



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

Printing date 14.07.2021


Version number 2

Revision: 14.07.2021

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

- **1.1 Product identifier**
 - Trade name: **dima Print Ortho, dima Print Guide**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
 - Product category PC0 Other
 - Application of the substance / the mixture 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
- **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 Chronic 3 H412 Harmful 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
 - **Signal word** Warning
 - **Hazard-determining components of labelling:**
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate
phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide
 - **Hazard statements**
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.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- **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:** -

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· Dangerous components:

CAS: 41637-38-1 EC number: 609-946-4	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid Aquatic Chronic 4, H413	≥75->90%
CAS: 72869-86-4 EINECS: 276-957-5 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	≥10-<25%
CAS: 162881-26-7 ELINCS: 423-340-5 Reg.nr.: 01-2119489401-38-xxxx	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide Skin Sens. 1, H317 Aquatic Chronic 4, H413	≥1-≤10%

· 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.

· After eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.

· After swallowing

In case of persistent symptoms consult doctor.

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

CO₂, extinguishing powder or water jet. Fight larger fires with water jet.

· For safety reasons unsuitable extinguishing agents Water with a full water jet.

· 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:

Wear self-contained breathing apparatus.

Wear full protective suit.

· Additional information -

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

Do not breathe vapor / mist / gas.

Avoid contact with eyes and skin.

· 6.2 Environmental precautions: Prevent material from reaching sewage system, holes and cellars.

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- **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**
Keep containers tightly sealed.
Ensure good ventilation/exhaustion at the workplace.
 - **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **7.2 Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and containers:**
Store in cool, dry place in tightly closed containers.
Protect from the effects of light.
 - **Information about storage in one common storage facility:**
Store away from oxidising agents.
 - **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**
 - **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	ge.pop., l.te, syst.	0.3 mg/Kg (nd)
Dermal	worker industr., l.te., syst.	1.3 mg/Kg/d (nd)
	ge.pop., l.te, syst.	0.7 mg/Kg/d (nd)
Inhalative	worker industr., l.te., syst.	3.3 mg/m ³ (nd)
	ge.pop., l.te, syst.	0.6 mg/m ³ (nd)
162881-26-7 phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide		
Oral	ge.pop., acu., syst.	1.67 mg/Kg (nd)
	ge.pop., l.te, syst.	1.5 mg/Kg (nd)
Dermal	worker industr., acute, syst.	3.33 mg/Kg/d (nd)
	worker industr., l.te., syst.	3.33 mg/Kg/d (nd)
	ge.pop., acu., syst.	1.67 mg/Kg/d (nd)
	ge.pop., l.te, syst.	1.5 mg/Kg/d (nd)

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<i>Inhalative</i>	<i>worker industr., acute, syst.</i>	7.84 mg/m ³ (nd)
	<i>worker industr., l.te., syst.</i>	7.84 mg/m ³ (nd)
	<i>ge.pop., acu., syst.</i>	3.92 mg/m ³ (nd)
	<i>ge.pop., l.te, syst.</i>	1.93 mg/m ³ (nd)

· 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

<i>freshwater</i>	0.01 mg/l (nd)
<i>marine water</i>	0.001 mg/l (nd)
<i>STP</i>	3.61 mg/l (nd)
<i>sedim., dw, fre.wat.</i>	4.56 mg/Kg (nd)
<i>sedim., dw, mar.wat.</i>	0.46 mg/Kg (nd)

162881-26-7 phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide

<i>freshwater</i>	0.001 mg/l (nd)
<i>marine water</i>	0.001 mg/l (nd)
<i>interm. wat. release</i>	0.001 mg/l (nd)
<i>STP</i>	1 mg/l (nd)
<i>sedim., dw, fre.wat.</i>	0.712 mg/Kg (nd)
<i>sedim., dw, mar.wat.</i>	0.712 mg/Kg (nd)
<i>soil,dw</i>	20 mg/Kg (nd)

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

· 8.2 Exposure controls

· Personal protective equipment

· General protective and hygienic measures

*Instantly remove any soiled and impregnated garments.
Wash hands during breaks and at the end of the work.*

· Breathing equipment: Filter P2.

· Protection of hands:

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

*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 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 protection: Tightly sealed safety glasses.

· Body protection: Light weight protective clothing

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SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
 - **General Information**
 - **Appearance:**
 - **Form:** Fluid
 - **Colour:** Blue
 - **Smell:** Ester-like
 - **Odour threshold:** Not determined.
 - **pH-value:** Not determined.
 - **Change in condition**
 - **Melting point/freezing point:** Not determined
 - **Initial boiling point and boiling range:** >200 °C
 - **Flash point:** Not applicable
 - **Inflammability (solid, gaseous)** Not applicable.
 - **Ignition temperature:** 375 °C
375 °C
 - **Decomposition temperature:** Not determined.
 - **Self-inflammability:** Product is not selfigniting.
 - **Explosive properties:** Product is not explosive.
 - **Critical values for explosion:**
 - **Lower:** Not determined.
 - **Upper:** Not determined.
 - **Steam pressure:** Not determined.
 - **Density** Not determined
 - **Relative density at 20 °C** 1.1 - 1.2 g/cm³
 - **Vapour density** Not determined.
 - **Evaporation rate** Not determined.
 - **Solubility in / Miscibility with**
 - **Water:** Not miscible or difficult to mix
 - **Partition coefficient: n-octanol/water:** Not determined.
 - **Viscosity:**
 - **dynamic at 20 °C:** 1.1 mPas
 - **kinematic:** Not determined.
- **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**
 - **Conditions to be avoided:** No decomposition if used and stored according to specifications.
- **10.3 Possibility of hazardous reactions**
 - Polymerisation
 - Photoreactive
- **10.4 Conditions to avoid** Heat, flames and sparks.
- **10.5 Incompatible materials:**
 - Reacts with peroxides and other radical forming substances

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Strong oxidizers

· **10.6 Hazardous decomposition products:** None

· **Additional information:**

If stored longer than recommended and/or above recommended temperature, product may polymerize generating heat.

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 that are relevant for classification:**

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

Oral LD50 >5000 mg/kg (rat) (OECD 401)

Dermal LD50 >2000 mg/kg (rat) (OECD 402)

162881-26-7 phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide

Oral LD50 >2000 mg/kg (rat)

Dermal LD50 >2000 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:**

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

162881-26-7 phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide

EC50/72h >0.26 mg/l (algae) (OECD 201)

EC50/48h >1.175 mg/l (daphnia) (OECD 202)

LC50/96h >0.09 mg/l (fish) (OESO 203)

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· **12.2 Persistence and degradability**

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

Biodegradation 22 % /28d (nd) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

- **12.3 Bioaccumulative potential** No further relevant information available.
- **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 Other adverse effects** No further relevant information available.

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.

· **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**

· **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.

· **Transport/Additional information:**

-

· **UN "Model Regulation":**

Void

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SECTION 15: Regulatory information

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

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.*
- H411 Toxic to aquatic life with long lasting effects.*
- H413 May cause long lasting harmful effects to aquatic life.*

· **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)*
 - 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*
 - vPvB: very Persistent and very Bioaccumulative*
 - Skin Sens. 1: Skin sensitisation – Category 1*
 - Skin Sens. 1B: Skin sensitisation – Category 1B*
 - 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*
 - 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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