



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

Printing date 03.06.2017

Version number 3

Revision: 03.06.2017

Hazardous according to criteria of Australian Safety and Compensation Council

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

· **Product identifier**

· **Trade name: Solitaire 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

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Heraeus Kulzer Australia Pty Ltd
Unit 32
11 – 21 Underwood Rd
HOMEBUSH NSW 2140
Australia

Tel: +61 (0) 2 9764 5222

· **Informing department:** see above

· **Emergency telephone number:** Emergency contact number: 13 11 26 (24 hours)

2 Hazards identification

· **Classification of the substance or mixture**

Skin Sens. 1 H317 May cause an allergic skin reaction.

· **Label elements**

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **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**

May cause an allergic skin reaction.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapours/spray.

Wear protective gloves/protective clothing/eye protection/face protection.

Contaminated work clothing should not be allowed out of the workplace.

Specific treatment (see on this label).

If skin irritation or rash occurs: Get medical advice/attention.

IF ON SKIN: Wash with plenty of water.

· **Other hazards** -

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- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

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3 Composition/information on ingredients

- **Chemical characterisation: Mixtures**
 - **Description:** Product based on methacrylates

- **Dangerous components:**

CAS: 55818-57-0 EINECS: 225-144-3	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	triethylen glycol dimethacrylate Skin Sens. 1B, H317	5-10%

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

4 First aid measures

- **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.
 - **Information for doctor**
 - **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
 - **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

- **Extinguishing media**
 - **Suitable extinguishing agents**
CO₂, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
 - **Protective equipment:** No special measures required.
- **Additional information** -

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.

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

7 Handling and storage

- **Handling**
 - **Precautions for safe handling** *No special measures required.*
 - **Information about protection against explosions and fires:** *No special measures required.*
- **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).*
- **Specific end use(s)** *No further relevant information available.*

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** *No further data; see item 7.*
- **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.

· **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

9 Physical and chemical properties

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

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
 - **Conditions to be avoided:** No decomposition if used and stored according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **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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11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity**

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

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

- **Primary irritant effect:**
 - **Skin corrosion/irritation** No irritant effect.
 - **Serious eye damage/irritation** No irritant effect.
 - **Respiratory or skin sensitisation** No sensitizing effect known.

- **Additional toxicological information:**

The product is not subject to classification according to the calculation method of the General EC Classification Guidelines for Preparations as issued in the latest version.

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12 Ecological information

- **Toxicity**

- **Aquatic toxicity:**

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

- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
 - **Bioaccumulative potential** No further relevant information available.

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- **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.
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
 - **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
 - **Recommendation** Smaller quantities can be disposed with household garbage.
- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

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

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - **GHS label elements**
The product is classified and labelled according to the Globally Harmonised System (GHS).

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· **Hazard pictograms**



GHS07

· **Signal word** Warning

· **Hazard-determining components of labelling:**

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· **Hazard statements**

May cause an allergic skin reaction.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapours/spray.

Wear protective gloves/protective clothing/eye protection/face protection.

Contaminated work clothing should not be allowed out of the workplace.

Specific treatment (see on this label).

If skin irritation or rash occurs: Get medical advice/attention.

IF ON SKIN: Wash with plenty of water.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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.

· **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

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)

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

· *** Data compared to the previous version altered.**