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

Printing date 14.01.2021 Version number 1 Revision: 14.01.2021

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

- · 1.1 Product identifier
 - · Trade name: dima Print Teeth & Temp
 - · UFI: KN70-707X-1001-QCYR
- 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.

Eve Irrit. 2 H319 Causes serious eve irritation. Skin Sens. 1 H317 May cause an allergic skin reaction. STOT SE 3 H335 May cause respiratory irritation.

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 CLP regulation.

Hazard pictograms





GHS09 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

(octahydro-4,7-methano-1H-indenyl)methyl acrylate phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide 2-hydroxyethyl acrylate

· Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

H411 Toxic to aquatic life with long lasting effects.

· Precautionary statements

P261 Avoid breathing mist/vapours/spray. P273 Avoid release to the environment. Wear protective gloves / eye protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water. P337+P313 If eye irritation persists: Get medical advice/attention.

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· 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: -

=		
· Dangerous components:		
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	≥25-≤50%
CAS: 93962-84-6 EC number: 300-723-4 Reg.nr.: 01-2120785023-58-xxxx	(octahydro-4,7-methano-1H-indenyl)methyl acrylate Aquatic Chronic 2, H411 Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1B, H317; STOT SE 3, H335	25-50%
CAS: 30697-40-6	Carboxylfuntional acrylate Skin Irrit. 2, H315; Eye Irrit. 2, H319	≥5-<10%
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-<5%
CAS: 818-61-1 EINECS: 212-454-9 Reg.nr.: 01-2119459345-34-xxxx	2-hydroxyethyl acrylate Acute Tox. 3, H311 (Skin Corr. 1B, H314 Aquatic Acute 1, H400 Acute Tox. 4, H302; Skin Sens. 1, H317 Specific concentration limit: Skin Sens. 1; H317: C ≥ 0.2 %	≥0.2-<0.25%
CAS: 131-57-7 EINECS: 205-031-5	2-Hydroxy-4-methoxy benzophenone Aquatic Acute 1, H400; Aquatic Chronic 2, H411	<0.25%

[·] 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

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• **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: Do not inhale explosion gases or combustion gases.
- 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.
- · 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.

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: 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.

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

· 8.2 Exposure controls

Personal protective equipment

General 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 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.

Solvent resistant gloves

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

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and General Information	chemical properties	
Appearance:		
Form:	Fluid	
· Colour:	White	
· Smell:	Characteristic	
· Odour threshold:	Not determined.	
· pH-value:	Not determined.	
· Change in condition · Melting point/freezing point: · Initial boiling point and boiling r	Not determined ange: >250 °C	
· Flash point:	>100 °C	
· Inflammability (solid, gaseous)	Not applicable.	
Decomposition temperature:	Not determined.	

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· Self-inflammability:	Product is not selfigniting.	
· Explosive properties:	Product is not explosive. Not determined.	
Critical values for explosion: Lower: Upper:	Not determined. Not determined.	
· Steam pressure:	Not determined.	
· Density · Relative density · Vapour density · Evaporation rate	Not determined Not determined. Not determined. Not determined.	
Solubility in / Miscibility with Water:	Not miscible or difficult to mix	
· Partition coefficient: n-octanol/	/water: Not determined.	
· Viscosity: · dynamic: · kinematic:	Not determined. 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

Photoreactive

Polymerisation

- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: None
 - · Additional information: -

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
 - · Acute toxicity Based on available data, the classification criteria are not met.

