values to be supervised 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.			
Personal protective equipment:			
General measures of protection and hygiene: normal hygienic measures			
Respiratory protection: not required			
Protection of hands: not required			
Eye protection: not absolute required			
9. Physical and chemical properties			
Appearance:			
Form:	paste		
Color:	bright purple		
Odor:	sweet-fruity		
	<u>Value</u>	<u>Unit</u>	<u>Method</u>
Information on change in the physical state			
Melting point/melting range:	n.a.		°C
Boiling point/boiling range:	n.a.		°C
Flash point:	n.a.		°C
Autoignition temperature:	n.a.		
Danger of explosion:	none		
Density:	1,47 (20°C)	g/cm ³	
Vapor pressure:	n.a.	mbar	
Viscosity:	paste		
pH:	neutral		
Solubility in/miscibility with:	Partially soluble in toluene, petrol ether		
Water:	insoluble		
Content of solvents:	none		
Organic solvents:	----		
Water:	----		
Content of solids:	n.a.		

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10. <u>Stability and reactivity</u>
<p>Conditions to avoid: No decomposition if used according to specification</p> <p>Hazardous decomposition products: none under normal conditions of storage and use</p>
11. <u>Toxicological information</u>
<p>Acute toxicity:</p> <p>Primary irritation:</p> <p>skin: no irritating effect</p> <p>eye: no irritating effect</p> <p>Additional toxicological information: When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.</p>
12. <u>Ecological information</u>
<p>General information: Avoid transfer into environment</p> <p>Classification of water endangerment: WGK 1 (German regulation) slightly hazardous for water</p>
13. <u>Disposal consideration</u>
<p>Product:</p> <p>Recommendation: Small quantities can be disposed of with household waste. Use proper landfill disposal or incineration in accordance with local, state and federal regulations.</p> <p>Uncleaned packaging:</p> <p>Recommendation: Disposal must be made according to official regulations.</p>
14. <u>Transport information</u>
<p>Land transport ADR, RID: -</p> <p>Maritime transport: IMDG-Code: -</p> <p>Air transport ICAO-TI/IATA-DGR: -</p>
15. <u>Regulatory information</u>
<p>Classification according to EC-guidelines: The product is a medical device according to EC-directive 93/42 EEC.</p> <p>Chemical safety assessment: A Chemical Safety Assessment has not been carried out.</p>
16. <u>Other information:</u>
<p>Changes compared with the previous version: Adaptation according to 1907/2006/EG, Article 31</p> <p>The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.</p>