

Page 1/9

Safety Data Sheet according to HPR, Schedule 1

Printing date 11/22/2022 Reviewed on 11/22/2022

1 Identification

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

· Application of the substance / the mixture Manufacture of dental prothesis

· Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany) Tel.: +49 (0)800 4372522

· Information department:

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545 e-mail: customer.servicehkna@kulzer-dental.com

Emergency telephone number:

Emergency CONTACT (24-Hour-Number) ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard identification

Classification of the substance or mixture

Skin Irritation - Category 2 H315 Causes skin irritation.

Eye Irritation - Category 2A H319 Causes serious eye irritation.

Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.

Reproductive Toxicity - Category 2 H361 Suspected of damaging fertility or the unborn child.

· Label elements

GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

Hazard pictograms





GHS07 GHS08

· Signal word Warning

· Hazard-determining components of labeling:

Ethoxylated o-phenylphenol acrylate Phenoxy polyethylene glycol acrylate

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

Hazard statements

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

Suspected of damaging fertility or the unborn child.

Precautionary statements

Avoid release to the environment.

Wear protective gloves / eye protection.

Wear protective clothing.

If on skin: Wash with plenty of soap and water.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

IF exposed or concerned: Get medical advice/attention.

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

If eye irritation persists: Get medical advice/attention.

(Contd. on page 2)



Page 2/9

Safety Data Sheet according to HPR, Schedule 1

Printing date 11/22/2022 Reviewed on 11/22/2022

Trade name: dima Print Gingiva Mask

(Contd. of page 1)

Take off contaminated clothing and wash it before reuse.

· Classification system

NFPA ratings for USA (scale 0-4)



Health = 2 Fire = 1 Reactivity = 0

· HMIS-Ratings (Scale 0-4)



Health = 2 Fire = 1 Reactivity = 0

· Other hazards -

3 Composition/Information on ingredients

- · Chemical characterization: Mixtures
 - Description: -

· Dangero	ous components:	
82339-25-1	poly(oxy-1,4-butanediyl), .alphahydroomegahydroxy-, polymer with 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane, 2-hydroxyethyl acrylate-blocked Skin Irritation - Category 2, H315; Eye Irritation - Category 2A, H319	≥25-≤50% w/w *
56641-05-5	Phenoxy polyethylene glycol acrylate Skin Sensitizer - Category 1A, H317	≥25- <i>≤</i> 50% w/w *
91442-24-9	Ethoxylated o-phenylphenol acrylate Reproductive Toxicity - Category 2, H361 Acute Toxicity (Oral) - Category 4, H302; Skin Sensitizer - Category 1, H317	≥25- <i>≤</i> 50% w/w *
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide Reproductive Toxicity - Category 2, H361 Skin Sensitizer - Category 1B, H317	≥1-≤5% w/w *

^{*} Actual concentration ranges are withheld as a trade secret.

4 First-aid measures

- · Description of first aid measures
 - After inhalation Supply fresh air; consult doctor in case of complaints.
 - 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 a doctor.

- Information for doctor
 - · Most important symptoms and effects, both acute and delayed Allergic reactions
 - Indication of any immediate medical attention and special treatment needed No further relevant information available.

CA

[·] Additional information For the wording of the listed hazard phrases refer to section 16.



Page 3/9

Safety Data Sheet according to HPR, Schedule 1

Printing date 11/22/2022

Reviewed on 11/22/2022

Trade name: dima Print Gingiva Mask

(Contd. of page 2)

5 Fire-fighting measures

Extinguishing media

Suitable extinguishing agents

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Use fire fighting measures that suit the environment.

· Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

Advice for firefighters

· Protective equipment: No special measures required.

· Additional information -

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

Do not breathe vapor / mist / gas.

Environmental precautions: Do not allow to enter sewers/ surface or ground water.

Methods and material for containment and cleaning up:

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

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 disposal information.

7 Handling and storage

· Handling

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.

· Conditions for safe storage, including any incompatibilities

Storage

Requirements to be met by storerooms and receptacles:

Protect from exposure to the light.

· Information about storage in one common storage facility: Not required.

Further information about storage conditions: None.

· Specific end use(s) No further relevant information available.

8 Exposure controls/ Personal protection

· Control parameters

· Components with limit 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.

• Additional information: The lists that were valid during the creation were used as basis.

(Contd. on page 4)



Page 4/9

Safety Data Sheet according to HPR, Schedule 1

Printing date 11/22/2022 Reviewed on 11/22/2022

Trade name: dima Print Gingiva Mask

(Contd. of page 3)

· Exposure controls

Personal protective equipment

General protective and hygienic measures
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.

