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

Printing date 22.11.2022 Version number 2 (replaces version 1) Revision: 22.11.2022

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

- · 1.1 Product identifier
  - · Trade name: dima Print Gingiva Mask
- · 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

H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction. H361d Suspected of damaging the unborn child. Repr. 2

Aguatic 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 GHS08 GHS09

- Signal word Warning
- · Hazard-determining components of labelling:

Ethoxylated o-phenylphenol acrylate

Phenoxy polyethylene glycol acrylate

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.

H361d Suspected of damaging the unborn child. H411 Toxic to aquatic life with long lasting effects.

Precautionary statements

Avoid release to the environment. P273 P280 Wear protective gloves / eye protection.

P280 Wear protective clothing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing.

P308+P313 IF exposed or concerned: Get medical advice/attention. P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

· 2.3 Other hazards -

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

### 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), .alphahydroomega 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: 56641-05-5 NLP: 500-133-9	Phenoxy polyethylene glycol acrylate Aquatic Chronic 2, H411 Skin Sens. 1A, H317	≥25-≤50%
CAS: 91442-24-9	Ethoxylated o-phenylphenol acrylate Repr. 2, H361d Aquatic Chronic 2, H411 Acute Tox. 4, H302; Skin Sens. 1, H317	≥25-≤50%
CAS: 75980-60-8 EINECS: 278-355-8 Reg.nr.: 01-2119972295-29-xxx	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Repr. 2, H361f Aquatic Chronic 2, H411 Skin Sens. 1B, H317	≥1-<2.5%

<sup>·</sup> 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 If skin irritation continues, consult a doctor.
  - After eye contact
  - Rinse opened eye for several minutes under running water. If symptoms persist, 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.

- 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.

  Do not breathe vapor / mist / gas.
- 6.2 Environmental precautions: Do not allow to enter drainage system, surface or ground water.
- · 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

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 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: 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
- 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.

DAG

#### · DNELs

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

Orai	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)
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 ma/Ka (not defined)

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

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· 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.

· Breathing equipment:

Use breathing protection only when aerosol or mist is formed. Filter P2.

· Hand protection

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

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/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: Red · Smell: Ether-like

Not determined. Odour threshold: 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. >100 °C

Flash point:

Not determined. Decomposition temperature:

SADT

Not determined. pН

Viscosity:

Kinematic viscosity Not determined. 1,199 mPas · dynamic at 20 °C:

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Solubility

Water:

Not miscible or difficult to mix

Partition coefficient n-octanol/water (log

value) · Steam pressure: Not determined. Not determined.

Density and/or relative density Density

· Density · Relative density · Vapour density Not determined Not determined. 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: Explosive properties:

Product is not selfigniting. Product is not explosive. Not determined.

· Solvent content: 0.3 %

Solids content: Change in condition

Evaporation rate Not determined.

· Information with regard to physical hazard classes

 Explosives Void · Flammable gases Void · Aerosols Void Oxidising gases
Gases under pressure Void Void · Flammable liquids Void Flammable solids Void · Self-reactive substances and mixtures Void · Pvrophoric liquids Void Pyrophoric solids Void · Self-heating substances and mixtures Void · Substances and mixtures, which emit flammable gases in contact with water Void Oxidising liquids Void · Oxidising solids Void · Organic peroxides Void · Corrosive to metals 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.

Void

10.3 Possibility of hazardous reactions

· Desensitised explosives

Photoreactive

Polymerisation

- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.

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· 10.6 Hazardous decomposition products: None 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:				
56641-05-5 Phenoxy polyethylene glycol acrylate				
Oral	LD0	5,000 mg/kg (rat) (OECD 401)		
Dermal	LD0	2,000 mg/kg (rat) (EU B.3)		
91442-24-9 Ethoxylated o-phenylphenol acrylate				
Oral	LD50	1,000 mg/kg (rat)		
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
- 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
- Suspected of damaging the unborn child.
- 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.
- · Additional toxicological information:
  - CMR effects (carcinogenity, mutagenicity and toxicity for reproduction) Repr. 2
- 11.2 Information on other hazards
  - Endocrine disrupting properties

None of the ingredients is listed.

## **SECTION 12: Ecological information**

#### · 12.1 Toxicity

· Aquatic toxicity:

#### 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)

1.56 mg/L (algae) (OECD 201) ErC10/72h

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· 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

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
  - Remark: Toxic for fish
  - · Additional ecological information:
    - General notes:

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

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

Also poisonous for fish and plankton in water bodies.

Toxic for aquatic organisms

#### 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

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.

14.1 UN number or ID number	UN3082
· ADR, IMDG, IATA	UN3002
14.2 UN proper shipping name	
· ADR	3082 ENVIRONMENTALLY HAZARDOU
ADI	SUBSTANCE, LIQUID, N.O.S. (Ethoxylated of
	phenylphenol acrylate, Phenoxy polyethylen
4400	glycol acrylate)
· IMDG	ENVIRONMENTALLY HAZARDOU
	SUBSTANCE, LIQUID, N.O.S. (Ethoxylated of
	phenylphenol acrylate, Phenoxy polyethylen
	glycol acrylate), MARINE POLLUTANT



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· IATA	ENVIRONMENTALLY HAZARDOU	
	SUBSTANCE, LIQUID, N.O.S. (Ethoxylated	
	phenylphenol acrylate, Phenoxy polyethyler glycol acrylate)	
14.3 Transport hazard class(es)	gryoor doryrator	
· ADR		
**************************************		
<b>*</b>		
·Class	<ol> <li>(M6) Miscellaneous dangerous substance and articles.</li> </ol>	
· Label	and articles. 9	
· IMDG, IATA		
·Class	9 Miscellaneous dangerous substances a	
· Label	articles. 9	
· 14.4 Packing group · ADR, IMDG, IATA	III	
14.5 Environmental hazards:		
Marine pollutant:	Symbol (fish and tree)	
· Special marking (ADR): · Special marking (IATA):	Symbol (fish and tree) Symbol (fish and tree)	
	, , , , ,	
14.6 Special precautions for user	Warning: Miscellaneous dangerous substances ar articles.	
· Kemler Number:	90	
· EMS Number:	F-A,S-F	
· Stowage Category	A	
· 14.7 Maritime transport in bulk according IMO instruments	<b>g to</b> Not applicable.	
· Transport/Additional information:	-	
· ADR		
· Limited quantities (LQ)	5L	
Excepted quantities (EQ)	Code: E1	
	Maximum net quantity per inner packagin 30 ml	
	Maximum net quantity per outer packagin	
	1000 ml	
· Transport category · Tunnel restriction code	3	
· IMDG		
Limited quantities (LQ)	5L	
Excepted quantities (EQ)	Code: E1	



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30 ml

Maximum net quantity per outer packaging:

1000 ml

· UN "Model Regulation":

UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (ETHOXYLATED O-PHENYLPHENOL ACRYLATE, PHENOXY POLYETHYLENE GLYCOL ACRYLATE), 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.
    - · Seveso category E2 Hazardous to the Aquatic Environment
    - 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.

H361d Suspected of damaging the unborn child.

H361f Suspected of damaging fertility. 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
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

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

Repr. 2: Reproductive toxicity – Category 2
Repr. 2: Reproductive toxicity – Category 2
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

\* Data compared to the previous version altered.