

SAFETY DATA SHEETS

This SDS packet was issued with item:

075928064

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

075928056 075928072 075928080

Safety Data Sheet

according to 91/155/EEC

1. Product identification/preparation/company undertaking		
Trade name:	REFORM	
	(AUTOMIX 4:1)	
Manufacturer/supplier:	S&C Polymer GmbH, D-25335 Elmshorn	
Emergency information:	Dr. Jürgen Engelbrecht ++49 4121 483-0	
2. <u>Composition/Information of Ingredients</u>		
Chemical characterization:	Mixture of polyfunctional acrylates and methacrylates, unsaturated esters and malonyl urea derivatives.	
Description:		
Hazardous components:	None	
<u>CAS-Nr.:</u>	<u>Name</u>	<u>R-classification</u>
3. <u>Hazards identification</u>		
Risk identification:		
Special risks for human beings and environment:		
Classification:	Classification corresponds to actual EEC guidelines, however completed with details from technical literature and company data.	
4. <u>First-aid measures</u>		
General information:		
after skin contact:	Wash with plenty of water and soap.	
after eye contact:	Rinse with plenty of water and consult a physician.	
after swallowing:	Seek medical advice immediately.	
5. <u>Fire fighting measures</u>		
Extinguishing media:	CO ₂ , water.	
Protective equipment:		

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6. <u>Accidental release measures</u> Personal precautions: Environmental precautions: Methods for cleaning up: Wipe out with absorbent material. Additional information:													
7. <u>Handling and storage</u> Handling: Handling procedures: None if proper stored or used. Recommendation for fire and explosion protection: storage: Dry place, room temperature, store away from food stuffs. Requirements at storerooms and containers: Requirements for storage with other products: Store away from food stuffs. Additional storage conditions: Storage classification: VBF-classification:													
8. <u>Exposure controls/personal protection</u> Additional information for technical plants: Components with limits of values to be supervised at the workplace: <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; border-bottom: 1px solid black;">CAS-Nr.</th> <th style="text-align: left; border-bottom: 1px solid black;">Name</th> <th style="text-align: left; border-bottom: 1px solid black;">%</th> <th style="text-align: left; border-bottom: 1px solid black;">art</th> <th style="text-align: left; border-bottom: 1px solid black;">value</th> <th style="text-align: left; border-bottom: 1px solid black;">unit</th> </tr> </thead> <tbody> <tr> <td colspan="6" style="padding-top: 10px;"> The product contains no relevant quantities of components with limits of values to be supervised at the workplace. </td> </tr> </tbody> </table> Additional information: Personal protective equipment: not necessary. General measures of protection and hygiene: normal hygienic measures. respiration: not necessary. hands: wear gloves. eyes: not necessary.		CAS-Nr.	Name	%	art	value	unit	The product contains no relevant quantities of components with limits of values to be supervised at the workplace.					
CAS-Nr.	Name	%	art	value	unit								
The product contains no relevant quantities of components with limits of values to be supervised at the workplace.													

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9. Physical and chemical properties

Appearance

Form:	Paste, white yelloish.
Colour:	Different (tooth coloured).
Odour:	Nearly odourless.
	<u>Value Unit Method</u>

Information on change in the physical state

Melting point/melting range:	N.a.
Boiling point/boiling range:	N.a.
Flash point:	Not determinated.
Autoignation temperature:	Not determinated.
Danger of explosion:	None
Density:	1.52 (20°C) g/cm ³
Vapour pressure:	Neglegtible.
Viscosity:	Pasteous.
pH:	Neutral.
Solubility in/miscibility with:	Slightly soluble in toluene, organic solvents.
Water:	Nearly insoluble.
Content of solvents:	None.
Organic solvents:	-
Water:	-
Content of solids:	N.a.

10. Stability and reactivity

	Unstable, avoid heat, direct sunlight.
Incompatibility with other substances:	Peroxides, metal powders, strong oxidizers, free radical initiators.
Hazardous discomposition products:	Not known.

11. Toxicological information

Acute toxicity:	
Primary irritation:	
skin:	Non toxic, no absorption.
eye:	Irritating.
inhalation:	Non volatile.
ingestion:	Possible toxic when swallowed.
Sensitization of product:	Not observed.
Additional toxikological information:	Allergic reation to methacrylate by chronic exposure to product are possible. During the long period of use as temporary crown and bridge material no health deseases are reported.

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12. <u>Ecological information</u>	
General information:	No data known.
Classification of water endangerment (self estimation):	WGK = 0 (generally nonpolluting substance).
13. <u>Disposal consideration</u>	
Product:	Use proper landfill disposal or incineration in accordance with local, state and federal regulations.
Recommendation:	
Disposal key number:	
Uncleaned packaging:	
Recommendation:	
14. <u>Transport information</u>	
Land transport ADR/RID and GGVS/GGVE (Germany)	Not classified as dangerous goods.
Sea transport IMDG	Not classified as dangerous goods.
Air transport ICAO-TI and IATA-DGR	Not classified as dangerous goods.
15. <u>Regulatory information</u>	
Classification according to EEC-guidelines:	No classification necessary to actual EEC guidelines.
National Prescriptions:	
Classification according to VbF:	N.a.
16. <u>Other information:</u>	
Preparation by:	<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>Dr. Jürgen Engelbrecht, Tel.: ++49/4121/483-0</p>

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
Product details Trade name: PROVI KB (AUTOMIX 4:1) Use or preparation: Dental product Manufacturer/supplier: Roydent Dental Products 608 Rolling Hills Drive Johnson City, TN, 37604 info@roydent.com Emergency information: Dr. Jürgen Engelbrecht ++49 4121 483-0
2. Hazards identification
Classification of the substance or mixture Classification according to Regulation (EC) 1272/2008: void Classification according to Directive 67/548/EEC or Directive 1999/45/EC: 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 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. Other hazards Results of PBT and vPvB assessment PBT: not applicable vPvB: not applicable
3. Composition/Information of Ingredients
Chemical characterization: Description: mixture of polyfunctional acrylates and methacrylates, unsaturated esters and malonyl urea derivatives Hazardous components: none
4. First-aid measures:
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. Fire fighting measures
Extinguishing media: CO ₂ , water Protective equipment: no special measures required

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according to 1907/2006/EC, Article 31

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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

Value	Unit	Method
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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/cm³**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
Conditions to avoid: heat, direct sunlight, peroxides, metal powders, strong oxidizers, free radical initiators Hazardous decomposition products: none under normal conditions of storage and use
11. Toxicological information
Acute toxicity: Primary irritation: skin: repeated and prolonged exposure may cause skin irritations eye: irritating Sensitization of product: not observed 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.
12. Ecological information
General information: Avoid transfer into environment Classification of water endangerment: -
13. Disposal consideration
Product: Recommendation: Small quantities can be disposed of with household waste. Use proper landfill disposal or incineration in accordance with local, state and federal regulations. Uncleaned packaging: Recommendation: Disposal must be made according to official regulations.
14. Transport information
Land transport ADR, RID: - Maritime transport: IMDG-Code: - Air transport ICAO-TI/IATA-DGR: -
15. Regulatory information
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. Chemical safety assessment: A Chemical Safety Assessment has not been carried out.
16. Other information:
Changes compared with the previous version: Adaptation according to 1907/2006/EG, Article 31 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. Preparation by Dr. Jürgen Engelbrecht, Tel: 04121/483-0