Version: 1 Replaces version:

Revision date: 12.02.2019 from:

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

1.1. Product identifier

**GR-18.1 IB** 

UV curable resin

CAS No.: EC No.: INDEX No.: **REACH No.:** 

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against Relevant identified uses: Manufacture. Uses advised against:

Private households (= general public).

## 1.3. Details of the supplier of the safety data sheet

Manufacturer pro3dure medical GmbH

Am Burgberg 13 D 58642 Iserlohn

#### Supplier

pro3dure medical GmbH

Am Burgberg 13 58642 D Iserlohn Telephone +49 (0)2374 920050-10 Telefax: +49 (0)2374 920050-50

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## Information contact

pro3dure medical GmbH

Information telephone +49 (0)2374 920050-10 Information telefax +49 (0)2374 920050-50 E-mail (competent person) info@pro3dure.com Website www.pro3dure.com

## **1.4. Emergency telephone number**

Diese Nummer ist nur zu Bürozeiten erreichbar

Telephone +49 (0)2374 920050-10

## **SECTION 2: Hazards identification**

## 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008: Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335

## 2.2. Label elements

Classification according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictograms

	GHS07
Signal word:	Warning
Hazard staten	nents:
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Precautionary	/ statements:
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash .? thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+352	IF ON SKIN: Wash with plenty of water/.?.
P304+340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+351+33	8 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if
present and ea	asy to do. Continue rinsing.
P312	Call a POISON CENTER/doctor/.?/if you feel unwell.
P321	Specific treatment (see .? on this label).
P332+313	If skin irritation occurs: Get medical advice/attention.
P333+313	If skin irritation or rash occurs: Get medical advice/attention.
P337+313	If eye irritation persists: Get medical advice/attention.
P362+364	Take off contaminated clothing and wash it before reuse.
P403+233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container to .?.

## Hazardous component(s) for labelling:

xxx (Methacrylsäuretetrahydrofurfurylester); xxx (Diphenyl-(2,4,6-trimethylbenzoyl)phosphinoxid )

# Special labelling of particular preparations: none

#### 2.3. Other hazards

Medical examination necessary even merely on suspicion of intoxication.

## **SECTION 3: Composition / information on ingredients**

#### 3.1. Substances

not applicable

## 3.2. Mixtures

Mixture related information

## **Composition/information on ingredients**

#### Revision date: 12.02.2019 Version: 1

Substance:	EC-no.:	CAS-No.:	INDEX no.:	REACH-no.:	Concentration:	Classification: EC 1272/2008 (CLP):
Esterification products of 4,4'- isopropylidenediphenol, ethoxylated and 2- methylprop-2-enoic acid	609-946-4	41637-38-1		01-2119980659-17- 0000	< 50 %	Skin Irrit. 2, H315; Skin Sens. 1/1A/1B, H317; Eye Irrit. 2, H319; STOT SE 3, H335
7,7,9(or 7,9,9)- trimethyl-4,13-dioxo- 3,14-dioxa-5,12- diazahexadecane-1,16- diyl bismethacrylate	276-957-5	72869-86-4		01-2120751202-68- 0000	< 50 %	Skin Sens. 1/1A/1B, H317
Methacrylsäuretetrahyd rofurfurylester	219-529-5	2455-24-5	607-134-00-4	01-2120748481-53- 0000	< 30 %	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335
Diphenyl-(2,4,6- trimethylbenzoyl)phosp hinoxid	278-355-8	75980-60-8		01-2119972295-29- 0000	< 2 %	Repr. 2, H361

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

## **SECTION 4: First aid measures**

## 4.1. Description of first aid measures

General information:	In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Take off immediately all contaminated clothing.
In case of inhalation:	Move victim to fresh air. Put victim at rest and keep warm. In case of irregular breathing or respiratory arrest provide artificial respiration. Position and transport victim on their side. In case of respiratory distress, bring into semi-upright, seated position. Call a physician immediately.
Following skin	After contact with skin, wash immediately with plenty of water and soap. Immerse
contact:	in cold water for a prolonged period. Call a physician immediately.
After eye contact:	In case of contact with eyes, rinse immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Subsequently consult an ophthalmologist.
After ingestion:	Rinse mouth immediately and drink plenty of water. No administration in cases of unconsciousness or cramps. Do NOT induce vomiting. Call a physician immediately.