· Breathing equipment:

Use suitable respiratory protective device only when aerosol or mist is formed. 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 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:

Fluid

Butyl rubber, BR

Nitrile rubber, NBR

- · Eye protection: Tightly sealed goggles.
- · Body protection: Light weight protective clothing

9 Physical and chemical properties
Information on basic physical and chemical properties
· General Information
· Appearance:

· Color: Red
· Odor: Ether-like
· Odor threshold: Not determined.

· pH-value: Not determined.

· Change in condition

Form:

Melting point/Melting range: undetermined undetermined
 Boiling point/Boiling range: undetermined
 Flash point: >100 °C (>212 °F)

Flammability (solid, gaseous) Not applicable.

Decomposition temperature: Not determined.

Auto igniting: Product is not selfigniting.

• **Danger of explosion:** Product does not present an explosion hazard. Not determined.

(Contd. on page 5)



Page 5/9

Safety Data Sheet according to HPR, Schedule 1

Printing date 11/22/2022 Reviewed on 11/22/2022

Trade name: dima Print Gingiva Mask

		(Contd. of page 4)
· Explosion limits:		
Lower:	Not determined.	
· Upper:	Not determined.	
· Vapor pressure:	Not determined.	
· Density:	Not determined	
· Relative density	Not determined.	
Vapor density	Not determined.	
Evaporation rate	Not determined.	
· Solubility in / Miscibility with		
· Water:	Not miscible or difficult to mix	
· Partition coefficient (n-octanol/w	vater): Not determined.	
· Viscosity:		
· dynamic at 20 °C (68 °F):	1.199 mPas	
· kinematic:	Not determined.	
· Solvent content:		
· Solids content:	0,3 %	
· Other information	No further relevant information available.	

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Possibility of hazardous reactions

Photoreactive Polymerization

- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: none
- · Additional information: -

11 Toxicological information

· Information on toxicological effects · Acute toxicity:

at are relevar	ues that are	ues that	lues tha	es that	hat a	are	re re	rele	lev	vai	nt	fo	rc	clá	as	ssif	ica	itio	n:								
ethylene gly	y polyethyle	y polyet	xy poly	polye	lyeth	thyl	ylen	ene	e g	gly	yc	ol i	ac	ry	/la	ate											
Oral LD0 5.000 mg/kg (rat) (OECD 401)																											
Dermal LD0 2.000 mg/kg (rat) (EU B.3)																											
-phenylpher	lated o-phen	lated o-p	/lated o	ited o-	l o-ph	pher	eny	ıylp	ph	hei	no	ıl a	ıcr	ryl	la	te											
oral LD50 1.000 mg/kg (rat)																											
6-trimethylbe	yl(2,4,6-trime	yl(2,4,6-t	ıyl(2,4,6	(2,4,6	4,6-tri	trim	met	ethy	างไ	lbe	en	ΖO	yl))p	h	osį	phi	ine	οх	ride	9						
kg (rat) (OEC	00 mg/kg (rat	00 mg/kg	000 mg/	0 mg/k	g/kg (g (ra	rat) (t) (C	OE	ΕC	CD	40	01))													
kg (rat) (OEC	00 mg/kg (rat	00 mg/kg	000 mg/	0 mg/k	g/kg (g (ra	rat) (t) (C	ΌE	EC	CD	4(<i>02)</i>)													
g (rat) (OECD g (rat) (EU B. p-phenylpher g (rat) 6-trimethylbe kg (rat) (OEC	0 mg/kg (rat) 0 mg/kg (rat) lated o-phen 0 mg/kg (rat) yl(2,4,6-trime 00 mg/kg (rat)	0 mg/kg (0 mg/kg (lated o-p 0 mg/kg (yl(2,4,6-t	00 mg/kg 00 mg/kg /lated o 00 mg/kg nyl(2,4,6 000 mg/	mg/kg mg/kg ited o- mg/kg (2,4,6 - 0 mg/k	/kg (ra /kg (ra l o-ph /kg (ra 4,6-tr i	(rat) (rat) pher (rat) trim g (rat	at) (C at) (E neny at) imeti (rat) ((OE (EU nylp ethy t) (C	DEC U I Iph	B. her	D 4 3.3) eno en: CD	401 o I a ozo	1) acr yl) 01)	ryi ()p	la	te		ine	ox	ride	e						

Sensitization: Sensitization possible through skin contact.

