

Safety Data Sheet

according to 1907/2006/EC, Article 31

Date of issue: 20.05.2015

Version: 4

Printing date: 19.01.2017

1. Identification of the substance/mixture and of the company/undertaking

Product Identifier
Trade name: Cubi Orth Seal Glaze
Use of the preparation: Dental product Hs Code : 3006 40 00
Details of the supplier of the safety data sheet:
Manufacturer/supplier:

SCP-Megadental Italia di Accardo Giovanni,

Via Caprera,16

91028 Partanna (Tp) Italy

info@megadentalitalia.it

Emergency telephone number:

+39 0924 88494

2. Hazards identification

Classification of the substance or mixture:
Classification according to Regulation (EC) No 1272/2008:

Flam. Liq. 2, H225 Highly flammable liquid and vapour

Skin Irrit. 2, H315 Causes skin irritation

Skin Sens1, H317 May cause allergic skin reaction

STOT SE 3, H335 May cause respiratory irritation.

Information concerning particular hazards for human and environment:

The product has to be labeled due to calculation procedure for the "General Classification guideline for preparations of the EU" in the latest version.

Label elements
Labeling according to Regulation (EC)
1272/2008: Hazard pictograms

Signal word

Danger

Hazard statements

H225 Highly flammable liquid and vapour

H315 Causes skin irritation

H317 May cause allergic skin reaction

H335 May cause respiratory irritation

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection. P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

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

vB: not applicable

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3. Composition/Information on
<p><u>Ingredients</u> Chemical characterization: Description: Light cure varnish based on multifunctional methacrylates and methylmethacrylate Hazardous components: 80-62-6 (CAS-No.) Methyl methacrylate GHS02, GHS07, H225, H315, H317, H335</p>
4. First-aid measures
<p>General information: Seek medical advice, if symptoms occur, which can be caused by the product after skin contact: Wash off with plenty of water. In case of skin irritation, consult a doctor. after inhalation: Fresh air. Consult a doctor if feeling unwell. after eye contact: Rinse opened eye for several minutes under running water and consult a doctor after swallowing: Rinse mouth immediately and drink plenty of water. Seek medical advice if necessary.</p>
5. Fire fighting measures
<p>Extinguishing media: CO2, powder, water, foam. Use extinguishing method and media suitable to surrounding fire. Special hazards arising from the substance or mixture No further relevant information available Protective equipment Wear self-contained respiratory protective equipment</p>
6. Accidental release measures
<p>Personal precautions, protective equipment and emergency procedures: Do not inhale vapours/aerosols. Avoid substance contact. Ensure supply of fresh air in enclosed rooms Environmental precautions: Do not allow to enter drains/surface water/ ground-water. Methods for cleaning up: Absorb with liquid binding material. Forward for disposal. Clean up affected area. Reference to other sections: See Section 7 for information on safe handling See Section 8 for information on personal protection equipment See Section 13 for disposal information</p>
7. Handling and storage
<p>Handling: This product should only be supplied or handled to dentists or dental technicians or upon their instructions. Precautions for safe handling: Observe normal care for working with chemicals Information about fire and explosion protection: Keep away from sources of ignition. Take measure to prevent electrostatic charge Storage: Store at a dry place, protected from light. Store tightly closed. Storage temperature <25°C. Requirements at storerooms and containers: Store only in the original containers Further information on storage conditions: Store away from food stuffs. Specific end uses: No further relevant information available</p>

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8. Exposure controls/personal protection

Components with limits of values to be supervised at the workplace:

CAS-No.	name	art	value	unit
[80-62-6]	Methyl methacrylate	TRGS 900 (Germany)	210	mg/m ³
		resp.	50	ml/m ³

Additional information: The lists valid during the making were used as basis

Personal protective equipment:

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs and beverages. Avoid contact with eyes or skin

Hand protection

Protective gloves.

Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection: safety glasses

Respiratory protection: Required, when vapors/aerosols are generated.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance

Form:	liquid						
Color:	slightly yellow						
Odor:	characteristic						
	<table border="1"> <thead> <tr> <th>Value</th> <th>Unit</th> <th>Method</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Value	Unit	Method			
Value	Unit	Method					

Safety relevant basic data

Melting point/melting range:	n.a.
Boiling point/boiling range:	100 °C
Flash point:	10 °C DIN 51794
Ignition temperature:	no information available
Danger of explosion:	Lower 2.1 Vol %
	Upper 12.5 Vol %
Density:	ca. 1 g/cm ³
Vapor pressure:	n.d.
pH:	n.a.
Solubility in/miscibility with:	
Water:	slightly soluble
Content of solvents:	
Organic solvents:	none

10. Stability and reactivity

Thermal decomposition / conditions to be avoided

Possibility of hazardous reactions: no information available

Conditions to avoid: Warming > 50°C. Exposure to light. Polymerization possible in presence of heat, light, radical starters as peroxides, reducing agents, etc. Do not use various plastics or rubber as working materials.

Hazardous decomposition products: No information available.

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11. Toxicological information**Acute toxicity: (methyl methacrylate)**

LD50 (oral, rat) 7872 mg/kg

Primary irritation:

skin: irritant

eye: irritant

Sensitization: Sensitizing in case of skin contact possible**Additional toxicological information:**

Allergic reactions to methacrylates after long-term exposure 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:** Do not allow to enter drains/canalisation/ground-water**Classification of water endangerment:** WGK=1 (slightly polluting substance).**13. Disposal considerations****Product:****Recommendation:**

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 and GGVS/GGVE (Germany):**

UN 1247 METHYLMETHACRYLAT, MONOMER, STABILISIERT, 3,II

Sea transport IMDG:

UN 1247 METHYL METHACRYLATE, MONOMER, STABILIZED, 3, II

EmS: F-E S-D

Air transport ICAO-TI and IATA-DGR:

UN 1247 METHYL METHACRYLATE, MONOMER, STABILIZED, 3, II

The transport regulations are cited according to international regulations and in the form applicable in Germany. Possible national deviations in other countries are not considered.

15. Regulatory information**Classification according to EC-guidelines:**

The product is a medical device according to EC-directive 93/42 EEC.

Chemical safety assessment:**15.2. Chemical safety assessment. Test Report N° 615-16en and N° 618-16en Pag.1/6 Time Schedule Of Study**

The study was started on the 28/02/16 and was completed on the 04/03/16

Test carried out by: Barbara Gottardi



ACCREDIA accreditation N° 1337

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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,
