

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:** Löffelmaterial UV

· **Article number:** 540 0011 0, 540 0016 6

· 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:** .

· **Application of the substance / the mixture:**

Tray material UV is suitable for the production of individual trays, functional trays and base plates to set up teeth on.

· 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(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate
(1-methyl-1,2-ethanediyl)bis[oxy(methyl-2,1-ethanediyl)] diacrylate

· **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.

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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 acrylate resins, inorganic fillers, initiators and colorants.· **Dangerous components:**

	Aliphatic urethane dimethacrylate ⚠ Aquatic Chronic 2, H411 ⚠ Skin Sens. 1, H317	10-25%
	Silicone und Siloxane, dimethyl-, Reaktionsprodukte mit Siliciumdioxid ⚠ Acute Tox. 4, H302	2.5-10%
CAS: 42978-66-5 EINECS: 256-032-2	(1-methyl-1,2-ethanediyl)bis[oxy(methyl-2,1-ethanediyl)] diacrylate ⚠ Aquatic Chronic 2, H411 ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	≤1%
CAS: 7473-98-5 EINECS: 231-272-0	2-hydroxy-2-methylpropiophenone ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410 ⚠ Acute Tox. 4, H302	≤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; consult doctor in case of complaints.· **After skin contact:** Immediately rinse with water.· **After eye contact:** Rinse opened eye for several minutes under running water. Then 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.

SECTION 5: Firefighting measures

· **5.1 Extinguishing media**· **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.· **5.2 Special hazards arising from the substance or mixture** No further relevant information available.· **5.3 Advice for firefighters**· **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

· **6.1 Personal precautions, protective equipment and emergency procedures** Not required.· **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.

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- **6.3 Methods and material for containment and cleaning up:**
Clean the affected area carefully; suitable cleaners are:
Organic solvent
- **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** No special precautions are necessary if used correctly.
- **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:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **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.
Wash hands before breaks and at the end of work.
- **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.
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).

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

· **Eye protection:** Not required.

SECTION 9: Physical and chemical properties

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

· **General Information**

· **Appearance:**

· Form:	Highly viscous
· Colour:	According to product specification
· Odour:	Characteristic
· Odour threshold:	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

· Melting point/freezing point:	Undetermined.
· Initial boiling point and boiling range:	Undetermined.

· **Flash point:** >150 °C

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

· **Ignition temperature:** >400 °C

· **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 applicable.
· Kinematic:	Not applicable.

· **Solvent content:**

· **Solids content:** 80 %

· **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.

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- **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:**
- | | |
|--|------------------------|
| 7473-98-5 2-hydroxy-2-methylpropiophenone | |
| Oral | LD50 1,694 mg/kg (rat) |
- **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.
- **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:**
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.
Harmful to aquatic organisms
- **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**
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.

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- **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: | |
| · 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.
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate (1-methyl-1,2-ethanediyl)bis[oxy(methyl-2,1-ethanediyl)] diacrylate
- **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.

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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.
 H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.
 H400 Very toxic to aquatic life.
 H410 Very toxic to aquatic life with long lasting effects.
 H411 Toxic 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
 Acute Tox. 4: Acute toxicity – Category 4
 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
 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
 Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
 Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
 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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