



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

Printing date 27.04.2021

Version number 4

Revision: 27.04.2021

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

- **1.1 Product identifier**
- **Trade name:** Fotoplast S IO coloured - transparent
- **CAS Number:**
41637-38-1
- **EC number:**
609-946-4
- **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 1-component resin for the production of earmoulds for ITE-hearing aids.
- **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**
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 substance is classified and labelled according to the CLP regulation.
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements**
H413 May cause long lasting harmful effects to aquatic life.
- **Precautionary statements**
P273 Avoid release to the environment.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.1 Chemical characterisation: Substances**
- **CAS No. Description**
41637-38-1 Ethoxylated (04) Bisphenol A Dimethacrylate

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- **Identification number(s)**
- **EC number:** 609-946-4
- **Description:** Light-curing 1-component resin

Dangerous components:

CAS: 75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphin oxide	≤2.5%
EINECS: 278-355-8	⚠ Repr. 2, H361f	

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **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.
- **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:**
CO₂, 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:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Avoid contact with skin and eyes.
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.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

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SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Avoid contact with skin and eyes.
- **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.

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:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not necessary if room is well-ventilated.
- **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.

- **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.

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

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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:**
 - Form:** Viscous
 - Colour:** Different according to colouring
 - **Odour:** Weak, characteristic
 - **Odour threshold:** Not determined.
- **pH-value:** Not determined.
- **Change in condition**
 - Melting point/freezing point:** Undetermined.
 - Initial boiling point and boiling range:** 290 °C
- **Flash point:** 211 °C
- **Flammability (solid, gas):** Not applicable.
- **Decomposition temperature:** Not determined.
- **Auto-ignition temperature:** Not determined.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**
 - Lower:** Not determined.
 - Upper:** Not determined.
- **Oxidising properties:** Not determined
Not applicable.
- **Vapour pressure:** Not determined.
- **Density at 20 °C:** 1.1 g/cm³
- **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.
- **9.2 Other information:** No further relevant information available.

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.

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- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **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** 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** Based on available data, the classification criteria are not met.
- **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**
- | | |
|------|----------|
| 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"> · 14.1 UN-Number · ADR, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class | Void |
| <ul style="list-style-type: none"> · 14.4 Packing group · ADR, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.5 Environmental hazards: · Marine pollutant: | No |
| <ul style="list-style-type: none"> · 14.6 Special precautions for user | Not applicable. |
| <ul style="list-style-type: none"> · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| <ul style="list-style-type: none"> · UN "Model Regulation": | 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** Substance is not listed.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **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**
H361f Suspected of damaging fertility.
- **Department issuing SDS:** Department Research & Development
- **Contact:** Dr. Thomas Veit, Lothar Sutor
- **Abbreviations and acronyms:**
 RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
 IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
 ICAO: International Civil Aviation Organisation
 ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)
 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

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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
Repr. 2: Reproductive toxicity – Category 2
Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4
• *** Data compared to the previous version altered.**

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