

Date of print: 2011-06-29  
 Date of last alteration: 2011-06-10 - Version: 2.0 English  
 Art. -No., product name: (Art.-No. see catalogue) **smartrepair®**



**1 Identification of the substance or preparation and of the company**

- 1.1 Identification of the substance/the preparation:  
 Commercial Product Name: smartrepair®
- 1.2 Use of the substance/the preparation: Professional.  
 Light curing repair material for use in dentistry.
- 1.3 Company / undertaking identification:  
 Manufacturer / distributor: DETAX GmbH & Co. KG  
 Street / POB-No.: Carl-Zeiss-Str. 4  
 State / postal code / city: D-76275 Ettlingen  
 Telephone: +49 7243/510-0 Telefax: +49 7243/510-100  
 E-Mail: post@detax.de
- 1.4 Emergency number: +49 7243/510-0  
 This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 a.m. - 4.00 p.m.)

**2 Hazards identification**

- 2.1 Classification  
 Classification (67/548/EEC, 1999/45/EC):


R-Phrases	Indication
R 36/37/38	Irritating to eyes, respiratory system and skin.
R 43	May cause sensitization by skin contact.

- 2.2 Labelling:  
 According to the Directive (EC) 1272/2008 (GHS), Art. 1 No. 5 (d), smartrepair® as a medical device must not be labelled in the sense of the Regulations for Hazardous Materials.

**3 Composition / information on ingredients**

- 3.1 Chemical characterisation (preparation):  
 Description: Mixture of methacrylic resins and silane treated glass with auxiliary matters and pigments.

- 3.2 Hazardous ingredients:

Ingredient	CAS-No.	EC-No.	Index-No.	Concentration	Hazard symbols	R-Phrases
Ethoxylated Bisphenol A dimethacrylate	41637-38-1	246-263-7	-	≤ 20%		36/37/38-43

- 3.3 Further information: The identification letters and the R-Phrases are described in section 16.

**4 First aid measures**

- 4.1 General information: In case of accident or if you feel unwell, seek medical advice (if possible, show the label or this MSDS).  
 Medical advice is necessary in case of symptoms evidently being due to the contact of this product with skin and eyes, or being due to the inhalation of its vapours.
- 4.2 After inhalation: Move to fresh air immediately and lay the victim restful down, in case of respiratory distress in a stable lateral position. Seek medical advice immediately.
- 4.3 After contact with the skin: Wash with plenty of water and soap. Do not use organic solvents! Avoid direct UV- or sunlight. In case of visible skin reaction or complaints, seek medical advice.

Date of print: 2011-06-29  
 Date of last alteration: 2011-06-10 - Version: 2.0 English  
 Art. -No., product name: (Art.-No. see catalogue) **smartrepair®**

**DETAX**

- 4.4 After contact with the eyes: Rinse the open eyes immediately with plenty of water for at least 15 minutes, seek immediately medical advice.
- 4.5 After swallowing: Seek immediately medical advice. Immediately rinse mouth well with water and drink plenty of water in small portions. Do not induce vomiting. In case of spontaneous vomiting take care of an unhindered flow out of the vomit (danger of suffocation).
- 4.6 Autoprotection of the first assistant: Take care of a sufficient autoprotection (hand protection, foil mask "Life key").

**5 Fire fighting measures**

- 5.1 Suitable extinguishing media: Water mist, dry powder, carbon dioxide, alcohol-resistant foam.
- 5.2 Extinguishing media which must not be used for safety reasons: Water jet.
- 5.3 Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases: Possible formation of acrid acrylic fumes. Do not breathe combustion gases.
- 5.4 Special protective equipment for fire fighting: Use respiratory protection independent of recirculated air. Wear suitable protective clothing. Accomplish decontamination by means of explosion-proofed equipment.

**6 Accidental release measures**

- 6.1 Personal precautions: Avoid unprotected exposure to the unpolymerised product. Wear suitable protective clothing. Provide for sufficient ventilation.
- 6.2 Environmental precautions: Keep away from sewage treatment plants, in-shore waters and earth. Observe local byelaws.
- 6.3 Methods for cleaning up: Absorb with liquid binding material (mica, diatomaceous earth) and collect it in a suitable container, labelled according to regulations (for disposal see section 13).

**7 Handling and storage**

- 7.1 Handling:
  - Precautions for safe handling: The usual precautions in handling with chemicals are to be observed. When using to not eat, drink or smoke. Avoid contact of the unpolymerised material with eyes, skin and clothing. Do not breathe vapours.
  - Precautions against fire and explosion: Take precautionary measures against static discharges. Remove all containers not yet affected by fire. Cool endangered containers with water mist.
- 7.2 Storage:
  - Conditions for storage rooms and vessels: Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs. Keep container always tightly closed.
  - Advice for storage of incompatible materials: Keep away from strong oxidising agents, alkaline or acidic substances.
  - Further information for storage: Keep at temperature not exceeding 25 °C / 77 °F. Keep away from all kind of light. An inert gas blanket should not be applied, because the stability of the product depends on the presence of oxygen (air).
- 7.3 Definite use: Composite repair material for dental restorations like provisional crowns and bridges; for use by trained specialist staff.

