



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

Printing date 29.07.2024

Version number 5 (replaces version 4)

Revision: 29.07.2024

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

- **1.1 Product identifier**
  - Trade name: **Pala cre-active gingiva**
- **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** Auxiliary for manufacture of dental prothesis
- **1.3 Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:**  
Kulzer GmbH  
Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522
  - **Informing department:** E-Mail: [msds@kulzer-dental.com](mailto:msds@kulzer-dental.com)
- **1.4 Emergency telephone number:** Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
  - **Classification according to Regulation (EC) No 1272/2008**

Skin Sens. 1 H317 May cause an allergic skin reaction.  
Aquatic Acute 1 H400 Very toxic to aquatic life.  
Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.
- **2.2 Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.

    - **Hazard pictograms**  
  
GHS07 GHS09
    - **Signal word** Warning
    - **Hazard-determining components of labelling:**  
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahehexadecane-1,16-diyl bismethacrylate  
Hexamethylene diisocyanate, trimers, reactionproducts with 2-hydroxyethyl acrylate  
1,12-Dodecanediol dimethacrylate  
diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
    - **Hazard statements**  
H317 May cause an allergic skin reaction.  
H400 Very toxic to aquatic life.  
H411 Toxic to aquatic life with long lasting effects.
    - **Precautionary statements**  
P273 Avoid release to the environment.  
P280 Wear protective gloves / eye protection.
  - **Additional information:**  
9.1 % of the mixture consists of component(s) of unknown toxicity.  
Contains 9.1 % of components with unknown hazards to the aquatic environment.
- **2.3 Other hazards -**

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· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

· **Determination of endocrine-disrupting properties**

131-57-7 Oxybenzone

List II

**SECTION 3: Composition/information on ingredients**

· **3.2 Mixtures**

· **Description:** Product based on methacrylates

· **Dangerous components:**

CAS: 72869-86-4 EINECS: 276-957-5 Index number: 607-134-00-4 Reg.nr.: 01-2120751202-68-xxxx	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate Aquatic Chronic 2, H411 Skin Sens. 1B, H317 EUH204	≥50-≤75%
CAS: 162492-01-5 NLP: 500-734-6	Hexamethylene diisocyanate, trimers, reactionproducts with 2-hydroxyethyl acrylate Skin Sens. 1A, H317 Aquatic Chronic 4, H413 EUH204	≥10-<25%
CAS: 68909-20-6 EINECS: 272-697-1	amorphe Kieselsäure, mit Sialamin oberflächenbehandelt STOT RE 2, H373 EUH066	≥5-<10%
CAS: 72829-09-5 EINECS: 276-900-4	1,12-Dodecanediol dimethacrylate Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=1) Skin Sens. 1B, H317	≥2.5-≤10%
CAS: 131-57-7 EINECS: 205-031-5	Oxybenzone Aquatic Acute 1, H400; Aquatic Chronic 2, H411	≥0.25-<1%
CAS: 75980-60-8 EINECS: 278-355-8 Index number: 015-203-00-X Reg.nr.: 01-2119972295-29-xxxx	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 1B, H360Fd Aquatic Chronic 2, H411 Skin Sens. 1B, H317	≥0.1-<0.25%

· **SVHC**

75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

· **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 symptoms.
- **After skin contact**  
Instantly wash with water and soap and rinse thoroughly.  
If skin irritation continues, consult a doctor.

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- **After eye contact**  
*Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.*
- **After swallowing**  
*Rinse out mouth and then drink plenty of water.  
In case of persistent symptoms 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**  
*CO<sub>2</sub>, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.  
Use fire fighting measures that suit the environment.*
- **5.2 Special hazards arising from the substance or mixture**  
*Formation of toxic gases is possible during heating or in case of fire.*
- **5.3 Advice for firefighters**
  - **Protective equipment:** *Put on breathing apparatus.*
  - **Additional information -**

### **SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures**  
*Wear protective clothing.  
Avoid contact with eyes and skin.*
- **6.2 Environmental precautions:**  
*Do not allow product to reach sewage system or water bodies.  
Do not allow to enter the ground/soil.*
- **6.3 Methods and material for containment and cleaning up:**  
*Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).  
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 information on disposal.*
- 

### **SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling** *No special measures required.*
  - **Information about protection against explosions and fires:** *No special measures required.*
- **7.2 Conditions for safe storage, including any incompatibilities**
  - **Storage**
    - **Requirements to be met by storerooms and containers:** *No special requirements.*
    - **Information about storage in one common storage facility:** *Not required.*
    - **Further information about storage conditions:** *Store cool (not above 25 °C).*

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· 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

· Components with critical 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.

Not required.

