

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

Printing date 09.03.2022

Version number 1

Revision: 12.08.2021

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

· **1.1 Product identifier**

· **Trade name:** visio.paint (alle Farben)

· **Article number:** 540 0125 0, 540 0125 1, 540 0125 2, 540 0125 3, 540 0125 4, 540 0125 5, 540 0125 6

· **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:**

Light-curing, methacrylate-based intensive stains for intra- and extraoral characterization/individualization of composite restorations and composite inlays and onlays.

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

· **Manufacturer/Supplier:**

bredent GmbH & Co.KG

Weißenhorn Straße 2

89250 Senden

Tel: +49 (0) 7309/872-0

Fax: +49 (0) 7309/872-24

· **Further information obtainable from:**

R & D

e-mail: R.D@bredent.com

· **1.4 Emergency telephone number:** (001) 352 323 3500

### SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**

· **Remark**

The device is a medical device pursuant to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. No safety data sheet is required for the device, so no claim is made to full compliance with the relevant statutory requirements.

· **Classification according to Regulation (EC) No 1272/2008**



health hazard

Repr. 1B H360 May damage fertility or the unborn child.



Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

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

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008**

Medical products and medical devices within the meaning of Directives 90/385/EEC and 93/42/EEC used in an invasive manner or in direct contact with the body as well as medical products and medical devices falling under Directive 98/79/EC are fully exempt from the provisions of the CLP Regulation and therefore do not need to be classified, packaged or labelled.

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

· **Hazard pictograms** GHS07, GHS08

· **Signal word** Danger

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

Bisphenol-A-Diglycidyl-Methacrylate

Ethyl 4-dimethylaminobenzoate

· **Hazard statements**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

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*H360 May damage fertility or the unborn child.*

· **Precautionary statements**

- P201 Obtain special instructions before use.  
 P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
 P280 Wear protective gloves/protective clothing/eye protection/face protection.  
 P305+P351+P338 **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P308+P313 **IF exposed or concerned:** Get medical advice/attention.  
 P321 Specific treatment (see on this label).  
 P362+P364 Take off contaminated clothing and wash it before reuse.

· **Additional information:**

Restricted to professional users.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

Polyetherpolyole tetraacrylate	2.5 - <10%
<span style="color: red;">⚠</span> Acute Tox. 4, H312; Eye Irrit. 2, H319	

· **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 inhalation:** Supply fresh air; consult doctor in case of complaints.

· **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

Generally the product does not irritate the skin.

If skin irritation continues, consult a doctor.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:** If symptoms persist 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>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire extinguishing methods suitable to surrounding conditions.

· **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.

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#### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

#### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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:** Store in dry conditions.
- **7.3 Specific end use(s)** No further relevant information available.

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

- **8.1 Control parameters**
- **Additional information about design of technical facilities:** No further data; see item 7.
- **Ingredients 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 valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling chemicals.  
Do not eat, drink, smoke or sniff while working.  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Protection of hands:**  
Not required.  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.  
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **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.
- **Eye protection:** Goggles recommended during refilling

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· **Body protection:** Protective work clothing

### SECTION 9: Physical and chemical properties

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

##### · General Information

##### · Appearance:

<b>Form:</b>	Fluid
<b>Colour:</b>	According to product specification
<b>Odour:</b>	Characteristic
<b>Odour threshold:</b>	Not determined.

· **pH-value:** Not determined.

##### · Change in condition

<b>Melting point/freezing point:</b>	Undetermined.
<b>Initial boiling point and boiling range:</b>	> 250 °C

· **Flash point:** > 100 °C· **Flammability (solid, gas):** Not applicable.· **Decomposition temperature:** Not determined.· **Auto-ignition temperature:** Product is not selfigniting.· **Explosive properties:** Product does not present an explosion hazard.

##### · Explosion limits:

<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.

· **Vapour pressure:** Not determined.· **Density:** Not determined.· **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:

<b>Dynamic at 20 °C:</b>	8000 mPas
<b>Kinematic:</b>	Not determined.

##### · Solvent content:

<b>Organic solvents:</b>	0.0 %
<b>VOC (EC)</b>	0.0 %

· **Solids content:** < 10 %· **9.2 Other information** No further relevant information available.

### SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.

#### · 10.2 Chemical stability

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

#### · 10.3 Possibility of hazardous reactions

Photoreactive.  
Reacts with peroxides.

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- *Danger of polymerisation.*
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Causes skin irritation.
- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **Respiratory or skin sensitisation**  
May cause an allergic skin reaction.
- **Additional toxicological information:**
- **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**  
May damage fertility or the unborn child.
- **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:** No further relevant information available.
- **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:**  
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water  
Do not allow product to reach ground water, water course or sewage system.  
Danger to drinking water if even small quantities leak into the ground.
- **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**  
Must be specially treated adhering to official regulations.  
Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

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### SECTION 14: Transport information

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

### SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Labelling according to Regulation (EC) No 1272/2008  
The product is classified and labelled according to the CLP regulation.
- Hazard pictograms GHS07, GHS08
- Signal word Danger
- Hazard-determining components of labelling:  
Bisphenol-A-Diglycidyl-Methacrylate  
Ethyl 4-dimethylaminobenzoate
- Hazard statements  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H317 May cause an allergic skin reaction.  
H360 May damage fertility or the unborn child.
- Precautionary statements  
P201 Obtain special instructions before use.  
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P308+P313 IF exposed or concerned: Get medical advice/attention.  
P321 Specific treatment (see on this label).  
P362+P364 Take off contaminated clothing and wash it before reuse.
- Directive 2012/18/EU
- Named dangerous substances - ANNEX I None of the ingredients is listed.
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

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· **Relevant phrases**

*H312 Harmful in contact with skin.*

*H319 Causes serious eye irritation.*

· **Department issuing SDS: R & D**

· **Contact: R & D**

· **Abbreviations and acronyms:**

*ADR: Accord relatif au transport international 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)*

*VOC: Volatile Organic Compounds (USA, EU)*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*

*Acute Tox. 4: Acute toxicity – Category 4*

*Skin Irrit. 2: Skin corrosion/irritation – Category 2*

*Eye Irrit. 2: Serious eye damage/eye irritation – Category 2*

*Skin Sens. 1: Skin sensitisation – Category 1*

*Repr. 1B: Reproductive toxicity – Category 1B*

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

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