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Safety data sheet according to UK REACH

Printing date 06.08.2025 Version number 1 Revision: 06.08.2025

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

- · 1.1 Product identifier
 - · Trade name: dima Print Guide Tray
- 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 GB CLP regulation.

Hazard pictograms



GHS07

- · Signal word Warning
- · Hazard statements

H317 May cause an allergic skin reaction.

H413 May cause long lasting harmful effects to aquatic life.

Precautionary statements

P273 Avoid release to the environment.

P280 Wear protective gloves / eye protection.

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

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

- · 2.3 Other hazards -
 - Results of PBT and vPvB assessment
 - **PBT:** Not applicable.
 - vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- 3.2 Mixtures
 - · Description: -

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· Dangerous components:		
CAS: 41637-38-1 EC number: 609-946-4 Reg.nr.: 01-2119980659-17-xxxx	bisphenol A polyethnylene glycol diether dimethacrylate Aquatic Chronic 4, H413	50-75%
CAS: 162881-26-7 ELINCS: 423-340-5 Index number: 015-189-00-5 Reg.nr.: 01-2119489401-38-xxxx	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide Skin Sens. 1A, H317 Aquatic Chronic 4, H413	≥1-<5%

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
 - General information Personal protection for the First Aider.
 - · 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 fire with 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: Wear self-contained breathing apparatus.
 - Additional information -

SECTION 6: Accidental release measures

• 6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with eyes and skin.

Wear protective equipment. Keep unprotected persons away.

Particular danger of slipping on leaked/spilled product.

6.2 Environmental precautions:

Inform respective authorities in case product reaches water or sewage system.

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Prevent material from reaching sewage system, holes and cellars.

6.3 Methods and material for containment and cleaning up:

Collect mechanically.

Send for recovery or disposal in suitable containers.

· 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

Avoid contact with eyes and skin.

Particular danger of slipping on leaked/spilled product.

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 only in the original container.
 - · Information about storage in one common storage facility:

Store away from oxidising agents.

Store away from reducing agents.

Further information about storage conditions:

Store cool (not above 25 °C).

Protect from heat and direct sunlight.

· 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

41637-38-1 bisphenol A polyethnylene glycol diether dimethacrylate Oral general population, long term, systemic 5 mg/Kg (not defined)

Dermal worker industrial, long term, systemic general population, long term, systemic worker industrial, long term, systemic yeneral population, long term, systemic general population, long term, systemic general population, long term, systemic 17.4 mg/m3 (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

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

- · Breathing equipment: Not necessary if room is well-ventilated.
- · 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 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

· Colour:

· Smell:

· Odour threshold:

· Melting point/freezing point:

· Boiling point or initial boiling point and

boiling range

· Flammability

· Lower and upper explosion limit

· Lower:

· Upper:

· Flash point:

Decomposition temperature:

SADT

· pH

· Viscosity:

· Kinematic viscosity

Liquid Yellow Ester-like

Not determined.

Not determined

>290 °C (41637-38-1 bisphenol A polyethnylene glycol diether dimethacrylate)

Not applicable.

Not determined. Not determined.

>100 °C

Not determined.

Not determined.

Not determined.

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· dynamic:	Not determined.
· Solubility	
· Water:	Fully miscible
· Partition coefficient n-octanol/water (log	1
value)	Not determined.
· Steam pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C	1.12 g/cm³
· Relative density	Not determined.
· Vapour density	Not determined.
9.2 Other information	No further relevant information available.
· Appearance:	No futifier relevant information available.
· Form:	Fluid
Important information on protection of hear	
and environment, and on safety.	iui
· Self-inflammability:	Product is not selfigniting.
· Explosive properties:	Product is not explosive.
Explosive properties.	Not determined.
· Solvent content:	Not determined.
Solids content:	0.0 %
	0.0 76
Change in condition Evaporation rate Information with regard to physical haza classes	Not determined.
· Evaporation rate	ord Void
Evaporation rate Information with regard to physical haza classes Explosives	void Void Void
· Evaporation rate · Information with regard to physical haza classes	void Void Void Void
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Evaporation rate Information with regard to physical haza classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure	void Void Void Void Void Void Void Void V
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Evaporation rate Information with regard to physical haza classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids	Void Void Void Void Void Void Void Void
· Evaporation rate · Information with regard to physical haza classes · Explosives · Flammable gases · Aerosols · Oxidising gases · Gases under pressure · Flammable liquids · Flammable solids · Self-reactive substances and mixtures	Void Void Void Void Void Void Void Void
Evaporation rate Information with regard to physical haza classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids	Void Void Void Void Void Void Void Void
Evaporation rate Information with regard to physical haza classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids	Void Void Void Void Void Void Void Void
· Evaporation rate · Information with regard to physical haza classes · Explosives · Flammable gases · Aerosols · Oxidising gases · Gases under pressure · Flammable liquids · Flammable solids · Self-reactive substances and mixtures	Void Void Void Void Void Void Void Void
Evaporation rate Information with regard to physical haza classes Explosives Flammable gases Aerosols Oxidising gases Gases under pressure Flammable liquids Flammable solids Self-reactive substances and mixtures Pyrophoric liquids	Void Void Void Void Void Void Void Void

