



**Safety data sheet  
according to 1907/2006/EC, Article 31**

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

- **1.1 Product identifier**
  - Trade name: **Solitaire 2**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**


No further relevant information available.

  - **Application of the substance / the mixture** Dental filling material
- **1.3 Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:**  
Kulzer GmbH  
Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522
  - **Informing department:** E-Mail: [msds@kulzer-dental.com](mailto:msds@kulzer-dental.com)
- **1.4 Emergency telephone number:** Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
    - **Classification according to Regulation (EC) No 1272/2008**  
Skin Sens. 1 H317 May cause an allergic skin reaction.
  - **2.2 Label elements**
    - **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.

      - **Hazard pictograms**
- 

GHS07
- **Signal word** Warning
  - **Hazard-determining components of labelling:**

4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid  
triethylen glycol dimethacrylate
  - **Hazard statements**

H317 May cause an allergic skin reaction.
  - **Precautionary statements**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P321 Specific treatment (see on this label).  
P363 Wash contaminated clothing before reuse.  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
P302+P352 IF ON SKIN: Wash with plenty of water.
  - **2.3 Other hazards -**
    - **Results of PBT and vPvB assessment**
      - **PBT:** Not applicable.

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· **vPvB:** Not applicable.

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**SECTION 3: Composition/information on ingredients**

· **3.2 Chemical characterisation: Mixtures**

· **Description:** Product based on methacrylates

· **Dangerous components:**

CAS: 55818-57-0 EINECS: 225-144-3 Reg.nr.: 01-2119490020-53-0001	4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid Skin Sens. 1, H317	5-10%
CAS: 109-16-0 EINECS: 203-652-6 Reg.nr.: 01-2119969287-21-0000	triethylen glycol dimethacrylate Skin Sens. 1B, H317	5-10%
CAS: 24650-42-8 EINECS: 246-386-6	2,2-dimethoxy-1,2-diphenylethan-1-one Aquatic Acute 1, H400; Aquatic Chronic 1, H410	< 1%

· **Additional information** For the wording of the listed hazard phrases refer to section 16.

**SECTION 4: First aid measures**

· **4.1 Description of first aid measures**

· **General information** No special measures required.

· **After skin contact** The product is not skin irritating.

· **After eye contact** Rinse opened eye for several minutes under running water.

· **After swallowing**

Rinse out mouth and then drink plenty of water.

In case of persistent symptoms consult doctor.

· **4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

**SECTION 5: Firefighting measures**

· **5.1 Extinguishing media**

· **Suitable extinguishing agents**

CO<sub>2</sub>, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.

Use fire fighting measures that suit the environment.

· **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

· **5.3 Advice for firefighters**

· **Protective equipment:** No special measures required.

· **Additional information** -

**SECTION 6: Accidental release measures**

· **6.1 Personal precautions, protective equipment and emergency procedures** Not required.

· **6.2 Environmental precautions:** No special measures required.

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- **6.3 Methods and material for containment and cleaning up:**  
*Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).*
- **6.4 Reference to other sections**  
*No dangerous materials are released.*  
*See Section 8 for information on personal protection equipment.*

**SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling** *No special measures required.*
  - **Information about protection against explosions and fires:** *No special measures required.*
- **7.2 Conditions for safe storage, including any incompatibilities**
  - **Storage**
    - **Requirements to be met by storerooms and containers:** *No special requirements.*
    - **Information about storage in one common storage facility:** *Not required.*
    - **Further information about storage conditions:** *Store cool (not above 25 °C).*
- **7.3 Specific end use(s)** *No further relevant information available.*

**SECTION 8: Exposure controls/personal protection**

- **Additional information about design of technical systems:** *No further data; see item 7.*
- **8.1 Control parameters**
  - **Components with critical values that require monitoring at the workplace:**  
*The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.*

· **DNELs**

**55818-57-0 4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid**

Dermal	worker industr., l.te., syst.	17.5 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	122.5 mg/m3 (nd)

**109-16-0 triethylen glycol dimethacrylate**

Dermal	worker industr., l.te., syst.	13.9 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	48.5 mg/m3 (nd)

· **PNECs**

**55818-57-0 4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid**

freshwater	0.1 mg/l (nd)
marine water	0.01 mg/l (nd)
interm. wat. release	1.0 mg/l (nd)
STP	10 mg/l (nd)
sedim., dw, fre.wat.	35.8 mg/Kg (nd)
soil,dw	71 mg/Kg (nd)

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**109-16-0 triethylen glycol dimethacrylate**

marine water	0.0164 mg/l (nd)
sedim., dw, fre.wat.	1.85 mg/Kg (nd)
sedim., dw, mar.wat.	0.185 mg/Kg (nd)
soil,dw	0.274 mg/Kg (nd)

· **Additional information:** The lists that were valid during the compilation were used as basis.

· **8.2 Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**

Instantly remove any soiled and impregnated garments.  
Wash hands during breaks and at the end of the work.

· **Breathing equipment:**

Not necessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).

· **Protection of hands:**

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

Check protective gloves prior to each use for their proper condition.  
recommended

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**

Butyl rubber, BR  
Nitrile rubber, NBR

· **Eye protection:** Protective goggles are recommended.

· **Body protection:** Light weight protective clothing

**SECTION 9: Physical and chemical properties**

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· **Form:**

Pasty

· **Colour:**

According to product specification

· **Smell:**

Nearly odourless

· **Odour threshold:**

Not determined.

· **pH-value:**

Not determined.

