

# 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 ® DirectCem DC

Order-No.: FDS426X, X depends on shade

1.2 Relevant identified uses of the substance or mixture and uses advised against  
Self-adhesive, dual-cure luting cement

### 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](mailto:info@r-dental.com)  
Web: [www.r-dental.com](http://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  
R-Classification, see chapter 16.

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 dimethacrylates,  
phosphoric esters, glass fillers,  
catalysts, stabilizers and pigments.

Name: Methacrylates  
R-Classification: R 36, 37, 38, Xi

Name: Phosphoric esters  
R-Classification: R 36, 37, 38, Xi

R-Sätze see chapter 16 e).

#### 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 consult a physician if necessary.
General information after swallowing:	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<sub>2</sub>, water, chemical foam and powder (extinguisher).

Unsuitable extinguishing media: Not known.

##### 5.2 Special hazards arising from the substance or mixture

Not applicable.

##### 5.3 Advice for firefighters

See subsection 5.1.

#### 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.  
Store away from food stuffs.  
During use do not eat, drink or smoke.

##### 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 and light protected between 50 °F – 77 °F.

## 8. Exposure controls/personal protection

### 8.1 Control parameters

The mixture 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:

None.

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:

Translucent and teeth-coloured.

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:

1,8 g/cm<sup>3</sup> (68 °F)

n) Solubility(ies):

Not soluble.

Water solubility:

Organic solvents. Slightly soluble in toluene.

Soluble in/miscible with:

o) Partition coefficient:

Not applicable.

p) Auto-ignition temperature:

Not applicable.

q) Decomposition temperature:

Not applicable.

r) Viscosity:

Low, flowable.

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 between 50 °F – 77 °F taking into account the expiry date.

### 10.3 Possibility of hazardous reactions

Not applicable.

### 10.4 Conditions to avoid

Avoid heat and direct sunlight.

### 10.5 Incompatible materials

Polymerizes in contact with peroxides, 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 diseases 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:

None.

f) carcinogenicity:

Not known.

g) mutagenicity:

Not known.

h) toxicity for reproduction

Not known.

Toxicological tests:

None.

Experience in practice:

Slightly irritating to the skin, strong 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.  
15.2 Chemical safety assessment No.

## 16. Other informations

a) Changes to previous version: -  
b) Legend to abbreviations: Not applicable.  
c) Literature references: Not applicable.  
d) Methods of evaluation information: Not applicable.  
e) R-phrases, stated: R 36 Irritating eyes  
R 37 Irritating respiratory system  
R 38 irritating skin  
f) Training advices: Not applicable.  
Data sheet producing area: Dr. Andreas Sprafke, R-dental Dentalerzeugnisse GmbH, Hamburg, Germany.

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.