

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 4

Revision: 12.08.2021

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

· 1.1 Product identifier

· Trade name: combo.lign

· Article number:

CO2x4A10, CO2x4A20, CO2x4A30, CO2x4A35, CO2x4A40, CO2x4B10, CO2x4B20, CO2x4B30, CO2x4B40, CO2x4C10, CO2x4C20, CO2x4C30, CO2x4C40, CO2x4D20, CO2x4D30, CO2x4D40, CO2x4BL3, CO2x4GUM

· 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:

Dental use.

Dualhärtendes Befestigungs-Composite

· 1.3 Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

bredent GmbH & Co.KG

Weißenhornstraße 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



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

· Signal word Warning

· Hazard-determining components of labelling:

7,7,9(or7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

tetramethylene dimethacrylate

dibenzoyl peroxide

· Hazard statements

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

· Precautionary statements

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

P273 Avoid release to the environment.

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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**· **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: 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 ⚠ Skin Sens. 1, H317 ⚠ Aquatic Chronic 3, H412	< 20%
CAS: 2082-81-7 EINECS: 218-218-1	tetramethylene dimethacrylate ⚠ Skin Sens. 1, H317	< 20%
CAS: 42594-17-2	Tricyclodecane Dimethanol Diacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	< 10%
CAS: 94-36-0 EINECS: 202-327-6	dibenzoyl peroxide ⚠ Org. Perox. B, H241 ⚠ Aquatic Chronic 1, H410 ⚠ Eye Irrit. 2, H319; 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:** Immediately wash with water and soap and rinse thoroughly.· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.· **After swallowing:**

Seek immediate medical advice.

Rinse out mouth and then drink plenty of water.

· **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:**

Foam

Fire-extinguishing powder

Carbon dioxide

Use fire extinguishing methods suitable to surrounding conditions.

· **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

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- **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**
Wear protective clothing.
Ensure adequate ventilation
- **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.
- **6.4 Reference to other sections**
No dangerous substances are released.
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**
Keep away from heat and direct sunlight.
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:** Store only in unopened original receptacles.
- **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.
- **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:**
Do not eat, drink, smoke or sniff while working.
The usual precautionary measures are to be adhered to when handling chemicals.
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.
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.

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· 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 480 minutes (Permeation according to EN 374 Part 3: Level 6).

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**· Body protection:** Protective work clothing

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties**· General Information****· Appearance:****Form:**

Pasty

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: Undetermined.**· Flash point:**

> 150 °C

· Flammability (solid, gas):

Not applicable.

· Ignition temperature:

nicht bestimmt

· 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 determined.

· Density at 20 °C:1.87 g/cm³**· Relative density**

Not determined.

· Vapour density

Not determined.

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· 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:	0.0 %
· 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**
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.

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** 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.

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- **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.
- **Ecotoxical 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**
 Can be disposed of with household garbage after solidification following consultation with the waste disposal facility operator and the pertinent authorities and adhering to the necessary technical regulations.
 Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:**
 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. |
| · 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.

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- **Hazard pictograms** GHS07
- **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
tetramethylene dimethacrylate
dibenzoyl peroxide
- **Hazard statements**
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.
- **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.
- **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.

- **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:**
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
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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