

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:** crea.lign (Transpa; GUM-colors; Modifier lila)
- **Article number:** CLFN00T1, CLFN00G1, CLFN00G2, CLFN00G3, CLFN00G4, CLFN00M4
- **1.2 Relevant identified uses of the substance or mixture and uses advised against:** -
- **Application of the substance / the mixture:** Dental use.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
bredent GmbH & Co.KG
Weißenhornher 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**



- | | |
|--|---|
| 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. |
| <hr style="border-top: 1px dashed #ccc;"/> | |
| 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
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
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 / eye protection / face protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

(Contd. on page 2)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 4

Revision: 12.08.2021

Trade name: *crea.lign (Transpa; GUM-colors; Modifier lila)*

(Contd. of page 1)

P337+P313 If eye irritation persists: Get medical advice/attention.
 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 acrylate resins, inorganic fillers, initiators and colorants.

- **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-diazahexadecane-1,16-diyl bismethacrylate ⚠ Skin Sens. 1, H317 Aquatic Chronic 3, H412	40 - 60%
CAS: 42594-17-2	Tricyclodecane Dimethanol Diacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	20 - 40%

- **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.
Seek medical treatment.
- **After inhalation:**
Supply fresh air.
Seek medical treatment.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
Seek medical treatment.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:** Do not induce vomiting; call for medical help 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:**
Foam
Fire-extinguishing powder
Carbon dioxide
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**
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.

(Contd. on page 3)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 4

Revision: 12.08.2021

Trade name: crea.lign (Transpa; GUM-colors; Modifier lila)

(Contd. of page 2)

· **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

Wear protective clothing.

· **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:**

Pick up mechanically.

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.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**

No special precautions are necessary if used correctly.

Ensure good ventilation/exhaustion at the workplace.

· **Information about fire - and explosion protection:** Keep ignition sources away - Do not smoke.

· **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:** Not required.

· **Further information about storage conditions:**

Store in a cool place.

Protect from exposure to the light.

· **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:**

The usual precautionary measures are to be adhered to when handling chemicals.

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

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Immediately remove all soiled and contaminated clothing

· **Respiratory protection:** Not required.

(Contd. on page 4)

GB

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

Printing date 09.03.2022

Version number 4

Revision: 12.08.2021

Trade name: crea.lign (Transpa; GUM-colors; Modifier lila)

(Contd. of page 3)

· **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

· **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:	> 100 °C

· Flash point:	> 100 °C
----------------	------------

· Flammability (solid, gas):	Not determined.
------------------------------	-----------------

· 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.

(Contd. on page 5)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 4

Revision: 12.08.2021

Trade name: crea.lign (Transpa; GUM-colors; Modifier lila)

(Contd. of page 4)

· Vapour pressure:	Not determined.
· Density at 20 °C:	1.1 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Insoluble.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· 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 and stored according to specifications.
Stable at environment temperature.
- **10.3 Possibility of hazardous reactions**
Exothermic polymerisation.
Reacts with peroxides and other radical forming substances.
Reacts with reducing agents.
Reacts with heavy metals.
- **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-diaza-hexadecane-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**
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.

(Contd. on page 6)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 4

Revision: 12.08.2021

Trade name: crea.lign (Transpa; GUM-colors; Modifier lila)

(Contd. of page 5)

- **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.
- **Ecotoxicological effects:**
- **Remark:** Toxic for fish
- **Additional ecological information:**
- **General notes:**
Also poisonous for fish and plankton in water bodies.
Toxic for 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 be specially treated adhering to official regulations.
Not cured product must not be disposed off together with household waste and must not reach the sewage system.
Smaller quantities of cured material may be disposed off together with household waste.
- **Uncleaned packaging:**
- **Recommendation:**
Packagings that may not be cleansed are to be disposed of in the same manner as the product.

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 |

(Contd. on page 7)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 4

Revision: 12.08.2021

Trade name: *crea.lign (Transpa; GUM-colors; Modifier lila)*

(Contd. of page 6)

- | | |
|--|-----------------|
| · 14.6 Special precautions for user | Not applicable. |
| · Stowage Category | A |
| · 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
- **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
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
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 / eye protection / face protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 If eye irritation persists: Get medical advice/attention.
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**
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H412 Harmful to aquatic life with long lasting effects.
- **Department issuing SDS:** R & D
- **Contact:** R & D
- **Abbreviations and acronyms:**
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

(Contd. on page 8)

GB

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

Printing date 09.03.2022

Version number 4

Revision: 12.08.2021

Trade name: crea.lign (Transpa; GUM-colors; Modifier lila)

(Contd. of page 7)

*PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**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 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3**. * **Data compared to the previous version altered.***

GB