



**Safety Data Sheet**  
**acc. to OSHA HCS**

Printing date 06/03/2017

Reviewed on 06/03/2017

## 1 Identification

· **Product identifier**

· **Trade name: Solitaire 2**

· **Application of the substance / the mixture** Dental filling material

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

· **Manufacturer/Supplier:**

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

· **Information department:**

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545

e-mail: [customer.servicehkna@kulzer-dental.com](mailto:customer.servicehkna@kulzer-dental.com)

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)

GBK/Infotrac ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

## 2 Hazard(s) identification

· **Classification of the substance or mixture**

Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.

· **Label elements**

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07

· **Signal word** Warning

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

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.

(Contd. on page 2)

CDN



**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

**Trade name: Solitaire 2**

(Contd. of page 1)

- **Hazard description:**
  - **Canadian Hazard Symbols**  
D2B - Toxic material causing other toxic effects



- **Classification system**
  - **NFPA ratings for USA (scale 0-4)**



- **HMIS-Ratings (Scale 0-4)**



- **Other hazards -**

### 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
  - **Description:** Composition based on methacrylates

- **Dangerous components:**

55818-57-0	4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, esters with acrylic acid Skin Sensitizer - Category 1, H317	5-10% w/w
------------	--	-----------

- **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** Generally the product does not irritate the skin.
  - **After eye contact** Rinse opened eye for several minutes under running water.
  - **After swallowing**  
Rinse out mouth and then drink plenty of water.  
If symptoms persist consult doctor.
  - **Information for doctor**
    - **Most important symptoms and effects, both acute and delayed**  
No further relevant information available.

(Contd. on page 3)



**Safety Data Sheet**  
**acc. to OSHA HCS**

Printing date 06/03/2017

Reviewed on 06/03/2017

**Trade name: Solitaire 2**

- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

(Contd. of page 2)

### 5 Fire-fighting measures

- **Extinguishing media**
  - **Suitable extinguishing agents**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray 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.
- **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 substances 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 receptacles:** No special requirements.
    - **Information about storage in one common storage facility:** Not required.
    - **Further information about storage conditions:** Keep cool, if possible (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 limit 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.
    - **Additional information:** The lists that were valid during the creation were used as basis.

(Contd. on page 4)



**Safety Data Sheet  
acc. to OSHA HCS**

Printing date 06/03/2017

Reviewed on 06/03/2017

**Trade name: Solitaire 2**

(Contd. of page 3)

· **Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**

Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of 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 through 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

· **Color:**

According to product specification

· **Odor:**

Nearly odorless

· **Odor threshold:**

Not determined.

· **pH-value:**

Not determined.

· **Change in condition**

· **Melting point/Melting range:**

undetermined

· **Boiling point/Boiling range:**

100 °C (212 °F)

· **Flash point:**

101 °C (214 °F)

· **Flammability (solid, gaseous)**

Not applicable.

· **Ignition temperature:**

400 °C (752 °F)

· **Decomposition temperature:**

Not determined.

(Contd. on page 5)



**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: **Solitaire 2**

(Contd. of page 4)

· <b>Auto igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.
· <b>Vapor pressure at 20 °C (68 °F):</b>	40 hPa (30 mm Hg)
· <b>Density at 20 °C (68 °F):</b>	1.740 g/cm <sup>3</sup> (14.52 lbs/gal)
· <b>Relative density</b>	Not determined.
· <b>Vapor density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with</b>	
· <b>Water:</b>	Not miscible or difficult to mix
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
· <b>dynamic:</b>	Not determined.
· <b>kinematic:</b>	Not determined.
· <b>Solvent content:</b>	
· <b>Solids content:</b>	75.0 %
· <b>Other information</b>	No further relevant information available.

**10 Stability and reactivity**

- **Reactivity** No further relevant information available.
- **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:**  
Product might polymerize after considerable exceeding of recommended storage time or temperature.

**11 Toxicological information**

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

· <b>LD/LC50 values that are relevant for classification:</b>		
<b>poröses Glas</b>		
Oral	LD50	3160 mg/kg (rat)
<b>41137-60-4 diurethandimethacrylate</b>		
Oral	LD50	>5000 mg/kg (rat)

(Contd. on page 6)



**Safety Data Sheet**  
**acc. to OSHA HCS**

Printing date 06/03/2017

Reviewed on 06/03/2017

**Trade name: Solitaire 2**

(Contd. of page 5)

**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)
Sensitization	Sensib.	(human) Haut sensibilisierend sensib. (mouse) (LLNA) LLNA (Local Lymph Node Assay)

**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:**
  - **on the skin:** No irritant effect.
  - **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**  
The product is not subject to classification according to the calculation method of the General EU 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.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

Butyl-hydroxy-toluol	3
----------------------	---

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

**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)  
Eigene Untersuchung von EVONIK

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

(Contd. on page 7)



**Safety Data Sheet**  
**acc. to OSHA HCS**

Printing date 06/03/2017

Reviewed on 06/03/2017

**Trade name: Solitaire 2**

(Contd. of page 6)

- **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 course 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 of with household waste.
- **Uncleaned packagings:**
  - **Recommendation:** Disposal must be made according to official regulations.

**14 Transport information**

· <b>UN-Number</b>	
· DOT, TDG, ADN, IMDG, IATA	Void
· <b>UN proper shipping name</b>	
· DOT, TDG, ADN, IMDG, IATA	Void
· <b>Transport hazard class(es)</b>	
· DOT, TDG, ADN, IMDG, IATA	
· Class	Void
· <b>Packing group</b>	
· DOT, TDG, IMDG, IATA	Void
· <b>Environmental hazards:</b>	
· Marine pollutant:	No
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	-
· <b>UN "Model Regulation":</b>	Void

**15 Regulatory information**

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **SARA Section 355 (extremely hazardous substances)**  
None of the ingredients is listed.

(Contd. on page 8)





**Safety Data Sheet**  
**acc. to OSHA HCS**

Printing date 06/03/2017

Reviewed on 06/03/2017

**Trade name: Solitaire 2**

(Contd. of page 7)

- **TSCA (Toxic Substances Control Act)** Medical devices are exempted from TSCA.
- **GHS label elements**  
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labeling:**  
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.
- **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.
- **Date of preparation / last revision** 06/03/2017 / 2
- **Abbreviations and acronyms:**  
IMDG: International Maritime Code for Dangerous Goods  
DOT: US Department of Transportation  
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)  
NFPA: National Fire Protection Association (USA)  
HMIS: Hazardous Materials Identification System (USA)  
WHMIS: Workplace Hazardous Materials Information System (Canada)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative
- **\* Data compared to the previous version altered.**