



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

Printing date 24.11.2022

Version number 1

Revision: 24.11.2022

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

· **1.1 Product identifier**

· Trade name: **dima Print Mouthguard**

· **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 Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

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 GB CLP regulation.

· **Hazard pictograms**



GHS07 GHS09

· **Signal word** Warning

· **Hazard-determining components of labelling:**

Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

· **Hazard statements**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H411 Toxic to aquatic life with long lasting effects.

· **Precautionary statements**

P202 Do not handle until all safety precautions have been read and understood.

P273 Avoid release to the environment.

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

P308+P313 IF exposed or concerned: Get medical advice/attention.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P410+P403 Protect from sunlight. Store in a well-ventilated place.

· **2.3 Other hazards -**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

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· **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**

· **Description:** -

· **Dangerous components:**

CAS: 82339-25-1 EC number: 691-081-7	poly(oxy-1,4-butanediyl), .alpha.-hydro-.omega.-hydroxy-, polymer with 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane, 2-hydroxyethyl acrylate-blocked Skin Irrit. 2, H315; Eye Irrit. 2, H319	25-50%
CAS: 75980-60-8 EINECS: 278-355-8 Reg.nr.: 01-2119972295-29-xxxx	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361 Aquatic Chronic 2, H411 Skin Sens. 1B, H317	≥1-<2.5%
CAS: 13826-35-2 EINECS: 237-525-1	3-phenoxybenzylic alcohol Aquatic Acute 1, H400; Aquatic Chronic 1, H410 Acute Tox. 4, H302	≥0.25-<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 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. Then 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** Allergic reactions

· **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 or alcohol-resistant foam.

Use fire fighting measures that suit the environment.

· **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:** No special measures required.

· **Additional information** -

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SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:**
Do not allow to enter drainage system, surface or ground water.
Prevent material from reaching sewage system, holes and cellars.
- **6.3 Methods and material for containment and cleaning up:**
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** 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:** Protect from the effects of light.
 - **Information about storage in one common storage facility:**
Store away from flammable substances.
Store away from oxidising agents.
Store away from reducing agents.
Do not store together with reducing agents, heavy-metal compounds, acids and alkalis.
 - **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		
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		
75980-60-8 Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide		
freshwater		0.0014 mg/l (not defined)
marine water		0.00014 mg/l (not defined)

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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**

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

· **Breathing equipment:**

Use breathing protection in case of insufficient ventilation.
Filter P2.

· **Hand protection**

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 through 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** Tightly sealed 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:**

White

Blue

· **Smell:**

Characteristic

· **Odour threshold:**

Not determined.

· **Melting point/freezing point:**

Not determined

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

Not determined

· **Flammability**

Not applicable.

· **Lower and upper explosion limit**

· **Lower:**

Not determined.

· **Upper:**

Not determined.

· **Flash point:**

203 °C

· **Ignition temperature:**

Not determined.

· **Decomposition temperature:**

Not determined.

· **SADT**

90 °C

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· pH	Not determined.
· Viscosity:	
· Kinematic viscosity at 40 °C	1700 mm ² /s
· dynamic:	Not determined.
· Solubility	
· Water:	Not miscible or difficult to mix
· Partition coefficient n-octanol/water (log value)	Not determined.
· Steam pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C	1.12 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· 9.2 Other information	No further relevant information available.
· Appearance:	
· Form:	Fluid
· Important information on protection of health and environment, and on safety.	
· Self-inflammability:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. Not determined.
· Change in condition	
· Evaporation rate	Not determined.
· Information with regard to physical hazard classes	
· Explosives	Void
	Void
· Flammable gases	Void
	Void
· Aerosols	Void
	Void
· Oxidising gases	Void
	Void
· Gases under pressure	Void
	Void
· Flammable liquids	Void
	Void
· Flammable solids	Void
	Void
· Self-reactive substances and mixtures	Void
	Void
· Pyrophoric liquids	Void
	Void
· Pyrophoric solids	Void
	Void
· Self-heating substances and mixtures	Void
	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
	Void
· Oxidising liquids	Void
	Void

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· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	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**
 - Photoreactive
 - Polymerisation
- **10.4 Conditions to avoid** Heat, flames and sparks.
- **10.5 Incompatible materials:**
 - Radical initiator
 - reducing agent
 - Strong oxidizers
- **10.6 Hazardous decomposition products:** Phosphorus oxides (e.g. P2O5)
 - **Additional information:** -

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:**

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)

13826-35-2 3-phenoxybenzylic alcohol

Oral	LD50	1,369.803 mg/kg (rat) ((Q)SAR)
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- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **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**

None of the ingredients is listed.

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SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

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

EC50/48h 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 1.56 mg/L (algae) (OECD 201)

· **12.2 Persistence and degradability**

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** 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 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.

Danger to drinking water if even 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.

· **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**

· **ADR**

3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide, 3-phenoxybenzyl alcohol)

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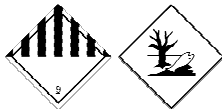
· **IMDG**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide, 3-phenoxybenzyl alcohol), MARINE POLLUTANT ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide, 3-phenoxybenzyl alcohol)

· **IATA**

· **14.3 Transport hazard class(es)**

· **ADR**



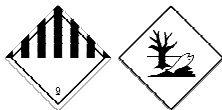
· **Class**

9 (M6) Miscellaneous dangerous substances and articles.

· **Label**

9

· **IMDG, IATA**



· **Class**

9 Miscellaneous dangerous substances and articles.

· **Label**

9

· **14.4 Packing group**

· **ADR, IMDG, IATA**

III

· **14.5 Environmental hazards:**

· **Marine pollutant:**

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

· **Stowage Category**

A

· **14.7 Maritime transport in bulk according to IMO instruments**

Not applicable.

· **Transport/Additional information:**

-

· **ADR**

· **Limited quantities (LQ)**

5L

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging:
30 ml

Maximum net quantity per outer packaging:

1000 ml

· **Transport category**

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· Tunnel restriction code	-
· IMDG	
· Limited quantities (LQ)	5L
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· UN "Model Regulation":	UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (DIPHENYL(2,4,6- TRIMETHYLBENZOYL)PHOSPHINE OXIDE, 3- PHENOXYBENZYLIC ALCOHOL), 9, III

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.
 - **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t
 - **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t
- **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**

- H302 Harmful if swallowed.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H361 Suspected of damaging fertility or the unborn child.
- 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.

- **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 (UK REACH)
- PNEC: Predicted No-Effect Concentration (UK REACH)
- 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

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Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1B: Skin sensitisation – Category 1B
Repr. 2: Reproductive toxicity – 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
*** Data compared to the previous version altered.**

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