· **Change in condition**

· **Melting point/Melting range:**

Not determined

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· <b>Boiling point/Boiling range:</b>	100 °C
· <b>Flash point:</b>	101 °C
· <b>Inflammability (solid, gaseous)</b>	Not applicable.
· <b>Ignition temperature:</b>	400 °C
· <b>Decomposition temperature:</b>	Not determined.
· <b>Self-inflammability:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product is not explosive.
· <b>Critical values for explosion:</b>	
· Lower:	Not determined.
· Upper:	Not determined.
· <b>Steam pressure at 20 °C:</b>	40 hPa
· <b>Density at 20 °C</b>	1.740 g/cm <sup>3</sup>
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· <b>Solubility in / Miscibility with</b>	
· Water:	Not miscible or difficult to mix
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
· dynamic:	Not determined.
· kinematic:	Not determined.
· <b>Solvent content:</b>	
· VOC EU	g/l
· <b>Solids content:</b>	75.0 %
· <b>9.2 Other information</b>	No further relevant information available.

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
  - **Conditions to be avoided:** No decomposition if used and stored according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None
  - **Additional information:**  
If stored longer than recommended and/or above recommended temperature, product may polymerize generating heat.

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**SECTION 11: Toxicological information**

· **11.1 Information on toxicological effects**

· **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values that are relevant for classification:**

<b>poröses Glas</b>		
Oral	LD50	3160 mg/kg (rat)
<b>41137-60-4 diurethandimethacrylate</b>		
Oral	LD50	>5000 mg/kg (rat)
<b>55818-57-0 4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid</b>		
Oral	LD50	>5000 mg/kg (rat) (OECD 401)
Dermal	LD50	>5000 mg/kg (rabbit)
Sensitisation	Sensib.	(human) sensib. (mouse) (LLNA)
<b>109-16-0 triethylen glycol dimethacrylate</b>		
Oral	LD50	> 5000 mg/kg (rat)
Dermal	LD50	> 2000 mg/kg (mouse)
<b>24650-42-8 2,2-dimethoxy-1,2-diphenylethan-1-one</b>		
Oral	LD50	>6000 mg/kg (rat)
Dermal	LD50	> 7100 mg/kg (rat)

· **Primary irritant effect:**

· **Skin corrosion/irritation** Based on available data, the classification criteria are not met.

· **Serious eye damage/irritation** Based on available data, the classification criteria are not met.

· **Respiratory or skin sensitisation**

May cause an allergic skin reaction.

· **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**

· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

· **Carcinogenicity** Based on available data, the classification criteria are not met.

· **Reproductive toxicity** Based on available data, the classification criteria are not met.

· **STOT-single exposure** Based on available data, the classification criteria are not met.

· **STOT-repeated exposure** Based on available data, the classification criteria are not met.

· **Aspiration hazard** Based on available data, the classification criteria are not met.

**SECTION 12: Ecological information**

· **12.1 Toxicity**

· **Aquatic toxicity:**

<b>55818-57-0 4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid</b>	
EC50/72h	> 110 mg/l (algae) (OECD 201)
LC50/96h	> 79 mg/l (fish) (OECD 203)
<b>109-16-0 triethylen glycol dimethacrylate</b>	
EC50/72h	> 100 mg/l (algae)

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- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
  - **Additional ecological information:**
    - **General notes:**  
Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.
- **12.5 Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

**SECTION 13: Disposal considerations**

- **13.1 Waste treatment methods**
  - **Recommendation** Smaller quantities can be disposed with household garbage.
  - **European waste catalogue**

18 01 06	chemicals consisting of or containing dangerous substances
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- **Uncleaned packagings:**
  - **Recommendation:** Disposal must be made according to official regulations.

**SECTION 14: Transport information**

- |  |                 |
|--|-----------------|
| · <b>14.1 UN-Number</b><br>· ADR, ADN, IMDG, IATA                                | Void            |
| · <b>14.2 UN proper shipping name</b><br>· ADR, ADN, IMDG, IATA                  | Void            |
| · <b>14.3 Transport hazard class(es)</b><br>· ADR, ADN, IMDG, IATA<br>· Class    | Void            |
| · <b>14.4 Packing group</b><br>· ADR, IMDG, IATA                                 | Void            |
| · <b>14.5 Environmental hazards:</b><br>· Marine pollutant:                      | No              |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable. |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| · <b>Transport/Additional information:</b>                                       | -               |
| · <b>UN "Model Regulation":</b>  | Void            |

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**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**SECTION 16: Other information**

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**
  - H317 May cause an allergic skin reaction.
  - H400 Very toxic to aquatic life.
  - H410 Very toxic to aquatic life with long lasting effects.
- **Abbreviations and acronyms:**
  - ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
  - IMDG: International Maritime Code for Dangerous Goods
  - IATA: International Air Transport Association
  - GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  - EINECS: European Inventory of Existing Commercial Chemical Substances
  - ELINCS: European List of Notified Chemical Substances
  - CAS: Chemical Abstracts Service (division of the American Chemical Society)
  - VOCV: Lenkungsabgabe auf flüchtigen organischen Verbindungen, Schweiz (Swiss Ordinance on volatile organic compounds)
  - DNEL: Derived No-Effect Level (REACH)
  - PNEC: Predicted No-Effect Concentration (REACH)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
  - Skin Sens. 1: Skin sensitisation – Category 1
  - Skin Sens. 1B: Skin sensitisation – Category 1B
  - Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
  - Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
- **\* Data compared to the previous version altered.**

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