· L	.D/LC5	0 values that are relevant for classification:
72869-8		7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl smethacrylate
Oral	LD50	>5000 mg/kg (rat) (OECD 401)
Dermal	LD50	>2000 mg/kg (rat) (OECD 402)
93962-8	84-6 (o	ctahydro-4,7-methano-1H-indenyl)methyl acrylate
Oral	LD0	>2000 mg/kg (rat) (OECD 423)
112945	-52-5 A	lmorphous silica

Oral LD50 >10000 mg/kg (rat)
Dermal LD50 >5000 mg/kg (rabbit)

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	-	henyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	
Oral	LD50	>2000 mg/kg (rat) (OECD 401)	
Dermal	LD50	>2000 mg/kg (rat) (OECD 402)	
818-61-	1 2-hy	droxyethyl acrylate	
Oral	LD50	>500 mg/kg (rat)	
		droxy-4-methoxy benzophenone	
		>12800 mg/kg (rat) (OECD 401)	
Dermal	LD50	>16000 mg/kg (rabbit) (OECD 402)	

- · Primary irritant effect:
 - Skin corrosion/irritation

Causes skin irritation.

- · Serious eye damage/irritation Causes serious eye irritation.
- Respiratory or skin sensitisation May cause an allergic skin reaction.
- · Additional toxicological information:

 - 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

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

Oral NOAEL (parental toxicity) >1000 mg/kg/d (rat)

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

STOT-single exposure

May cause respiratory irritation.

- · 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-diyl bismethacrylate

LC50/96h | 10.1 mg/l (fish)

112945-52-5 Amorphous silica

LC50/96h >10000 mg/l (fish)

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

Also poisonous for fish and plankton in water bodies.

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Toxic for aquatic organisms

Do not allow product to reach ground water, water bodies or sewage system.

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

· 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.

European waste catalogue

18 01 06* chemicals consisting of or containing hazardous substances

Uncleaned packagings:

Recommendation:

Disposal must be made according to official regulations. Non contaminated packagings can be used for recycling.

14.1 UN-Number · ADR, IMDG, IATA	UN3082
14.2 UN proper shipping name · ADR	3082 ENVIRONMENTALLY HAZARDOUSUBSTANCE, LIQUID, N.O.S. (7,7,9) 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,1 diazahexadecane-1,16-diyl bismethacrylat (octahydro-4,7-methano-1H-indenyl)methacrylate)
· IMDG	ENVIRONMENTALLY HAZARDOU SUBSTANCE, LIQUID, N.O.S. (7,7,9(7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,1 diazahexadecane-1,16-diyl bismethacrylat (octahydro-4,7-methano-1H-indenyl)meth acrylate), MARINE POLLUTANT
·IATA	ENVIRONMENTALLY HAZARDOU SUBSTANCE, LIQUID, N.O.S. (7,7,9(7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,1 diazahexadecane-1,16-diyl bismethacrylat (octahydro-4,7-methano-1H-indenyl)meth acrylate)



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(Contd. of page 7) · 14.3 Transport hazard class(es) · ADR 9 (M6) Miscellaneous dangerous · Class substances and articles. · Label 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 (IATÁ): Symbol (fish and tree) Warning: Miscellaneous dangerous substances · 14.6 Special precautions for user and articles. 90 · Kemler Number: F-A,S-F · EMS Number: · Stowage Category · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable. · Transport/Additional information: · ADR Limited quantities (LQ) Excepted quantities (ÉQ) Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml · Transport category · Tunnel restriction code ·IMDG · Limited quantities (LQ) 5L (Contd. on page 9)



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· 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. (7,7,9(OR 7,9,9)-TRIMETHYL-4,13-DIOXO-3,14-DIOXA-5,12-DIAZAHEXADECANE-1,16-DIYL BISMETHACRYLATE, (OCTAHYDRO-4,7-METHANO-1H-INDENYL) METHYL

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
 - REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
 - · DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

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

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

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)

LC50: Lethal concentration, 50 percent

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LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 4: Acute toxicity — Category 4
Acute Tox. 3: Acute toxicity — Category 3
Skin Corr. 1B: Skin corrosion/irritation — Category 1B
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. 1B: Skin sensitisation — Category 1B
STOT SE 3: Specific target organ toxicity (single exposure) — Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard — Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard — Category 4
* Data compared to the previous version altered.