

according to Regulation (EC) No 1907/2006

medicalprint® shell beige

Revision date: 17.12.2020

Product code: 1005

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

medicalprint® shell beige

UFI: RWM0-S1KJ-C009-A5DA

1.2. Relevant identified uses of the substance or mixture and uses advised against**Use of the substance/mixture**

Ligth curing one component material for the fabrication of earmoulds.

1.3. Details of the supplier of the safety data sheet

Company name:	DETAX GmbH & Co. KG	
Street:	Carl-Zeiss-Strasse	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
e-mail:	post@detax.de	
Internet:	www.detax.de	
Responsible Department:	Emergency number:	
	+49 7243/510-0	
	This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 a.m. - 4.00 p.m.)	
	+49 7243/510-0	
	This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 - 4.00 p.m.)	

1.4. Emergency telephone number:**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Regulation (EC) No. 1272/2008**

Hazard categories:

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2

Respiratory or skin sensitisation: Skin Sens. 1

Reproductive toxicity: Repr. 2

Specific target organ toxicity - single exposure: STOT SE 3

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

Suspected of damaging fertility or the unborn child.

May cause respiratory irritation.

Harmful to aquatic life with long lasting effects.

2.2. Label elements**Regulation (EC) No. 1272/2008**

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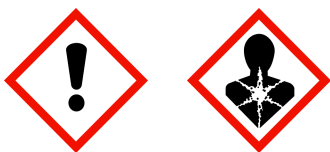
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Hazard components for labelling

isopropylidenediphenol peg-2 dimethacrylate
 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate
 Urethane Dimethacrylate
 Hydroxy propyl methacrylate
 tetrahydrofurfuryl methacrylate THFMA purified grade
 diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
 2-hydroxyethyl methacrylate
 aliphatic urethane acrylate
 phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide

Signal word: Warning

Pictograms:



Hazard statements

H315 Causes skin irritation.
 H317 May cause an allergic skin reaction.
 H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.
 H361 Suspected of damaging fertility or the unborn child.
 H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
 P302+P352 IF ON SKIN: Wash with plenty of water.
 P362+P364 Take off contaminated clothing and wash it before reuse.
 P501 Dispose of contents/ container in accordance with local and national regulations.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Mixture of acrylic/ methacrylic resins with auxilliary matters.

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Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
41637-38-1	isopropylidenediphenol peg-2 dimethacrylate			35 - < 40 %
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1A, STOT SE 3; H315 H319 H317 H335			
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazaheptadecane-1,16-diyl bismethacrylate			20 - < 25 %
	276-957-5		01-2120751202-68	
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411			
72869-86-4	Urethane Dimethacrylate			15 - < 20 %
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H315 H319 H317 H335			
72829-09-5	1,12-Dodecanediol Dimethacrylate			5 - < 10 %
	Skin Irrit. 2, Eye Irrit. 2; H315 H319			
27813-02-1	Hydroxy propyl methacrylate			1 - < 5 %
	248-666-3		01-2119490226-37	
	Eye Irrit. 2, Skin Sens. 1; H319 H317			
2455-24-5	tetrahydrofurfuryl methacrylate THFMA purified grade			1 - < 5 %
	Repr. 2, Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H361 H315 H319 H317 H335			
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide			1 - < 5 %
	278-355-8	015-203-00-X		
	Repr. 2, Skin Sens. 1B, Aquatic Chronic 2; H361f H317 H411			
868-77-9	2-hydroxyethyl methacrylate			< 1 %
	212-782-2	607-124-00-X		
	Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1; H315 H319 H317			
	aliphatic urethane acrylate			< 1 %
	906-949-5		01-2120266262-60	
	Skin Sens. 1B, Aquatic Chronic 2; H317 H411			
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide			< 1 %
	423-340-5	015-189-00-5	01-2119489401-38	
	Skin Sens. 1, Aquatic Chronic 4; H317 H413			

Full text of H and EUH statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

After contact with skin

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

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After contact with eyes

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

After ingestion

Rinse mouth immediately and drink plenty of water.

