

Page 1/7

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

Printing date 13.07.2017 Version number 1 Revision: 13.07.2017

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

- · 1.1 Product identifier
 - · Trade name: dima Print Ortho
- · 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 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 4 H413 May cause long lasting harmful effects to aquatic life.

- · 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:

Methacrylic oligomer

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

Hazard statements

H317 May cause an allergic skin reaction.

H413 May cause long lasting harmful effects to aquatic life.

· Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P273 Avoid release to the environment.

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.

P302+P352 IF ON SKIN: Wash with plenty of water.

· 2.3 Other hazards -

- · Results of PBT and vPvB assessment
 - · PBT: Not applicable.
 - · vPvB: Not applicable.

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Page 2/7

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

Printing date 13.07.2017 Version number 1 Revision: 13.07.2017

Trade name: dima Print Ortho

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
 - · Description: -

· Dangerous components:			
CAS: 41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated	50-75%	
EC number: 609-946-4	and 2-methylprop-2-enoic acid		
	Aquatic Chronic 4, H413		
CAS: 72896-86-4	Methacrylic oligomer	10-25%	
	Skin Sens. 1, H317		
CAS: 162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	0-5%	
ELINCS: 423-340-5	Skin Sens. 1, H317; Aquatic Chronic 4, H413		

· 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

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

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.

(Contd. on page 3)



Page 3/7

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

Printing date 13.07.2017 Version number 1 Revision: 13.07.2017

Trade name: dima Print Ortho

(Contd. of page 2)

· 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.

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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.

- · 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

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:

Use breathing protection in case of insufficient ventilation.

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

(Contd. on page 4)



Page 4/7

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

Printing date 13.07.2017 Version number 1 Revision: 13.07.2017

Trade name: dima Print Ortho

(Contd. of page 3)

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

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and General Information	l chemical properties	
· Appearance:	EL: A	
Form:	Fluid	
· Colour:	Blue	
· Smell:	Ester-like	
· Odour threshold:	Not determined.	
· pH-value:	Not determined.	
Change in condition Melting point/Melting range: Boiling point/Boiling range:	Not determined >200 °C	
· Flash point:	Not applicable	
· Inflammability (solid, gaseous)	Not applicable.	
· Ignition temperature:	375 ℃	
· Decomposition temperature:	Not determined.	
· Self-inflammability:	Product is not selfigniting.	
· Danger of explosion:	Product is not explosive.	
 Critical values for explosion: Lower: Upper: 	Not determined. Not determined.	
· Steam pressure:	Not determined.	
 Density Relative density at 20 °C Vapour density Evaporation rate 	Not determined 1.1 - 1.2 g/cm3 Not determined. Not determined.	
· Solubility in / Miscibility with · Water:	Not miscible or difficult to mix	
· Partition coefficient (n-octanol/wat	ter): Not determined.	
Viscosity: dynamic at 20 °C:	1.1 mPas	
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Page 5/7

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

Printing date 13.07.2017 Version number 1 Revision: 13.07.2017

Trade name: dima Print Ortho

(Contd. of page 4)

· 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 No dangerous reactions known
- · 10.4 Conditions to avoid Heat, flames and sparks.
- · 10.5 Incompatible materials:

Radical initiator

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:

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

Oral 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.

- · CMR effects (carcinogenity, 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:

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)

- 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.

(Contd. on page 6)



Page 6/7

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

Printing date 13.07.2017 Version number 1 Revision: 13.07.2017

Trade name: dima Print Ortho

(Contd. of page 5)

- · 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

Small quantities can be polymerized by light and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.

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

SECTION 14: Transport information	tion	
· 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 An of Marpol and the IBC Code	nex II Not applicable.	
· Transport/Additional information:	-	
UN "Model Regulation":	Void	

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

(Contd. on page 7)



Page 7/7

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

Printing date 13.07.2017 Version number 1 Revision: 13.07.2017

Trade name: dima Print Ortho

(Contd. of page 6)

· Relevant phrases

H317 May cause an allergic skin reaction.

H413 May cause long lasting harmful effects to aquatic life.

· Abbreviations and acronyms:

Abbreviations and acronyms:

ADR: Accord européen sur le transport 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

Skin Sens. 1: Skin sensitisation — Category 1

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard — Category 4

· * Data compared to the previous version altered.