

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022


Version number 3

Revision: 09.03.2022

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


- **1.1 Product identifier**
- **Trade name:** Opaquer combo.lign
- **Article number:** CO1X4KAT, CO1X4OPG, CO1X4OPI, CO1X4OPL, CO1X4OPM
- **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
Weißenhornor 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

Carc. 2



Skin Sens. 1

H317 May cause an allergic skin reaction.

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** GHS07, GHS08
- **Signal word** Warning
- **Hazard-determining components of labelling:**
7,7,9(or7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diaza-hexadecane-1,16-diyl bismethacrylate
titanium dioxide
tetramethylene dimethacrylate
dibenzoyl peroxide
- **Hazard statements**
H317 May cause an allergic skin reaction.
H351 Suspected of causing cancer. Route of exposure: Inhalation.
H412 Harmful to aquatic life with long lasting effects.

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· Precautionary statements

- P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P302+P352 IF ON SKIN: Wash with plenty of water.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P405 Store locked up.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· Additional information:

Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.

· 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:** Paste of dimethacrylates, inorganic fillers, catalysts, stabilizers and pigments.

· Dangerous components:

CAS: 72869-86-4 EINECS: 276-957-5	7,7,9(or7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazaheptadecane-1,16-diyl bismethacrylate <div> <div>⚠</div> <div>Skin Sens. 1, H317</div> <div>Aquatic Chronic 3, H412</div> </div>	< 20%
CAS: 2082-81-7 EINECS: 218-218-1	tetramethylene dimethacrylate <div> <div>⚠</div> <div>Skin Sens. 1, H317</div> </div>	< 20%
CAS: 42594-17-2	Tricyclodecane Dimethanol Diacrylate <div> <div>⚠</div> <div>Skin Irrit. 2, H315; Eye Irrit. 2, H319</div> </div>	< 10%
CAS: 94-36-0 EINECS: 202-327-6	dibenzoyl peroxide <div> <div>⚠</div> <div>Org. Perox. B, H241</div> <div> <div>⚠</div> <div>Aquatic Chronic 1, H410</div> <div> <div>⚠</div> <div>Eye Irrit. 2, H319; Skin Sens. 1, H317</div> </div> </div> </div>	< 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.
 Seek medical treatment.
 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:

Seek medical treatment.
 Immediately wash with water and soap and rinse thoroughly.

· After eye contact:

Seek medical treatment.
 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.

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SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
 - Foam
 - Fire-extinguishing powder
 - Carbon dioxide
 - CO₂, sand, extinguishing powder. Do not use water.
 - Use fire extinguishing methods suitable to surrounding conditions.
- **For safety reasons unsuitable extinguishing agents:** Water
- **5.2 Special hazards arising from the substance or mixture**
 - In case of fire, the following can be released:
 - Carbon monoxide (CO)
 - carbon dioxide
 - Under certain fire conditions, traces of other toxic gases cannot be excluded.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.
- **Additional information**
 - Collect contaminated fire fighting water separately. It must not enter the sewage system.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
 - Ensure adequate ventilation
 - Use respiratory protective device against the effects of fumes/dust/aerosol.
 - Wear protective clothing.
 - 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:**
 - 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.
- **Information about fire - and explosion protection:**
 - Keep ignition sources away - Do not smoke.
 - Protect against electrostatic charges.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
 - Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
 - Information about storage in one common storage facility:** Store away from foodstuffs.
 - Further information about storage conditions:**
 - Protect from exposure to the light.
 - Store in a cool place.
 - Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

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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:**

13463-67-7 titanium dioxide ($\leq 3\%$)	
WEL (Great Britain)	Long-term value: $10 \cdot 4^{**} \text{ mg/m}^3$ *total inhalable **respirable
94-36-0 dibenzoyl peroxide ($\leq 1\%$)	
WEL (Great Britain)	Long-term value: 5 mg/m^3

- **Additional information:** The lists valid during the making were used as basis.

- **8.2 Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

Be sure to clean skin thoroughly after work and before breaks.

Do not eat, drink, smoke or sniff while working.

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:**

Not necessary if room is well-ventilated.

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:**

Solvent resistant gloves



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**

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:**



Tightly sealed goggles

- **Body protection:** Light weight protective clothing

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Pasty
Colour:	Coloured
Odour:	Characteristic
Odour threshold:	Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/freezing point:	unbekannt °C
Initial boiling point and boiling range:	>100 °C

· Flash point: >150 °C

· Flammability (solid, gas): Undetermined.

· Ignition temperature: Undetermined.

· Decomposition temperature: Not determined.

· Auto-ignition temperature: Product is not selfigniting.

· Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

· Vapour pressure: Not applicable.

· Density: Not determined.

· Relative density: Not determined.

· Vapour density: Not applicable.

· Evaporation rate: Not applicable.

· Solubility in / Miscibility with water:

Insoluble.

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic:	Not determined.
Kinematic:	Not applicable.

· 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

Reacts with peroxides.

Photoreactive.

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.

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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity Based on available data, the classification criteria are not met.

LD/LC50 values relevant for classification:

72869-86-4 7,7,9(or7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahehexadecane-1,16-diyl bismethacrylate

Oral	LD50	>2,000 mg/kg (rat) (OECD 401)
	LC50 / 96 h	10.1 mg/l (brachidanio rerio) (OECD 203)

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.

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

Suspected of causing cancer. Route of exposure: Inhalation.

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:

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

12.2 Persistence and degradability Not easily biodegradable

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 1 (German Regulation) (Self-assessment): slightly hazardous for water

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

Smaller quantities of cured material may be disposed off together with household waste.

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

Uncleaned packaging:

Recommendation:

Non contaminated packagings may be recycled.

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Empty contaminated packagings thoroughly. They may be recycled after thorough and proper cleaning.

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.
· Stowage Category	D
· 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 Warning
- Hazard-determining components of labelling:
7,7,9(or7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate
titanium dioxide
tetramethylene dimethacrylate
dibenzoyl peroxide
- Hazard statements
H317 May cause an allergic skin reaction.
H351 Suspected of causing cancer. Route of exposure: Inhalation.
H412 Harmful to aquatic life with long lasting effects.
- Precautionary statements
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- Directive 2012/18/EU
- Named dangerous substances - ANNEX I None of the ingredients is listed.

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· **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**

H241 Heating may cause a fire or explosion.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H410 Very toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

· **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)

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Org. Perox. B: Organic peroxides – Type B

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

Carc. 2: Carcinogenicity – Category 2

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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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