Harmful

In lifetime inhalation studies of rats, airborne respirable-size titanium dioxide particles have been shown to cause an increase in lung tumors at concentrations associated with substantial particle (Contd. on page 6)

[·] Additional toxicological information:



Page 6/9

Safety Data Sheet according to HPR, Schedule 1

Printing date 11/22/2022 Reviewed on 11/22/2022

Trade name: dima Print Gingiva Mask

(Contd. of page 5)

lung burdens and consequential pulmonary overload and inflammation. The potential for these adverse health effects appears to be closely related to the particle size and the amount of the exposed surface area that comes into contact with the lung.

However, tests with other laboratory animals, such as mice and hamsters, indicate that rats are significantly more susceptible for the pulmonary overload and inflammation that may lead to lung cancer.

Epidemiology studies do not suggest an increased risk of cancer in humans from occupational exposure to titanium dioxide.

Titanium dioxide has been characterized by IARC as possibly carcinogenic to humans (Group 2B) through inhalation (not ingestion). It has not been characterized as a potential carcinogen by either NTP or OSHA.

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

13463-67-7 Titanium dioxide

2B

· NTP (National Toxicology Program)

None of the ingredients is listed.

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

12 Ecological information

· 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) ErC10/72h 1,56 mg/L (algae) (OECD 201)

· Persistence and degradability

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

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

- · Behavior in environmental systems:
 - · Bioaccumulative potential

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

Biokonzentrationefaktor (BCF) 47-55 (not defined)

- Mobility in soil No further relevant information available.
- · Ecotoxical effects:
 - · Remark: Toxic for fish
- Additional ecological information:
 - General notes:

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

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

Also poisonous for fish and plankton in water bodies.

Toxic for aquatic organisms

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

(Contd. on page 7)



Page 7/9

Safety Data Sheet according to HPR, Schedule 1

Printing date 11/22/2022

Reviewed on 11/22/2022

Trade name: dima Print Gingiva Mask

· Other adverse effects No further relevant information available.

(Contd. of page 6)

13 Disposal considerations

- · 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.

UN-Number	
· DOT/TDG	Void
ADR, IMDG, IATA	UN3082
UN proper shipping name	
DOT/TDG	Void
· ADR	3082 ENVIRONMENTALLY HAZARDOU SUBSTANCE, LIQUID, N.O.S. (Ethoxylated phenylphenol acrylate, Phenoxy polyethylene glycacrylate)
·IMDG	ENVIRONMENTALLY HAZARDOU SUBSTANCE, LIQUID, N.O.S. (Ethoxylated phenylphenol acrylate, Phenoxy polyethylene glyd acrylate), MARINE POLLUTANT
·IATA	ENVIRONMENTALLY HAZARDOU SUBSTANCE, LIQUID, N.O.S. (Ethoxylated phenylphenol acrylate, Phenoxy polyethylene glyd acrylate)
Transport hazard class(es)	
· DOT/TDG (Transport dangerous goods): · Class	Void
· ADR	
·Class	9 (M6) Miscellaneous dangerous substance and articles
· Label	9



Page 8/9

Safety Data Sheet according to HPR, Schedule 1

Printing date 11/22/2022 Reviewed on 11/22/2022

Trade name: dima Print Gingiva Mask

(Contd. of page 7)

· IMDG, IATA



· Class 9 Miscellaneous dangerous substances and

articles

· Label

 Packing group · DOŤ/ŤDG Void · ADR, IMDG, IATA

· Environmental hazards:

Symbol (fish and tree) Marine pollutant: Special marking (ADR): Symbol (fish and tree) Special marking (IATÁ): Symbol (fish and tree)

Warning: Miscellaneous dangerous substances and · Special precautions for user

· Hazard identification number (Kemler

code): · EMS Number: F-A,S-F · Stowage Category

· Transport in bulk according to Annex II of

MARPOL73/78 and the IBC Code Not applicable.

· Transport/Additional information:

· ADR

· Excepted quantities (EQ) Code: E1

Maximum net quantity per inner packaging: 30

Maximum net quantity per outer packaging:

1000 ml

· IMDG

· Limited quantities (LQ) 5L

· Excepted quantities (ÉQ) Code: E1

Maximum net quantity per inner packaging: 30

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

15 Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.

(Contd. on page 9)



Page 9/9

Safety Data Sheet according to HPR, Schedule 1

Printing date 11/22/2022

Reviewed on 11/22/2022

Trade name: dima Print Gingiva Mask

(Contd. of page 8)

· SARA Section 355 (extremely hazardous substances)

None of the ingredients is listed.

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

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.

Date of the latest revision of the safety data sheet 11/22/2022

Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
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)
NEPA: National Fire Protection Association (USA)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

* * Data compared to the previous version altered.