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

No known symptoms to date.

**4.3. Indication of any immediate medical attention and special treatment needed** No special measures are necessary.

## **SECTION 5: Firefighting measures**

## 5.1. Extinguishing media

Suitabledry extinguishing powder. Carbon dioxide (CO2).extinguishing mediaWater fog. High power water jet. Water.extinguishing mediaVater fog. High power water jet. Water.

## 5.2. Special hazards arising from the substance or mixture

Vapours may form explosive mixtures with air. In case of fire may be liberated: Pyrolysis products, toxic.

#### 5.3. Advice for firefighters General information

General Information

Co-ordinate fire-fighting measures to the fire surroundings. Use water spray jet to protect personnel and to cool endangered containers. Move undamaged containers from immediate hazard area if it can be done safely.

#### Special protective equipment for fire-fighters:

In case of fire: Use acid-proof equipment only. Wear a self-contained breathing apparatus and chemical protective clothing.

## **SECTION 6: Accidental release measures**

#### 6.1. Personal precautions, protective equipment and emergency procedures

Wear personal protection equipment. Remove persons to safety. Provide adequate ventilation. Keep away from unprotected people. Keep upwind.

#### 6.2. Environmental precautions

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

#### 6.3. Methods and material for containment and cleaning up

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

#### Advices on safe handling

Avoid contact with skin and eyes. Do not breathe gas/fumes/vapour/spray.

#### Precautions against fire and explosion:

Take precautionary measures against static discharges.

#### 7.2. Conditions for safe storage, including any incompatibilities

**Requirements for storage rooms and vessels** Keep container tightly closed. Restrict access to stockrooms.

#### Hints on joint storage

Do not store together with: metal. Keep away from food, drink and animal feedingstuffs.

#### 7.3. Specific end use(s)

Observe instructions for use.

## **SECTION 8: Exposure controls/personal protection**

#### 8.1. Control parameters

occupational exposure limit value

Substance:	CAS-No.:	Source:	Occupational	Occupational	Limitation of	Remark:
			exposure limit	exposure limit	exposure	
			value:[ppm]	value:[mg/m <sup>3</sup> ]	peaks:	

Substance with a common (EC) occupational exposure limit value.

Substance:	CAS-No.:	Source:	Occupational	Occupational	Limitation of	Remark:
			exposure limit	exposure limit	exposure	
			value:[ppm]	value:[mg/m <sup>3</sup> ]	peaks:	

## **DNEL-/PNEC-values**

**DNEL** value

Substance:	CAS-No.:	DNEL/DMEL
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid	41637-38-1	worker inhalative xxx(systemisch) 3,52 mg/m <sup>3</sup> worker dermal xxx(systemisch) 2 xxx(mg/m3/24h) xxx(Verbraucher) inhalative xxx(systemisch) 870 µg/m <sup>3</sup> xxx(Verbraucher) dermal xxx(systemisch) 1 xxx(mg/m3/24h) xxx(Verbraucher) xxx(systemisch) 500 xxx(µg/m3/24h)
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12- diazahexadecane-1,16-diyl bismethacrylate	72869-86-4	worker inhalative xxx(systemisch) 3,3 mg/m <sup>3</sup> worker dermal xxx(systemisch) 1,3 xxx(mg/kg bw /24h) xxx(Verbraucher) inhalative xxx(systemisch) 0,6 mg/m <sup>3</sup> xxx(Verbraucher) dermal xxx(systemisch) 0,7 xxx(mg/kg bw/24h) xxx(Verbraucher) xxx(systemisch) 0,3 xxx(mg/kg bw/24h)

## **PNEC** Value

Substance:	CAS-No.:	PNEC
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12- diazahexadecane-1,16-diyl bismethacrylate	72869-86-4	xxx(Süßwasser) 0,01 mg/l xxx(Meerwasser) 0,001 mg/l xxx(Kläranlagen) 3,61 mg/l xxx(Süßwassersediment) 4,56 xxx(mg/kg Sediment) xxx(Meeressediment) 0,46 xxx(mg/kg Sediment) soil 0,91 xxx(mg/kg Boden)

## Additional information

Does not contain substances above concentration limits fixing an occupational exposure limit.