· DNELs

**72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate**

Oral	general population, long term, systemic	0.3 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	1.3 mg/Kg/d (not defined)
	general population, long term, systemic	0.7 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	3.3 mg/m3 (not defined)
	general population, long term, systemic	0.6 mg/m3 (not defined)

**162492-01-5 Hexamethylene diisocyanate, trimers, reactionproducts with 2-hydroxyethyl acrylate**

Oral	general population, long term, systemic	3.3 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	66.7 mg/Kg/d (not defined)
	general population, long term, systemic	33.3 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	32.9 mg/m3 (not defined)
	general population, long term, systemic	5.8 mg/m3 (not defined)

**131-57-7 Oxybenzone**

Oral	general population, long term, systemic	2 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	39 mg/Kg/d (not defined)
	general population, long term, systemic	20 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	27.7 mg/m3 (not defined)
	general population, long term, systemic	6.8 mg/m3 (not defined)

**75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide**

Oral	general population, long term, systemic	0.0833 mg/Kg (not defined)
Dermal	worker industrial, long term, systemic	0.233 mg/Kg/d (not defined)
	general population, long term, systemic	0.0833 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	0.822 mg/m3 (not defined)
	general population, long term, systemic	0.145 mg/m3 (not defined)

· PNECs

**72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate**

freshwater	0.01 mg/l (not defined)
marine water	0.001 mg/l (not defined)

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sewage treatment plant	3.61 mg/l (not defined)
sediment, dry weight, freshwater	4.56 mg/Kg (not defined)
sediment, dry weight, marine water	0.46 mg/Kg (not defined)
soil, dry weight	0.91 mg/Kg (not defined)
<b>162492-01-5 Hexamethylene diisocyanate, trimers, reactionproducts with 2-hydroxyethyl acrylate</b>	
freshwater	0.1 mg/l (not defined)
marine water	0.01 mg/l (not defined)
sewage treatment plant	3.493 mg/l (not defined)
sediment, dry weight, freshwater	5.734 mg/Kg (not defined)
sediment, dry weight, marine water	0.573 mg/Kg (not defined)
soil, dry weight	1.088 mg/Kg (not defined)
<b>131-57-7 Oxybenzone</b>	
freshwater	0.00067 mg/l (not defined)
marine water	0.000067 mg/l (not defined)
sewage treatment plant	10 mg/l (not defined)
sediment, dry weight, freshwater	0.066 mg/Kg (not defined)
sediment, dry weight, marine water	0.007 mg/Kg (not defined)
soil, dry weight	0.013 mg/Kg (not defined)
<b>75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide</b>	
freshwater	0.0014 mg/l (not defined)
marine water	0.00014 mg/l (not defined)
sediment, dry weight, freshwater	0.115 mg/Kg (not defined)
sediment, dry weight, marine water	0.0115 mg/Kg (not defined)
soil, dry weight	0.0222 mg/Kg (not defined)

· **Additional information:** The lists that were valid during the compilation were used as basis.

· **8.2 Exposure controls**

· **Individual protection measures, such as personal protective equipment**

· **General protective and hygienic measures**

- Keep away from foodstuffs, beverages and food.
- Instantly remove any soiled and impregnated garments.
- Wash hands during breaks and at the end of the work.
- Avoid contact with the eyes and skin.

· **Breathing equipment:** Not necessary if room is well-ventilated.

· **Hand protection**

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

Solvent resistant gloves

Check protective gloves prior to each use for their proper condition.  
recommended

· **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

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- and has therefore to be checked prior to the application.
- **Penetration time of glove material**  
The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**  
Butyl rubber, BR  
Nitrile rubber, NBR
- **Eye/face protection** Safety glasses
- **Body protection:** Light weight protective clothing

**SECTION 9: Physical and chemical properties**

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

· **General Information**

· **Physical state**

Fluid

· **Colour:**

Brown

White

Pink

· **Smell:**

Weak, characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Not determined

· **Boiling point or initial boiling point and boiling range**

140 °C (72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate)

· **Flammability**

Not applicable.

· **Lower and upper explosion limit**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

>100 °C (72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate)

· **Decomposition temperature:**

Not determined.

· **SADT**

· **pH**

Mixture is non-soluble (in water).

· **Viscosity:**

· **Kinematic viscosity**

Not determined.

· **Kinematic viscosity**

· **dynamic:**

Not determined.

· **Solubility**

· **Water:**

Not miscible or difficult to mix

· **Partition coefficient n-octanol/water (log value)**

Not determined.

· **Steam pressure:**

Not determined.