Date of print: 2011-06-29  
 Date of last alteration: 2011-06-10 - Version: 2.0 English  
 Art. -No., product name: (Art.-No. see catalogue) **smartrepair®**



**8 Exposure controls and personal protection**

- 8.1 Exposition limit values:  
 Associate substances with specific control parameters such as limit values:  
 No associated substances with specific control parameters.
- 8.2 Limitation and control of the exposition
- 8.2.1 Limitation and control of the exposition at the place of work:  
 General protection and hygiene measures: The usual precautions in handling with chemicals must be respected. When using to not eat, drink or smoke. Take off immediately all contaminated clothing. Do not breathe vapours. Provide for sufficient ventilation/suction system.
- Personal protection equipment:  
 Respiratory protection: In exceptional situations like insufficient ventilation, liberation of vapours due to overheating, respiratory protection should be worn. (Respiratory protection: Gas filter A). Consider the maximum period for wear.
- Hand protection: Use protective gloves. Check the tightness before wear. Gloves should be well cleaned before being removed, then stored in a well ventilated location.  
Suitable are gloves of the following material (permeation time  $\geq 1$  hour):  
 Butyl rubber – Butyl (0.5 mm).  
Unsuitable are gloves of the following materials:  
 Natural rubber/Natural latex - NR; Polychloroprene – CR; Nitrile rubber/Nitrile latex – NBR; Fluoro carbon rubber – FKM; Polyvinyl chloride – PVC.  
 Textile or leather gloves are completely unsuitable.  
 The times listed are suggested by measurements taken at 22 °C / 72 °F and constant contact. Temperatures raised by warmed substances, body heat, etc. and a weakening of the effective layer thickness caused by expansion can lead to a significantly shorter breakthrough time.  
 In case of doubt contact the gloves' manufacturer.
- Eye protection: Wear protective glasses / face protection.  
 Body protection: Wear working clothing.
- 8.2.2 Limitation and control of the environmental exposition: Don't let the material penetrate into sewage treatment plants, in-shore waters and earth.

**9 Physical and chemical properties**

- 9.1 Appearance  
 Form: paste  
 Colour: tooth-like  
 Odour: almost odourless
- 9.2 Important information on health and environmental protection and on safety: Method (67/548/EEC)
- |   |  |            |
|---|--|------------|
| pH-value .....                            | n.a.   |            |
| Boiling point .....                       | not tested                                     | DIN 51356  |
| Flash point .....                         | > 100 °C / 212 °F                              | DIN 51755  |
| Ignition temperature .....                | not tested                                     | DIN 51794  |
| Vapour pressure .....                     | < 1 hPa at 20 °C / 68 °F                       |            |
| Density .....                             | approx. 1.5 g/cm <sup>3</sup> at 20 °C / 68 °F | DIN 51757  |
| Solubility in water .....                 | virtually insoluble                            |            |
| Distribution coefficient octanol / water: | n.a.   |            |
| Viscosity, dynamic .....                  | not tested                                     | Brookfield |
| Explosion limits .....                    | n.a.   |            |

Date of print: 2011-06-29  
 Date of last alteration: 2011-06-10 - Version: 2.0 English  
 Art. -No., product name: (Art.-No. see catalogue) **smartrepair®**



9.3 Further information:  
 Thermal decomposition .....: not tested

**10 Stability and reactivity**

- 10.1 Conditions to avoid: Ultra-violet light and daylight initiate polymerisation of the product. Therefore keep only in tightly closed containers away from any sources of light. Keep at temperature not exceeding 25 °C / 77 °F.
- 10.2 Materials to avoid: Reacts violently with strong oxidising agents, free-radical producing initiators, heavy metal ions.
- 10.3 Hazardous decomposition products: No decomposition, If stored and handled in accordance with standard industrial practices. In case of fire, acrid acrylic fumes may occur.

**11 Toxicological information**

- 11.0 General information: In case of prolonged or intense exposure, unprotected handling of the unpolymerised product may irritate the eyes, respiratory system and the skin. In persons bearing a special disposition, the product may cause allergic reactions by repeated skin contact.
- 11.1 Toxicological tests
  - Acute toxicity
  - Acute oral toxicity: For the product itself no toxicological data are available. In products with a comparable composition, a LD<sub>50</sub> (orally, species rat) of more than 5 000 mg/kg has been found.
  - Irritative effect to the skin: The irritative capacity of products with a comparable composition has been tested: Rabbit, 4 hours, different methods, occlusive, diluted and undiluted. Not any effects up to slightly irritant effects occurred. In case of prolonged and/or frequent skin contact, irritations cannot be excluded.
  - Irritative effect to the eyes: Analogous products have been tested with rabbits. Slight irritations arised. In case of prolonged exposure, irritations to the mucosal membranes of the eyes are possible.
  - Mutagenicity / Reproductive toxicity / Fertility: With analogous products, no mutagenic or reproduction toxic effects could be derived from animal in-vitro and in-vivo tests.

