

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

Printing date 11.01.2022

Version number 5

Revision: 11.01.2022

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

- **1.1 Product identifier**
- **Trade name: FotoTec SL.A**
- **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**  
Methacrylic material for stereolithography systems with solid-state laser for the production of ITE and BTE earmoulds
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Dreve Otoplastik GmbH  
Max-Planck-Straße 31  
59423 Unna / Germany  
Tel.: +49 2303 / 8807-0  
Fax.: +49 2303 / 8807-29
- **Further information obtainable from:**  
Department Research & Development  
Fax: +49 2303 / 8807-562  
Email: sicherheitsdatenblatt@dreve.de
- **1.4 Emergency telephone number:**  
Tel.: +49 211 / 797-3350  
Plant Fire Department Henkel

### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS07

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

Aquatic Chronic 4    H413 May cause long lasting harmful effects to aquatic life.

- **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:**  
Diurethandimethacrylat  
1,4 Butanediol dimethacrylate  
phenyl bis(2,4,6-trimethylbenzoyl)-phosphineoxide
- **Hazard statements**  
H317 May cause an allergic skin reaction.  
H413 May cause long lasting harmful effects to aquatic life.

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- **Precautionary statements**

- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P273 Avoid release to the environment.
- P280 Wear protective gloves.
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P321 Specific treatment (see on this label).
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **2.3 Other hazards**

Uncontrollable exothermic product polymerisation possible in case of storage above 60°C or exposure to direct sunlight.

- **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: consisting of the following components.

- **Dangerous components:**

CAS: 41637-38-1 EC number: 609-946-4	Ethoxylated (04) Bisphenol A Dimethacrylate Aquatic Chronic 4, H413	50-100%
CAS: 24448-20-2 EINECS: 246-263-7	ethoxylated bishenol A dimethacrylate Aquatic Chronic 4, H413	10-25%
	Diurethandimethacrylat ⚠ Skin Sens. 1, H317	10-25%
CAS: 2082-81-7 EINECS: 212-218-1	1,4 Butanediol dimethacrylate ⚠ Skin Sens. 1, H317	2.5-10%
CAS: 162881-26-7 ELINCS: 423-340-5	phenyl bis(2,4,6-trimethylbenzoyl)-phosphineoxide ⚠ Skin Sens. 1, H317; Aquatic Chronic 4, H413	≤2.5%

- **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:** Immediately remove any clothing soiled by the product.
- **After inhalation:**  
Supply fresh air and to be sure call for a doctor.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**  
Immediately wash with water and soap and rinse thoroughly.  
If skin irritation continues, consult a doctor.
- **After eye contact:**  
Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**  
Do not induce vomiting.  
Call a doctor immediately.
- **4.2 Most important symptoms and effects, both acute and delayed**  
No further relevant information available.

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- **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.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture**  
The thermal decomposition may cause the formation of irritating vapours or gases or even fire.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Avoid contact with skin and eyes.  
Ensure adequate ventilation  
Keep away from ignition sources.  
Wear protective clothing.
- **6.2 Environmental precautions:**  
Do not allow product to reach sewage system or any water course.  
Inform respective authorities in case of seepage into water course or sewage system.  
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).  
Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.
- **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**  
Avoid contact with skin and eyes.  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.
- **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:** Protect from heat and direct sunlight.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

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### SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
- **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:**  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.
- **Respiratory protection:**  
Not necessary if room is well-ventilated.  
Use suitable respiratory protective device in case of insufficient ventilation.
- **Protection of hands:**



Protective gloves

Protective gloves should be changed regularly, especially after intensive contact with the product. For every workplace a suitable type of protective gloves must be selected. The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

- **Material of gloves**  
Nitrile rubber, NBR (0,4 mm)  
As there are many different conditions in every day work these indications can only serve as an aid to orientation for the selection of suitable gloves for the handling of chemical products. By no means they can replace qualifying examinations by the end-user. These recommendations only apply to the product mentioned in the safety data sheet. When mixing with other substances or under conditions deviant from norm EN 374 a manufacturer of CE-approved gloves should be referred to. 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.  
The determined penetration times according to EN 16523-1:2015 are not performed under practical conditions. Therefore a maximum wearing time, which corresponds to 50% of the penetration time, is recommended.
- **Eye protection:** Goggles recommended during refilling
- **Body protection:** Protective work clothing

