

Safety Data Sheet according to Regulation (EU) No. 453/2010

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

1.1 Product identifier

Trade name: FANTESTIC ® FILL Ceram in syringes and tips

Order-No.: FCX38XX, X depends on syringe or tip and shade

1.2 Relevant identified uses of the substance or mixture and uses advised against

Light-cure micro hybrid composite with nano-ceramic fillers

1.3 Details of the supplier of the safety data sheet

Manufacturer: R-dental Dentalerzeugnisse GmbH
Winterhuder Weg 88
D-22085 Hamburg
Germany
E-mail: info@r-dental.com
Web: www.r-dental.com

1.4 Emergency telephone number Phone: + 49-40-22 75 76 17

2. Hazards identification

2.1 Classification of the substance or mixture See chapter 15.

2.2 Label elements Not applicable.

2.3 Other hazards Avoid contact with skin and eyes.

3. Composition/information on ingredients

3.1 Substances Not applicable.

3.2 Mixtures Mixture of poly- and dimethacrylates, barium glass filler, fumed silica, catalysts, stabilizers and pigments.

4. First-aid measures

4.1 Description of first aid measures

General information after inhalation: Not applicable.
General information after skin contact: Wash with plenty of water and soap and consult a physician if necessary.

General information after eye contact: Rinse with plenty of water and

General information after swallowing:	consult a physician if necessary. Immediately consult a physician.
4.2 Most important symptoms and effects, both acute and delayed	See subsection 4.1. Consult physician when in doubt.
4.3 Indication of any immediate medical attention and special treatment needed	See subsection 4.1
5. Fire fighting measures	
5.1 Extinguishing media	
Extinguishing media:	CO ₂ , water.
Unsuitable extinguishing media:	Not known.
5.2 Special hazards arising from the substance or mixture	
	Not applicable.
5.3 Advice for firefighters	
	Not applicable.
6. Accidental release measures	
6.1 Personal precautions, protective equipment and emergency procedures	
	Avoid contact with unpolymerized material. Take up the material with absorbent materials.
6.2 Environmental precautions	
	Do not let liquid material come into contact with the environment.
6.3 Methods and material for containment and cleaning up	
	Take up the material with absorbent materials.
6.4 Reference to other sections	
	See section 13.
7. Handling and storage	
7.1 Precautions for safe handling	
	This product should only be used by a dentist and/or a licensed professional.
7.2 Conditions for safe storage, including any incompatibilities	
	Store in dry place, at room temperature or cool and away from food stuffs.
7.3 Special end use(s)	
	Store cool, dry and light protected under 77 °F.
8. Exposure controls/personal protection	
8.1 Control parameters	
	The product contains no relevant quantities of components with limits of values to be supervised at the workplace. Fresh air is recommended.
8.2 Exposure controls	
Eyes:	Wear eye glasses if necessary.

Hands:	Wear protective gloves if necessary.
Respiration:	Not applicable.
Thermal driven:	No.
Environmental exposure:	See subsection 6.2.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Appearance:	Paste.
aa) Colour:	Tooth shades.
b) Odour:	Odourless.
c) Odour threshold:	Not applicable.
d) pH:	Neutral.
e) Melting point/freezing point:	Not applicable.
f) Initial boiling point and boiling range:	Not applicable.
g) Flash point:	Not applicable.
h) Evaporation rate:	Not applicable.
i) Flammability (solid/gas):	Not applicable.
j) Upper/lower flammability or explosive limits:	Not applicable.
k) Vapour pressure:	Not applicable.
l) Vapour density:	Not applicable.
m) Relative density:	2,0 g/cm ³ (68 °F)
n) Solubility(ies):	
Water solubility:	Not soluble.
Soluble in/miscible with:	
o) Partition coefficient:	Not applicable.
p) Auto-ignition temperature:	Not applicable.
q) Decomposition temperature:	Not applicable.
r) Viscosity:	High, mouldable.
s) Explosive properties:	Not applicable.
t) Oxidising properties:	Not applicable.

9.2 Other information None.

10. Stability and reactivity

10.1 Reactivity	See section 2.
10.2 Chemical stability	Stable when storing cool and light protected under 77 °F taking into account the expiry date.
10.3 Possibility of hazardous reactions	Not applicable.
10.4 Conditions to avoid	Avoid heat and direkt sun light.
10.5 Incompatible materials	Polymerizes in contact with peroxids, metal powders, strong oxidizers and free radical starters.
10.6 Hazardous decomposition products	None under normal conditions.

11. Toxicological information

11.1 Information on toxicological effects	During a long period of use as methacrylate based materials no health deseases are reported.
a) acute toxicity:	Not toxic.
b) irritation:	Allergic reactions to methacrylates by chronic exposure to methacrylates are possible.
c) corrosivity:	Not applicable.
d) sensitisation:	See b).

e) repeated dose toxicity:	No.
f) carcinogenicity:	Not known.
g) mutagenicity:	Not known.
h) toxicity for reproduction	Not known.
Toxicological tests:	No.
Experience in practice:	Slightly irritating to the skin, irritating to eyes.
Informations on ingredients:	See section 3.
Additional toxicological information:	Experience shows when properly used by authorized personnel no health hazards.

12. Ecological information

12.1 Toxicity	Do not let the material come in contact with the environment.
12.2 Persistence and degradability	No data available.
12.3 Bioaccumulative potential	No data available.
12.4 Mobility in soil	No data available.
12.5 Results of PBT and vPvB assessment	Not applicable.
12.6 Other adverse effects	When properly handled no specific environmental problems are expected.

13. Disposal considerations

13.1 Waste treatment methods	Use proper landfill disposal or incineration in accordance with local, state and federal regulations.
Disposal key number:	Not known.
Uncleaned packaging:	When used properly, no ecological problems are expected.
Cleaned packaging:	See subsection 13.1.

14. Transport information

14.1 UN Number	Not applicable.
14.2 UN proper shipping name	Not applicable.
14.3 Transport hazard class(es)	
Land transport RID/ADR, GGVS/GGVE:	Not classified as dangerous goods.
Sea transport IMDG/GGVSea:	Not classified as dangerous goods.
Air transport ICAO-TI and IATA-DGR:	Not classified as dangerous goods.
14.4 Packing group	Not applicable.
14.5 Environmental hazards	Not applicable.
14.6 Special precautions for user	Not applicable.
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	The product is a class IIa medical device according to the MDD 93/42/EEC.
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15.2 Chemical safety assessment No.

16. Other informations

- a) Changes to previous version: Preparing the Material Safety Data Sheet according to (EU) No. 453/2010.
- b) Legend to abbreviations: Not applicable.
- c) Literature references: Not applicable.
- d) Methods of evaluation information: Not applicable.
- e) R-phrases, stated: See section 2-15.
- f) Training advices: Not applicable.
- Data sheet producing area: Dr. Andreas Sprafke, R-dental Dentalerzeugnisse GmbH, Hamburg.

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 product properties. However users of the product should satisfy themselves that the information given above is sufficient and correct for their circumstances of use.

Prepared by: Dr. Andreas Sprafke, R-dental Dentalerzeugnisse GmbH.