Seek immediately medical advice. Do not induce vomiting. In case of spontaneous vomiting take care of an unhindered flow out of the vomit (danger of suffocation).

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately.

Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaust at critical locations.

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Hints on joint storage

Keep away from spontaneous flammable or combustible substances.

Further information on storage conditions

Keep only in the original container in a dry and well-ventilated place, away from foodstuffs. Keep away from all kind of lighth. An inert gas blanket should not be applied, because the stability of the product depends on the presence of oxygen (air).

7.3. Specific end use(s)

Lighth curing material for the generative manufacturing of earmoulds.

For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.

Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

Eye/face protection

Suitable eye protection: goggles.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Suitable are gloves of the following material: Butyl caoutchouc (butyl rubber)

Skin protection

Wear suitable protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid:
Colour:	beige
Odour:	faintly like esters

Test method

pH-Value:	not determined
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Changes in the physical state

Melting point:	not determined
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Initial boiling point and boiling range:	not determined
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Flash point:	>100 °C DIN 51755
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Flammability

Solid:	not applicable
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Gas:	not applicable
Lower explosion limits:	not determined
Upper explosion limits:	not determined
Auto-ignition temperature	
Solid:	not applicable
Gas:	not applicable
Decomposition temperature:	>=190 °C
Oxidizing properties	
Not oxidizing.	
Vapour pressure:	<1 hPa
(at 20 °C)	
Density (at 20 °C):	1,09 g/cm³ DIN 51757
Water solubility:	insoluble
Solubility in other solvents	
not determined	
Partition coefficient:	not determined
Vapour density:	not determined
Evaporation rate:	not determined
9.2. Other information	
Solid content:	not determined

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Reacts with : strong oxidising agents, strong alkaline or acidic materials.

10.4. Conditions to avoid

Ultra-violet light and daylight initiate polymerisation of the product. Therefore keep only in tightly closed containers away from any sources of light at 15°C - 28°C / 59°F - 82 °F.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

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

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate				
	oral	LD50 >5000 mg/kg	Rat	OECD 401	
	dermal	LD50 >2000 mg/kg	Rat	OECD 402	
27813-02-1	Hydroxy propyl methacrylate				
	oral	LD50 >2000 mg/kg	Rat	OECD 401	
	dermal	LD50 >5000 mg/kg	Rabbit		
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide				
	oral	LD50 >5000 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rat		
868-77-9	2-hydroxyethyl methacrylate				
	oral	LD50 5050 mg/kg	Rat		
	aliphatic urethane acrylate				
	oral	LD50 >5000 mg/kg	Rat	OECD 401	
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide				
	oral	LD50 >2000 mg/kg	Rat	OECD 401	
	dermal	LD50 >2000 mg/kg	Rat	OECD 402	

Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

Sensitising effects

May cause an allergic skin reaction. (isopropylidenediphenol peg-2 dimethacrylate; 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate; Urethane Dimethacrylate; Hydroxy propyl methacrylate; tetrahydrofurfuryl methacrylate THFMA purified grade; diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide; 2-hydroxyethyl methacrylate; aliphatic urethane acrylate; phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide)

Carcinogenic/mutagenic/toxic effects for reproduction

Suspected of damaging fertility or the unborn child. (tetrahydrofurfuryl methacrylate THFMA purified grade; diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide)

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

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

STOT-single exposure

May cause respiratory irritation. (isopropylidenediphenol peg-2 dimethacrylate)

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 information on tests

This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 [CLP]. Special hazards

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arising from the substance or mixture!

SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahehexadecane-1,16-diyl bismethacrylate					
	Acute crustacea toxicity	EC50 mg/l	>1,2	48 h	Daphnia magna (Big water flea)	OECD 202
27813-02-1	Hydroxy propyl methacrylate					
	Acute fish toxicity	LC50	493 mg/l	96 h	Leuciscus idus (golden orfe)	
	Acute algae toxicity	ErC50 mg/l	>97,2	72 h	Pseudokirchneriella subcapitata	OECD 201
	Acute crustacea toxicity	EC50	380 mg/l	48 h	Daphnia magna (Big water flea)	OECD 202
2455-24-5	tetrahydrofurfuryl methacrylate THFMA purified grade					
	Acute fish toxicity	LC50 mg/l	34,7	96 h		GESTIS
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide					
	Acute algae toxicity	ErC50 mg/l	>2,01	72 h	Scenedesmus subspicatus	
	Acute crustacea toxicity	EC50 mg/l	3,53	48 h	Daphnia magna (Big water flea)	
	Acute bacteria toxicity	(>1000 mg/l)		3 h	Activated sludge	
868-77-9	2-hydroxyethyl methacrylate					
	Acute fish toxicity	LC50	227 mg/l	96 h	Pimephales promelas	
	aliphatic urethane acrylate					
	Acute algae toxicity	ErC50 mg/l	>0,68	72 h	(algae)	OECD 201
	Acute crustacea toxicity	EC50 mg/l	>1,2	48 h	(daphnia)	OECD 202
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide					
	Acute fish toxicity	LC50 mg/l	>0,09	96 h	Brachydanio rerio (zebra-fish)	OECD 203
	Acute algae toxicity	ErC50 mg/l	>0,26	72 h	Desmodesmus subspicatus.	OECD 201
	Acute crustacea toxicity	EC50 mg/l	>1,175	48 h	Daphnia magna (Big water flea)	OECD 202
	Crustacea toxicity	NOEC mg/l	>0,008	21 d	Daphnia magna (Big water flea)	OECD 211
	Acute bacteria toxicity	(>100 mg/l)		3 h	OECD 209	

12.2. Persistence and degradability

The product has not been tested.

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CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
72829-09-5	1,12-Dodecanediol Dimethacrylate			
	OECD 301C/ ISO 9408/ EEC 92/69/V, C.4-F	90 %	28	
27813-02-1	Hydroxy propyl methacrylate			
	OECD	94%	28	
	Readily biodegradable (according to OECD criteria).			
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide			
		0-10%	28	
	Not readily biodegradable (according to OECD criteria)			
868-77-9	2-hydroxyethyl methacrylate			
	84	%	28	
	Leicht biologisch abbaubar			
	aliphatic urethane acrylate			
	OECD 301B	22%	28	
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide			
	CO2 formation (% of the theoretical value).	1%	29	
	Not readily biodegradable (according to OECD criteria)			

12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
27813-02-1	Hydroxy propyl methacrylate	0,97
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	3,1
868-77-9	2-hydroxyethyl methacrylate	0,47
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	5,8

BCF

CAS No	Chemical name	BCF	Species	Source
72829-09-5	1,12-Dodecanediol Dimethacrylate	1230		
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	47-55	Cyprinus carpio (Common Carp)	
162881-26-7	phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	<5	Cyprinus carpio (Common Carp)	OECD 305

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

Not identified as PBT/ vPvB substances

12.6. Other adverse effects

No information available.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste

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according to applicable legislation.

Contaminated packaging

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulatory information

Employment restrictions:	Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.
Water hazard class (D):	3 - strongly hazardous to water
Skin resorption/Sensitization:	Causes allergic hypersensitivity reactions.

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route

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(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 Harmonized 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

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]

Classification	Classification procedure
Skin Irrit. 2; H315	Calculation method
Eye Irrit. 2; H319	Calculation method
Skin Sens. 1; H317	Calculation method
Repr. 2; H361	Calculation method
STOT SE 3; H335	Calculation method
Aquatic Chronic 3; H412	Calculation method

Relevant H and EUH statements (number and full text)

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H361	Suspected of damaging fertility or the unborn child.
H361f	Suspected of damaging fertility.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)