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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 Splint clear
- · 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

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.

STOT SE 3 H335 May cause respiratory irritation.

- · 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



GHS07

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

Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid

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

Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

· Precautionary statements

P261 Avoid breathing mist/vapours/spray.
P280 Wear protective gloves / eye protection.

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

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

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

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

P337+P313 If eye irritation persists: Get medical advice/attention.

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: 41637-38-1 EC number: 609-946-4 Reg.nr.: 01-2119980659-17-xxxx	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	>90%
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%

[·] 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 rinse with water.

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. Do not use water.

Use fire fighting measures that suit the environment.

· For safety reasons unsuitable extinguishing agents

Water jet.

Water.

· 5.2 Special hazards arising from the substance or mixture

In case of fire the following can be released:

Carbon dioxide (CO2)

Carbon monoxide (CO)

- · 5.3 Advice for firefighters
 - Protective equipment:

Wear self-contained breathing apparatus.

Wear full protective suit.

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· 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.

Avoid contact with eyes and skin.

Ensure adequate ventilation

- **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

Ensure good ventilation/exhaustion at the workplace.

Avoid contact with eyes and skin.

Keep away from heat and direct sunlight.

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 in cool, dry place in tightly closed containers.

Protect from the effects of light.

Information about storage in one common storage facility:

Store away from oxidising agents.

- · 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

41637-38-1 Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2methylprop-2-enoic acid

Dermal	worker industrial, long term, systemic	2 mg/Kg/d (not defined)
	general population, long term, systemic	1 mg/Kg/d (not defined)
Inhalative	worker industrial, long term, systemic	3.52 mg/m3 (not defined)
	general population, long term, systemic	0.87 mg/m3 (not defined)

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• 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

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:

Not necessary if room is well-ventilated.

Filter P2.

· Hand protection

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/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: Clear · Smell: Ester-like

Not determined. Odour threshold: Melting point/freezing point:
Boiling point or initial boiling point and Not determined

boiling range Not determined · Flammability Not applicable.

· Lower and upper explosion limit

· Lower: Not determined. · Upper: Not determined.

211 °C (41637-38-1 Esterification products of Flash point:

4,4'-isopropylidenediphenol, ethoxylated and 2-

methylprop-2-enoic acid)

· Decomposition temperature: Not determined.

SADT

· pH Not determined.

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Not miscible or difficult to mix

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· Viscosity:

* Kinematic viscosity Not determined. * dynamic at 20 °C: 0.4-1.5 mPas

Solubility

· Water:

· Partition coefficient n-octanol/water (log

value) Not determined.
Steam pressure: Not determined.

Density and/or relative density

Density at 20 °C
 Relative density
 Vapour density
 Not determined.
 Not determined.

• **9.2 Other information** No further relevant information available.

· Appearance:

Fluid

Important information on protection of health and environment, and on safety.

• Self-inflammability: Product is not selfigniting. • Explosive properties: Product is not explosive.

Solvent content:

· Solids content: 0.0 %

· Change in condition

· Evaporation rate Not determined.

Information with regard to physical hazard classes

· Explosives Void Flammable gases Void · Aerosols Void · Oxidising gases Void · Gases under pressure Void · Flammable liquids Void · Flammable solids Void · Self-reactive substances and mixtures Void · Pyrophoric liquids Void Pyrophoric solids Void Void · Self-heating substances and mixtures 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 · Desensitised explosives Void

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
 - · Conditions to be avoided: Protect from heat and direct sunlight.
- · 10.3 Possibility of hazardous reactions Polymerisation
- · 10.4 Conditions to avoid Heat, flames and sparks.
- 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:

41637-38-1 Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2methylprop-2-enoic acid

LD50 >2000 mg/kg /read-acro (rat) (OECD 423) Oral

Dermal LD50 >2000 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 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.
- 11.2 Information on other hazards
 - Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquati	c toxicity:
41637-38-	1 Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid
LL50/96h	100 mg/L (fish)
EL50/48h	6 mg/L (daphnia) (OECD 202)
EL50/72h	100 mg/L (algae) (OECD 201)
162881-26	3-7 phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide
FC50/72h	>0.26 mg/l (algae) (OECD 201)

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

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· 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, even in small

Danger to drinking water if even extremely 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

· European waste catalogue

08 04 09* waste adhesives and sealants containing organic solvents or other hazardous substances

15 01 10* packaging containing residues of or contaminated by hazardous substances

Uncleaned packagings:

Recommendation: Disposal must be made according to official regulations.

•	tion	
14.1 UN number or ID number · ADR, ADN, 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 accordi IMO instruments	ng to Not applicable.	
· Transport/Additional information:	-	
UN "Model Regulation":	Void	

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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.
 - 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

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H413 May cause long lasting harmful effects to aquatic life.

- Date of previous version: 18.12.2020
- Version number of previous version: 1
- 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

INDES. 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

Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)
DNEL: Derived No-Effect Level (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative 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 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

* Data compared to the previous version altered.