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### SECTION 9: Physical and chemical properties

<ul style="list-style-type: none"> <li>· <b>9.1 Information on basic physical and chemical properties</b></li> <li>· <b>General Information</b></li> <li>· <b>Appearance:</b> <ul style="list-style-type: none"> <li>Form: Fluid</li> <li>Colour: Beige opaque</li> </ul> </li> <li>· <b>Odour:</b> Characteristic</li> <li>· <b>Odour threshold:</b> Not determined.</li> </ul>	
· <b>pH-value:</b>	Not determined.
<ul style="list-style-type: none"> <li>· <b>Change in condition</b> <ul style="list-style-type: none"> <li>Melting point/freezing point: Undetermined.</li> <li>Initial boiling point and boiling range: &gt;114 °C</li> </ul> </li> </ul>	
· <b>Flash point:</b>	>100 °C
· <b>Flammability (solid, gas):</b>	Not applicable.
· <b>Ignition temperature:</b>	400 °C
· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
<ul style="list-style-type: none"> <li>· <b>Explosion limits:</b> <ul style="list-style-type: none"> <li>Lower: Not determined.</li> <li>Upper: Not determined.</li> </ul> </li> <li>· <b>Oxidising properties</b> <ul style="list-style-type: none"> <li>Not determined</li> <li>Not applicable.</li> </ul> </li> </ul>	
· <b>Vapour pressure:</b>	Not determined.
<ul style="list-style-type: none"> <li>· <b>Density at 20 °C:</b> 1.1 g/cm<sup>3</sup></li> <li>· <b>Relative density</b> Not determined.</li> <li>· <b>Vapour density</b> Not determined.</li> <li>· <b>Evaporation rate</b> Not determined.</li> </ul>	
· <b>Solubility in / Miscibility with water:</b>	Not miscible or difficult to mix.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
<ul style="list-style-type: none"> <li>· <b>Viscosity:</b> <ul style="list-style-type: none"> <li>Dynamic at 23 °C: 0.8 mPas</li> <li>Kinematic: Not determined.</li> </ul> </li> <li>· <b>9.2 Other information</b> No further relevant information available.</li> </ul>	

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No dangerous reactions if used according to specifications.
- **10.2 Chemical stability** Stable if used according to specifications.
- **Thermal decomposition / conditions to be avoided:**
  - Protect from heat and direct sunlight.
  - No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions**
  - Reacts with peroxides and other radical forming substances.

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Reacts with heavy metals.

Reacts with reducing agents.

- **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 decomposition if used according to specifications.

### 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** 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:** 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:**  
Do not allow undiluted product or large quantities of it to reach ground water, water course 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**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.  
Disposal must be made according to official regulations.

- **European waste catalogue**

HP13	Sensitising
HP14	Ecotoxic

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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |   |                 |
|---|-----------------|
| <ul style="list-style-type: none"> <li>· <b>14.1 UN-Number</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>  | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> </ul>                            | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.3 Transport hazard class(es)</b></li> <li>· <b>ADR, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.4 Packing group</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>   | Void            |
| <ul style="list-style-type: none"> <li>· <b>14.5 Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> </ul>                                | No              |
| <ul style="list-style-type: none"> <li>· <b>14.6 Special precautions for user</b></li> </ul>  | Not applicable. |
| <ul style="list-style-type: none"> <li>· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b></li> </ul>                        | Not applicable. |
| <ul style="list-style-type: none"> <li>· <b>UN "Model Regulation":</b></li> </ul>   | Void            |

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
New Zealand Regulatory Information  
HSNO Approval Number: HSR002644 - Polymers (Subsidiary Hazard) Group Standard 2017
- **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.

- **Relevant phrases**  
H317 May cause an allergic skin reaction.  
H413 May cause long lasting harmful effects to aquatic life.
- **Department issuing SDS:** Department Research & Development
- **Contact:** Dr. Thomas Veit, Lothar Sutor, Susanne Weber

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**· 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)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Skin Sens. 1: Skin sensitisation – Category 1  
Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

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