## 8.2. Exposure controls

#### Occupational exposure controls:

Provide adequate ventilation as well as local exhaustion at critical locations. Technical measures and the application of suitable work processes have priority over personal protection equipment.

#### General protection and hygiene measures:

When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work. Apply skin care products after work. Wash contaminated clothing prior to re-use.

#### **Personal protection equipment**

Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500.

#### **Respiratory protection**

Respiratory protection necessary at: Formation of aerosol. Suitable respiratory protection apparatus: Combination filter device (DIN EN 141)..

#### Hand protection

Tested protective gloves are to be worn: DIN-/EN-Norms: DIN EN 374

#### **Eye/face protection**

Tightly sealed safety glasses. Eye-shade.

#### **Body protection:**

For the protection against direct skin contact, body protective clothing is essential (in addition to the usual working clothes). Only wear fitting, comfortable and clean protective clothing. Barrier creams are not substitutes for body protection.

#### **Environmental exposure controls**

refer to chapter 7. No further action is necessary.

#### **Consumer exposure controls**

refer to chapter 7. No further action is necessary.

Exposure Scenario: none

#### SECTION 9: Physical and chemical properties 9.1. Information on basic physical and chemical properties Appearance Physical state: Liquid Colour: various Odour: characteristic like: ester **Odour threshold:** No data available Safety relevant basis data parameter Value unit Remark pH: No data available Melting point/freezing point: No data available Initial boiling point and boiling No data available range: Flash point: No data available **Evaporation rate:** No data available Flammability (solid, gas): No data available **Explosivity:** No data available Upper flammability or No data available explosive limits: lower flammability or No data available explosive limits: Vapour pressure: No data available Vapour density: No data available **Relative density:** at room ca. 1,1 g/mL temperatur е No data available **Density:** Soluble (g/L) in: No data available Water solubility (g/L): No data available Fat solubility (g/L): No data available Partition coefficient: n-No data available octanol/water: Ignition temperature: No data available **Decomposition temperature:** No data available Viscosity: at room ca. 2 (Pas) temperatur е **Oxidizing properties:** No data available

## 9.2. Other information

none

## **SECTION 10: Stability and reactivity**

## 10.1. Reactivity

Vapours may form explosive mixtures with air.

## **10.2. Chemical stability**

Decomposition with: UV-radiation/sunlight. heat.

## 10.3. Possibility of hazardous reactions

Vapours may form explosive mixtures with air.

#### 10.4. Conditions to avoid

heat. UV-radiation/sunlight.

## 10.5. Incompatible materials

Alkalis (alkalis). metal.

#### **10.6. Hazardous decomposition products**

In case of fire may be liberated: Phosphorus oxides.

#### **SECTION 11: Toxicological information**

#### 11.1. Information on toxicological effects

There are no data available on the preparation/mixture itself.

M-factor:	-	Acute toxicity (dermal):	•
Acute toxicity (oral):	-	Acute toxicity (inhalative):	-

#### Acute toxicity

Substance:	CAS-No.:	Toxicological information
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-	72869-86-4	LD50 oral (rat) > 5000 mg/kg
diazahexadecane-1,16-diyl bismethacrylate		
Diphenyl-(2,4,6-trimethylbenzoyl)phosphinoxid	75980-60-8	
Methacrylsäuretetrahydrofurfurylester	2455-24-5	
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated	41637-38-1	LD50 oral (rat) 2000 mg/kg
and 2-methylprop-2-enoic acid		XXX 2000 mg/kg

#### Skin corrosion/irritation:

irritant.

#### Serious eye damage/irritation:

strongly irritant.

#### Respiratory or skin sensitisation:

May cause an allergic skin reaction.

#### CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity: No indications of human carcinogenicity exist. Germ cell mutagenicity: No indications of human germ cell mutagenicity exist. Reproductive toxicity: No indications of human reproductive toxicity exist.

#### STOT-single exposure:

The following symptoms may occur: Corneal opacity. Coughing.

#### STOT-repeated exposure:

none

# Aspiration hazard: irritant.

rritant.

