

Safety Data Sheet

according to 1907/2006/EC, Article 31

Revision Date: 08.01.2014

Version: 7

Date of Print: 10.01.2014

1. Product identification/preparation/company undertaking
<p>Product details</p> <p>Trade name: PROVI KB (AUTOMIX 4:1)</p> <p>Use or preparation: Dental product</p> <p>Manufacturer/supplier: Roydent Dental Products 608 Rolling Hills Drive Johnson City, TN, 37604 info@roydent.com</p> <p>Emergency information: Dr. Jürgen Engelbrecht ++49 4121 483-0</p>
2. Hazards identification
<p>Classification of the substance or mixture</p> <p>Classification according to Regulation (EC) 1272/2008: void</p> <p>Classification according to Directive 67/548/EEC or Directive 1999/45/EC: void</p> <p>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.</p> <p>Label elements:</p> <p>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 dangerous substance Directive 1999/45/EWG.</p> <p>Other hazards</p> <p>Results of PBT and vPvB assessment</p> <p>PBT: not applicable</p> <p>vPvB: not applicable</p>
3. Composition/Information of Ingredients
<p>Chemical characterization:</p> <p>Description: mixture of polyfunctional acrylates and methacrylates, unsaturated esters and malonyl urea derivatives</p> <p>Hazardous components: none</p>
4. First-aid measures:
<p>General information: no special measures required</p> <p>after skin contact: wash with plenty of water and soap</p> <p>after eye contact: rinse with plenty of water and consult a doctor</p> <p>after swallowing: If symptoms persist consult a doctor</p>
5. Fire fighting measures
<p>Extinguishing media: CO₂, water</p> <p>Protective equipment: no special measures required</p>

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6. Accidental release measures			
Personal precautions: not required			
Environmental precautions: Do not allow to enter drains/surface water/ ground-water			
Methods for cleaning up: wipe out with absorbent material			
Additional information: none			
7. Handling and storage			
Handling: This product should only be supplied or handled to dentists, dental technicians or upon their instructions.			
Information for safe handling: For dental use only. No special measures required.			
Recommendation for fire and explosion protection: No special measures required			
Storage: store at a dry place, storage temperature <25°C			
Requirements at storerooms and containers: Store only in the original containers.			
Requirements for storage with other products: Keep away from foodstuffs.			
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:	tooth colored		
Odor:	nearly odorless		
	<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.d.		°C
Autoignition temperature:	n.d.		
Danger of explosion:	none		
Density:	1,52 (20°C)	g/cm ³	
Vapor pressure:	n.a.	mbar	
Viscosity:	paste		
pH:	neutral		
Solubility in/miscibility with:	partially soluble in toluene		
Water:	insoluble		
Content of solvents:	none		
Organic solvents:	-----		
Water:	-----		
Content of solids:	n.a.		

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10. Stability and reactivity
<p>Conditions to avoid: heat, direct sunlight, peroxides, metal powders, strong oxidizers, free radical initiators</p> <p>Hazardous decomposition products: none under normal conditions of storage and use</p>
11. Toxicological information
<p>Acute toxicity:</p> <p>Primary irritation: skin: repeated and prolonged exposure may cause skin irritations eye: irritating</p> <p>Sensitization of product: not observed</p> <p>Additional toxicological information: Allergic reaction to methacrylate by chronic exposure to product are possible. 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. Ecological information
<p>General information: Avoid transfer into environment</p> <p>Classification of water endangerment: -</p>
13. Disposal consideration
<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. Transport information
<p>Land transport ADR, RID: -</p> <p>Maritime transport: IMDG-Code: -</p> <p>Air transport ICAO-TI/IATA-DGR: -</p>
15. Regulatory information
<p>Classification according to EC-guidelines: The product is a medical device according to EC-directive 93/42 EEC. The product must not be labelled according to EC-regulations or the corresponding national regulations.</p> <p>Chemical safety assessment: A Chemical Safety Assessment has not been carried out.</p>
16. Other information:
<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> <p>Preparation by Dr. Jürgen Engelbrecht, Tel: 04121/483-0</p>