

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022


Version number 2

Revision: 09.03.2022


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

- **1.1 Product identifier**
- **Trade name:** Kompaktopaker UV tooth shades.
- **Article number:** 540 0010 5
- **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:** Opaquer for covering model castings.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
bredent GmbH & Co.KG
Weißenhorn Str. 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**
- 

flame

Flam. Liq. 2 H225 Highly flammable liquid and vapour.
- 

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.

STOT SE 3 H335 May cause respiratory irritation.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- **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** GHS02, GHS07
- **Signal word** Danger
- **Hazard-determining components of labelling:**
methyl methacrylate
2-Propenoic acid, reaction products with
dipentaerythritol
Fatty acids, C18-unsatd., trimers, compds. with oleylamine
Fettsäuren, Tallöl-, Verbindungen mit Oleylamin

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2-(Dimethylamino)ethyl benzoate

· Hazard statements

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

H412 Harmful to aquatic life with long lasting effects.

· Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

P403+P235 Store in a well-ventilated place. Keep cool.

· Additional information:

Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist.

· 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:**

CAS: 80-62-6 EINECS: 201-297-1	methyl methacrylate ⚠ Flam. Liq. 2, H225 ⚠ Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	25-50%
	??	10-25%
CAS: 75980-60-8 EINECS: 278-355-8	diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide ⚠ Repr. 2, H361f	≤ 3%
CAS: 2208-05-1	2-(Dimethylamino)ethyl benzoate ⚠ Skin Irrit. 2, H315; Skin Sens. 1, H317	≤ 1%

· 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**· 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:

If skin irritation continues, consult a doctor.

Immediately wash with water and soap and rinse thoroughly.

· 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.

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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:** CO₂, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture**
During heating or in case of fire poisonous gases are produced.
- **5.3 Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Mount respiratory protective device.
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:**
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).
Ensure adequate ventilation.
Do not flush with water or aqueous cleansing agents
- **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**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
Keep respiratory protective device available.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:**
Keep container tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
- **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.

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· **Ingredients with limit values that require monitoring at the workplace:**

80-62-6 methyl methacrylate (25-50%)

WEL (Great Britain)	Short-term value: 416 mg/m ³ , 100 ppm Long-term value: 208 mg/m ³ , 50 ppm
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· **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.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· **Protection of hands:**



Protective gloves

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**

Butyl rubber, BR

Recommended thickness of the material: ≥ 0.5 mm

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 penetration time has to be at least 60 minutes (Permeation according to EN 374 Part 3: Level 3).

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles

SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

Form: Fluid

Colour: According to product specification

· **Odour:** Ester-like

· **Odour threshold:** Not determined.

· **pH-value:** Not determined.

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· Change in condition Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
· Flash point:	10 °C
· Flammability (solid, gas):	Not applicable.
· Ignition temperature:	415 °C
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· Explosion limits: Lower:	2.1 Vol %
Upper:	12.5 Vol %
· Vapour pressure at 20 °C:	47 hPa
· 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: Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content: Organic solvents:	< 1 %
VOC (EC)	30 - 35 %
Solids content:	20.0 %
· 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** 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.

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· LD/LC50 values relevant for classification:

1384855-91-7 2-Propenoic acid, reaction products with dipentaerythritol

Oral LD50 > 2000 mg/kg (rat) (OECD 423)

Dermal LD50 > 2000 mg/kg (rabbit) (OECD 402)

??

Oral LD50 > 2000 mg/kg (rat)

75980-60-8 diphenyl(2,4,6- trimethylbenzoyl)phosphine oxide

Oral LD50 > 5000 mg/kg (rat)

· 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** Based on available data, the classification criteria are not met.

· STOT-single exposure

May cause respiratory irritation.

· **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.

· Ecotoxicological effects:

· **Remark:** Harmful to fish

· Additional ecological information:

· General notes:

Harmful to aquatic organisms

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 not be disposed together with household garbage. Do not allow product to reach sewage system.

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

SECTION 14: Transport information

· 14.1 UN-Number	UN1247
· ADR, IMDG, IATA	
· 14.2 UN proper shipping name	1247 METHYL METHACRYLATE MONOMER, STABILIZED
· ADR	
· IMDG, IATA	METHYL METHACRYLATE MONOMER, STABILIZED
· 14.3 Transport hazard class(es)	
· ADR, IMDG, IATA	
	
· Class	3 Flammable liquids.
· Label	3
· 14.4 Packing group	II
· ADR, IMDG, IATA	
· 14.5 Environmental hazards:	
· Marine pollutant:	Yes
· 14.6 Special precautions for user	Warning: Flammable liquids.
· Hazard identification number (Kemler code):	339
· EMS Number:	F-E,S-D
· Stowage Category	B
· Stowage Code	SW2 Clear of living quarters.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category	2
· Tunnel restriction code	D/E
· IMDG	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1247 METHYL METHACRYLATE MONOMER, STABILIZED, 3, II

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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** GHS02, GHS07
- **Signal word** Danger
- **Hazard-determining components of labelling:**
methyl methacrylate
2-Propenoic acid, reaction products with
dipentaerythritol
Fatty acids, C18-unsatd., trimers, compds. with oleylamine
Fettsäuren, Tallöl-, Verbindungen mit Oleylamin
2-(Dimethylamino)ethyl benzoate
- **Hazard statements**
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.
H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P403+P233 Store in a well-ventilated place. Keep container tightly closed.
P403+P235 Store in a well-ventilated place. Keep cool.
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category** P5c FLAMMABLE LIQUIDS
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5.000 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50.000 t
- **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**
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.
H361f Suspected of damaging fertility.
- **Department issuing SDS:** R & D
- **Contact:** R & D
- **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)
ICAO: International Civil Aviation Organisation
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

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*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)**LC50: Lethal concentration, 50 percent**LD50: Lethal dose, 50 percent**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**Flam. Liq. 2: Flammable liquids – Category 2**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. 2: Reproductive toxicity – Category 2**STOT SE 3: Specific target organ toxicity (single exposure) – Category 3**Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3*

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

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