## **SECTION 12: Ecological information**

## 12.1. Toxicity

none

#### Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-	72869-86-4	> 1,2 mg/l
diazahexadecane-1,16-diyl bismethacrylate		> 0,68 mg/l
Diphenyl-(2,4,6-trimethylbenzoyl)phosphinoxid	75980-60-8	
Methacrylsäuretetrahydrofurfurylester	2455-24-5	
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated	41637-38-1	LC50 (fish, 96 h) 100 mg/l
and 2-methylprop-2-enoic acid		LC50 (crustaceans, 48h) 6 mg/l
		XXX 100 mg/l

## 12.2. Persistence and degradability

Not easily bio-degradable (according to OECD-criteria).

## 12.3. Bioaccumulative potential

No indication of bioaccumulation potential.

## 12.4. Mobility in soil

If product enters soil, it will be mobile and may contaminate groundwater.

## 12.5. Results of PBT and vPvB assessment

This substance does not meet the criteria for classification as PBT or vPvB.

## 12.6. Other adverse effects

none

## **SECTION 13: Disposal considerations**

## 13.1. Waste treatment methods

#### Appropriate disposal/Product:

Waste disposal according to directive 2008/98/EC, covering waste and dangerous waste.

## Appropriate disposal / Package

Can be incinerated together with household waste in compliance with applicable technical regulations following consultation with approved waste disposal management companies and authorities in charge.

#### List of proposed waste codes / waste designations according to EWC / AVV

-

According to EAKV, allocation of waste identity numbers/waste descriptions must be carried out in a specific way for every industry and process.

Waste key product:

## Waste key packaging:

## **SECTION 14: Transport information**

#### 14.1. UN number UN No.:

UN NO.:

## 14.2. UN proper shipping name

Land transport (ADR/RID)

-

Sea transport (IMDG), Air transport (ICAO-TI / IATA-DGR)

Safety Data Sheet according to Regulation (EC) No. 1907/2 GR-18.1 IBT	2006 (REACH) Revision date: 12.02.2019 Version: 1
- - 14.3. Transport hazard class(es) Hazard label(s) / Label: -	Classification code: / Classification - Code:
14.4. Packing group Packing group/ Packing Group:	-
14.5. Environmental hazards	
ADR/RID / IMDG / ICAO-TI / IATA-DGR: Marine pollutant:	Yes No
14.6. Special precautions for user Land transport (ADR/RID) transport category: - Special provisions: -	tunnel restriction code: - Limited quantity (LQ): -
Sea transport (IMDG) EmS-No: - Special provisions: - Limited	l quantity (LQ): -
14.7. Transport in bulk according to An Remark none	nex II of MARPOL 73/78 and the IBC Code

## **SECTION 15: Regulatory information**

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

#### EU legislation

Information on Regulation (EC) No 166/2006 establishing a European Pollutant Release and Transfer Register: not relevant

Regulation (EC) No. 1005/2009 on substances that lead to the depletion of the ozone layer: not relevant

Regulation (EC) No. 648/2004 (Detergents regulation) not relevant

Regulation (EC) No 850/2004 [POP-Regulation]: not relevant

Regulation (EU) No 649/2012 on the export and import of dangerous chemicals: not relevant

Use restriction according to REACH annex XVII, no.:: Use restriction according to REACH annex XVII, no.:

#### **National regulations**

Observe in addition any national regulations!

## **Restrictions of occupation**

Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers. According to directive 94/33/EC, juveniles are only allowed to handle this product as long as all effects of dangerous substances are prevented.

# Other regulations, restrictions and prohibition regulations none

## 15.2. Chemical Safety Assessment

**For this preparation a chemical safety assessment has been carried out.** For this substance a chemical safety assessment is not required.

## **SECTION 16: Other information**

## Relevant H- and EUH-phrases (Number and full text):

Hazard statements

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

#### Training advice

Make sure that employees are aware of the intoxication risk. Poeple wearing breathing apparatus must be appropriately trained.

#### **Recommended restrictions of use:**

refer to chapter 1.

#### Further remarks:

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

#### **Documentation of changes:**

none

#### Key literature references and sources for data

Data arise from reference works and literature.

## Abbreviations and acronyms

none