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· Substances and mixtures, which emit		
flammable gases in contact with water	Void	
_	Void	
· Oxidising liquids	Void	
	Void	
· Oxidising solids	Void	
	Void	
· Organic peroxides	Void	
•	Void	
· Corrosive to metals	Void	
	Void	
· Desensitised explosives	Void	
•	Void	

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability

Not stable, avoid heat and direct sunlight; polymerizes in the presence of metal powders, peroxides, strong oxidizing agents and free radical initiators.

- · Conditions to be avoided: No decomposition if used and stored according to specifications.
- 10.3 Possibility of hazardous reactions Exothermic polymerisation
- · 10.4 Conditions to avoid Heat, flames and sparks.
- · 10.5 Incompatible materials:

Strong acids

Strong oxidizers

Radical initiator

· 10.6 Hazardous decomposition products:

Carbon monoxide and carbon dioxide

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:

41637-38-1 bisphenol A polyethnylene glycol diether dimethacrylate

Oral LD50 >2,000 mg/kg (rat) (OECD 423)

Dermal LD50 >2,000 mg/kg (rat) (OECD 402)

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

Oral LD50 >2,000 mg/kg (rat) (OECD 401)

Dermal LD50 >2,000 mg/kg (rat) (OECD 402)

Primary irritant effect:

Skin corrosion/irritation Based on available data, the classification criteria are not met.

· Respiratory or skin sensitisation May cause an allergic skin reaction.

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- · 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.

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

Oral NOAEL (parental toxicity) >1,000 mg/kg/d (rat)

- 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.

SECTION 12: Ecological information

· 12.1 Toxicity

	· A	auatic	toxicity:
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41637-38-1	bisphenol A polyethnylene glycol diether dimethacrylate
EC50/72h	>100 mg/l (2/g2a) (OECD 201)

	>100 mg/l (algae) (OECD 201)
	>100 mg/L (fish) (OECD 203)
	>100 mg/L (daphnia) (OECD 202)
EL50/72h	>100 mg/L (algae) (OECD 201)
NOEC / 21d	≥22.4 mg/l (daphnia) (OECD 211)
NOEC 28d	14.3 mg/l (bacteria)

NOELR 100 mg/L /48h (daphnia) (OECD 202)

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

41637-38-1 bisphenol A polyethnylene glycol diether dimethacrylate

Biodegradation 24 % /28d (not defined) (OECD 301D)

- 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

The product does not contain substances with endocrine disrupting properties.

• 12.7 Other adverse effects No further relevant information available.



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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.

Recommended cleaning agent: Water, if necessary with cleaning agent.

14.1 UN number or ID number ADR, 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 Maritime transport in bulk according instruments	to IMO 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
 - · Poisons Act
 - · Regulated explosives precursors

None of the ingredients is listed.

· Regulated poisons

None of the ingredients is listed.

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· Reportable explosives precursors

None of the ingredients is listed.

· Reportable poisons

None of the ingredients is listed.

- Directive 2012/18/EU
 - Named dangerous substances ANNEX I 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

H317 May cause an allergic skin reaction.

H413 May cause long lasting harmful effects to aquatic life.

· 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

IMDS. International Maintime Code to 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)

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

Skin Sens. 1A: Skin sensitisation - Category 1A

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

* Data compared to the previous version altered.