· **Vapour pressure:**

· **Density and/or relative density**

· **Density**

Not determined

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· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>9.2 Other information</b>	No further relevant information available.
· <b>Appearance:</b>	
· <b>Form:</b>	Viscous
· <b>Important information on protection of health and environment, and on safety.</b>	
· <b>Self-inflammability:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product is not explosive. Not determined.
· <b>Change in condition</b>	
· <b>Evaporation rate</b>	Not determined.
· <b>Information with regard to physical hazard classes</b>	
· <b>Explosives</b>	Void
· <b>Flammable gases</b>	Void
· <b>Aerosols</b>	Void
· <b>Oxidising gases</b>	Void
· <b>Gases under pressure</b>	Void
· <b>Flammable liquids</b>	Void
· <b>Flammable solids</b>	Void
· <b>Self-reactive substances and mixtures</b>	Void
· <b>Pyrophoric liquids</b>	Void
· <b>Pyrophoric solids</b>	Void
· <b>Self-heating substances and mixtures</b>	Void
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	Void
· <b>Oxidising liquids</b>	Void
· <b>Oxidising solids</b>	Void
· <b>Organic peroxides</b>	Void
· <b>Corrosive to metals</b>	Void
· <b>Desensitised explosives</b>	Void

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
  - **Conditions to be avoided:** No decomposition if used and stored according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** None
  - **Additional information:**  
If stored longer than recommended and/or above recommended temperature, product may polymerize generating heat.

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**SECTION 11: Toxicological information**

**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

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

· **LD/LC50 values that are relevant for classification:**

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

Oral LD50 >5,000 mg/kg (rat) (OECD 401)

Dermal LD50 >2,000 mg/kg (rat) (OECD 402)

**162492-01-5 Hexamethylene diisocyanate, trimers, reactionproducts with 2-hydroxyethyl acrylate**

Oral LD50 5,000 mg/kg (rat) (OECD 423)

Dermal LD50 >2,000 mg/kg (rat) (OECD 402)

**Aerosil R 812\_ALT (siehe 66006689)**

Oral LD50 >5,000 mg/kg (rat)

**72829-09-5 1,12-Dodecanediol dimethacrylate**

Oral LD0 >2,000 mg/kg (rat) (OECD 423)

**131-57-7 Oxybenzone**

Oral LD50 >12,800 mg/kg (rat) (OECD 401)

Dermal LD50 >16,000 mg/kg (rabbit) (OECD 402)

**75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide**

Oral LD50 >5,000 mg/kg (rat) (OECD 401)

Dermal LD50 >2,000 mg/kg (rat) (OECD 402)

· **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.

· **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.

**11.2 Information on other hazards**

· **Endocrine disrupting properties**

131-57-7 Oxybenzone

List II

128-37-0 2,6-di-tert-butyl-p-cresol

List II

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**SECTION 12: Ecological information**

**12.1 Toxicity**

**Aquatic toxicity:**

**72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate**

EC50/48h	>1.2 mg/l (daphnia) (OECD 202)
LC50/96h	10.1 mg/l (fish) (OECD 203)
ErC50 / 72 h	>0.68 mg/l (algae) (OECD 201)
NOEC / 72h	0.21 mg/l (algae) (OECD 201)

**162492-01-5 Hexamethylene diisocyanate, trimers, reactionproducts with 2-hydroxyethyl acrylate**

LL50/96h	>100 mg/L (fish) (OECD 203)
EL50/48h	>100 mg/L (daphnia) (OECD 202)
EL50/72h	>100 mg/L (algae) (OECD 201)
NOELR	9.77 mg/L /72h (algae) (OECD 201)
	≥100 mg/L /48h (daphnia) (OECD 202)
	≥100 mg/L /96h (fish) (OECD 203)

**131-57-7 Oxybenzone**

EC50/48h	1.87 mg/l (daphnia) (OECD 202)
LC50/96h	3.8 mg/l (fish) (OECD 203)
ErC50 / 72 h	0.67 mg/l (algae) (OECD 201)
NOEC / 72h	0.18 mg/l (algae) (OECD 201)
NOEC / 96h	0.72 mg/l (fish) (OECD 203)
NOEC / 48h	1.15 mg/l (daphnia) (OECD 202)

**75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide**

EC50/48h	10,100 mg/l (algae)
	3.53 mg/l (daphnia) (OECD 202)
LC50/96h	1.4 mg/l (fish) (OECD 203)
ErC50 / 72 h	>2.01 mg/l (algae) (OECD 201)
ErC10/72h	1.56 mg/L (algae) (OECD 201)

**12.2 Persistence and degradability**

**72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate**

Biodegradation	22 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
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**162492-01-5 Hexamethylene diisocyanate, trimers, reactionproducts with 2-hydroxyethyl acrylate**

Biodegradation	0 % /29d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)
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**131-57-7 Oxybenzone**

Biodegradation	60-70 % /28d (not defined)
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**75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide**

Biodegradation 0-10 % /28d (not defined) (OECD 301F; ISO 9408/ EEC 92/69/V, C.4-D)

· **12.3 Bioaccumulative potential**

**131-57-7 Oxybenzone**

Bloconcentration factor (BCF) >33-<160 (fish) (OECD 305)

**75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide**

Bloconcentration factor (BCF) 47-55 (not defined)

· **12.4 Mobility in soil** No further relevant information available.