**12 Ecological information**

- 12.1 Ecological toxicity:
  - Effects in sewage treatment plants (bacteria toxicity: respiration-/reproduction inhibition): Do not introduce into purification plants.
- 12.2 Mobility: No data available.
- 12.3 Persistence and degradability
  - Biodegradation / further information: No data available.
- 12.4 Potential of biological accumulation: No data available.
- 12.5 Other harmful effects: A hazard for drinking water sources only is possible when very large quantities get into the ground-water.
- 12.6 Further ecotoxicological effects: Avoid escape into water, drainage, sewer, or the ground.

Date of print: 2011-06-29  
 Date of last alteration: 2011-06-10 - Version: 2.0 English  
 Art. -No., product name: (Art.-No. see catalogue) **smartrepair®**



**13 Disposal considerations**

- 13.1 Waste management (product): Recommendation: Dispose of according to regulations by incineration in a special waste incinerator. Observe the local byelaws.  
 European Waste Catalogue Ref.No.: 07 02 08 (AVV)
- 13.2 Contaminated packaging: Recommendation: Fully empty containers (no tear drops, no powder rest, scraped carefully). Containers may be recycled or re-used. Observe local/national byelaws.

**14 Transportation information**

- 14.1 Land transportation ADR/RDI and GGVS/GGVE:  
 GGVS/GGVE-class ..... : Non-hazardous material  
 ADR/RID-class ..... : Non-hazardous material  
 Transportation emergency card number:  
 Warning board - Hazard No.:  
 Nomenclature ..... :  
 Further information ..... :  
 Limited Quantities ..... :
- 14.2 Inland navigation ADN/ADNR:  
 Further information: Non-hazardous material
- 14.3 Transportation by sea IMDG/GGVsea:  
 IMDG/GGVsea-class .. : Non-hazardous material  
 EmS-No ..... :  
 Marine pollutant ..... :  
 Proper shipping name.. :  
 Technical name ..... :  
 LTD. QTY ..... :
- 14.4 Air transportation ICAO-TI and IATA-DGR transportation by air:  
 ICAO/IATA-class ..... : Non-hazardous material  
 Proper shipping name.. :  
 Technical name ..... :

**15 Regulatory information**

- 15.1 National regulations (Germany):  
 Observe local/national byelaws.  
 Information for labelling is given in section 2 of this document.  
 Occupational restrictions: Observe the restrictions on juvenile employment as defined in the „Jugendarbeitsschutzgesetz”.  
 Observe the restrictions on the employment of expectant and nursing mothers as defined in the „Mutterschutzverordnung”.  
 Classification of possible adverse effects in the aquatic environment (Wassergefährdungsklasse):  
 Class 1 (slight adverse effects in the aquatic environment).

**16 Other information**

- 16.1 Wording of the R-phrases under section 3:  
 R-Phrases and identification letters  
 R-Phrases:  
 R 36/37/38 Irritating to eyes, respiratory system and skin  
 R 43 May cause sensitization by skin contact  
 Identification letters:  
 Xi Irritating

Date of print: 2011-06-29  
Date of last alteration: 2011-06-10 - Version: 2.0 English  
Art. -No., product name: (Art.-No. see catalogue) **smartrepair®**

**DETAX****16.2 Further information**

Explanation of the abbreviations:

n.a. = not applicable

n.s. = not subject to

**16.3 Literature register:**

Richtlinie 1999/45/EG für die Einstufung, Verpackung und Kennzeichnung gefährlicher Zubereitungen

Richtlinie 67/548/EWG für die Einstufung, Verpackung und Kennzeichnung gefährlicher Stoffe, Anhang I

Neue Datenblätter für gefährliche Arbeitsstoffe nach der Gefahrstoffverordnung, WEKA-Verlag, Loseblattsammlung mit Ergänzungslieferungen

Sicherheitstechnische Kenndaten chemischer Stoffe, ecomed-Verlag, Loseblattsammlung mit Ergänzungslieferungen

Handbuch der Abfallentsorgung, ecomed-Verlag, Loseblattsammlung mit Ergänzungslieferungen

Allgemeine Verwaltungsvorschrift zur Änderung der Verwaltungsvorschrift wassergefährdender Stoffe - VwVwS vom 27. Juli 2005

Safety data sheets and further information from manufacturers / distributors

BGIA GESTIS-Stoffdatenbank, Online research

**16.4 Product:**

The given information describes exclusively the safety requirements of the product(s) and is based on our present-day knowledge. It does not represent a guarantee for the properties of the product(s) described in terms of the legal warranty regulations.

This Safety Data Sheet has been adjusted to the Directive (EC) 453/2010.