

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 3

Revision: 12.08.2021

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

- **1.1 Product identifier**
- **Trade name:** crea.lign Opaker
- **Article number:**
CLFHOGUM, CLFHOP01, CLFHOP02, CLFHOP03, CLFHOP04, CLFHOP05, CLFHOP06, CLFHOP07, CLFHOP08, CLFHOP09, CLFHOP0Z, CLFHOPSET
- **1.2 Relevant identified uses of the substance or mixture and uses advised against:**
No further relevant information available.
- **1.3 Details of the supplier of the safety data sheet**
- **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**



corrosion

Eye Dam. 1 H318 Causes serious eye damage.



Skin Irrit. 2 H315 Causes skin irritation.

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** GHS05, GHS07
- **Signal word** Danger
- **Hazard-determining components of labelling:**
2-propenoic acid reaction products with pentaerythritol
- **Hazard statements**
H315 Causes skin irritation.
H318 Causes serious eye damage.
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**
P273 Avoid release to the environment.
P280 Wear protective gloves / eye protection / face protection.
P302+P350 IF ON SKIN: Gently wash with plenty of soap and 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.

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P333+P313 If skin irritation or rash occurs: 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 substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 7534-94-3	exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-ylmethacrylate ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	< 25%
CAS: 1245638-61-2 EC number: 629-850-6	2-propenoic acid reaction products with pentaerythritol ⚠ Eye Dam. 1, H318 ⚠ Aquatic Chronic 2, H411 ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315; Skin Sens. 1, H317	< 10%
CAS: 75980-60-8 EINECS: 278-355-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide ⚠ Repr. 2, H361f	< 3%

- **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.
- **After inhalation:**
Supply fresh air.
Call a doctor immediately.
- **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. If symptoms persist, 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
- **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
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

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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 equipment. Keep unprotected persons away.

Use respiratory protective device against the effects of fumes/dust/aerosol.

6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up:

Pick up mechanically.

Dispose of the material collected according to regulations.

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.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles: No special requirements.

Information about storage in one common storage facility: Not required.

Further information about storage conditions: Keep container tightly sealed.

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:

13463-67-7 titanium dioxide ($\leq 3\%$)

WEL (Great Britain)	Long-term value: $10 \cdot 4^{**} \text{ mg/m}^3$ *total inhalable **respirable
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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: Avoid contact with the eyes and skin.

Respiratory protection: Not required.

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.

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

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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:** 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:	Characteristic
Odour threshold:	Not determined.

· **pH-value:** Not applicable.· **Change in condition****Melting point/freezing point:** Undetermined.· **Flash point:** >100 °C· **Flammability (solid, gas):** Not determined.· **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:**

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 at 20 °C:	20000 - 40000 mPas
Kinematic:	Not applicable.

· **Solvent content:****Organic solvents:** 0.0 %**Solids content:** 100.0 %· **9.2 Other information** No further relevant information available.

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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** Exothermic 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.
- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye damage.
- **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.
- **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.

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SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation

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

Not cured product must not be disposed off together with household waste and must not reach the sewage system.

Must be specially treated adhering to official regulations.

· Uncleaned packaging:

· Recommendation: Disposal must be made according to official regulations.

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:

Not applicable.

· 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.

· Hazard pictograms GHS05, GHS07

· Signal word Danger

· Hazard-determining components of labelling:

2-propenoic acid reaction products with pentaerythritol

· Hazard statements

H315 Causes skin irritation.

H318 Causes serious eye damage.

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

· Precautionary statements

P273 Avoid release to the environment.

P280 Wear protective gloves / eye protection / face protection.

P302+P350 IF ON SKIN: Gently wash with plenty of soap and 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.

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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**

H302 Harmful if swallowed.
 H315 Causes skin irritation.
 H317 May cause an allergic skin reaction.
 H318 Causes serious eye damage.
 H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.
 H361f Suspected of damaging fertility.
 H411 Toxic 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)
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative
 Acute Tox. 4: Acute toxicity – Category 4
 Skin Irrit. 2: Skin corrosion/irritation – Category 2
 Eye Dam. 1: Serious eye damage/eye irritation – Category 1
 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 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
 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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