· **12.5 Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **12.6 Endocrine disrupting properties**

For information on endocrine disrupting properties see section 11.

· **12.7 Other adverse effects**

· **Additional ecological information:**

· **General notes:**

Do not allow product to reach ground water, water bodies or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into soil.

**SECTION 13: Disposal considerations**

· **13.1 Waste treatment methods**

· **Recommendation**

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

Disposal must be made according to official regulations.

· **European waste catalogue**

18 01 06\* chemicals consisting of or containing hazardous substances

· **Uncleaned packagings:**

· **Recommendation:**

Disposal must be made according to official regulations.

Non contaminated packagings can be used for recycling.

**SECTION 14: Transport information**

· **14.1 UN number or ID number**

· **ADR, IMDG, IATA**

UN3082

· **14.2 UN proper shipping name**

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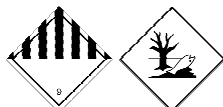
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· <b>ADR</b>	3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate, 1,12-Dodecanediol dimethacrylate)
· <b>IMDG</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate, 1,12-Dodecanediol dimethacrylate), MARINE POLLUTANT
· <b>IATA</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate, 1,12-Dodecanediol dimethacrylate)

· **14.3 Transport hazard class(es)**

· **ADR**



· **Class**

9 (M6) Miscellaneous dangerous substances and articles.  
9

· **Label**

· **IMDG, IATA**



· **Class**

9 Miscellaneous dangerous substances and articles.  
9

· **Label**

· **14.4 Packing group**

· **ADR, IMDG, IATA**

III

· **14.5 Environmental hazards:**

· **Marine pollutant:**

No  
Symbol (fish and tree)

· **Special marking (ADR):**

Symbol (fish and tree)

· **Special marking (IATA):**

Symbol (fish and tree)

· **14.6 Special precautions for user**

Warning: Miscellaneous dangerous substances and articles.

· **Kemler Number:**

90

· **EMS Number:**

F-A,S-F

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· <b>Stowage Category</b>	A
· <b>14.7 Maritime transport in bulk according to IMO instruments</b>	Not applicable.
· <b>Transport/Additional information:</b>	-
· <b>ADR</b>	
· <b>Limited quantities (LQ)</b>	5L
· <b>Excepted quantities (EQ)</b>	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· <b>Transport category</b>	3
· <b>Tunnel restriction code</b>	(-)
· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	5L
· <b>Excepted quantities (EQ)</b>	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· <b>UN "Model Regulation":</b>	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (7,7,9(OR 7,9,9)-TRIMETHYL-4,13-DIOXO-3,14-DIOXA-5,12-DIAZAHEXADECANE-1,16-DIYL BISMETHACRYLATE, 1,12-DODECANEDIOL DIMETHACRYLATE), 9, III

**SECTION 15: Regulatory information**

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Directive 2012/18/EU**

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t

· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

no information available

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**· Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

no information available

**· Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

**· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

**· REGULATION (EC) No 1005/2009 on substances that deplete the ozone layer – ANNEX I (Ozone-depleting potential)**

**· Other regulations, limitations and prohibitive regulations**

**· Substances of very high concern (SVHC) according to REACH, Article 57**

75980-60-8 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

**· 15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**SECTION 16: Other information**

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

**· Relevant phrases**

H317 May cause an allergic skin reaction.

H360Fd May damage fertility. Suspected of damaging the unborn child.

H373 May cause damage to organs through prolonged or repeated exposure.

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.

H413 May cause long lasting harmful effects to aquatic life.

EUH066 Repeated exposure may cause skin dryness or cracking.

EUH204 Contains isocyanates. May produce an allergic reaction.

**· Date of previous version:** 30.06.2022

**· Version number of previous version:** 4

**· Abbreviations and acronyms:**

SADT: Self Accelerating Decomposition Temperature

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)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1A: Skin sensitisation – Category 1A

Skin Sens. 1B: Skin sensitisation – Category 1B

Repr. 1B: Reproductive toxicity – Category 1B

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STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2  
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 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4  
· **\* Data compared to the previous version altered.**

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