

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

1.1. Product identifier

printodent GR-11.1 tray

UFI 0M01-S5Y7-ST3Q-W3QR

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

Relevant identified uses: 3D printing
Uses advised against: Private households (= general public). Observe instructions for use.

1.3. Details of the supplier of the safety data sheet

Manufacturer

pro3dure medical GmbH

Am Burgberg 13
D 58642 Iserlohn

Telephone +49 (0)2374 920050-10
Telefax:

Supplier

pro3dure medical GmbH

Am Burgberg 13
D 58642 Iserlohn

Telephone +49 (0)2374 920050-10
Telefax:

Information contact

pro3dure medical GmbH

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

1.4. Emergency telephone number

pro3dure medical GmbH
This number is serviced during office hours.

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. 1B, H317

2.2. Label elements

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

Hazard pictograms



Signal word: GHS07
Warning
Hazard statements:

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

Precautionary statements:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P264.1 Wash hands 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+352.1 IF ON SKIN: Wash with plenty of soap and water.

P304+340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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 in accordance with local and national regulations.

Special labelling of particular preparations:

EUH 204 Contains isocyanates. May produce an allergic reaction. Hazardous component(s) for labelling: Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate, Urethane Acrylate

2.3. Other hazards

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

No endocrine-disrupting properties known (see section 12)

Use restriction according to REACH annex XVII, no.: 75, 78 not applicable;

CA Proposition 65 : Substance(s) not listed.

SECTION 3: Composition / information on ingredients

3.1. Substances

not applicable

3.2. Mixtures

Mixture with, among others, the following ingredients and other non-hazardous admixtures

Composition/information on ingredients

Substance:	CAS-No.:	REACH-no.:	Concentration:	Classification: EC 1272/2008 (CLP):	M, ATE, Note
Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate	84434-11-7	01-2119987994-10-XXXX	1-4	Skin Sens. 1, H317; Aquatic Chronic 2, H411	M = 0 ATE (dermal) = >2000 mg/kg ATE (oral) = >5000 mg/kg ATE (inhalativ) = >2700 mg/L
Urethane Acrylate			10-20	Skin Irrit. 2, H315; Eye Irrit. 2, H319	ATE (dermal) = - ATE (oral) = - ATE (inhalativ) = -

(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 Remove contaminated, saturated clothing immediately. Medical attention is required if symptoms clearly result from contact with the product on skin, eyes, or from inhalation of vapors.
In case of inhalation:	Provide fresh air. Seek medical attention if problems persist.
Following skin contact:	After contact with skin, wash immediately with plenty of water and soap. In case of skin irritation, consult a physician.
After eye contact:	In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and 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

Possible harmful effect(s) on human beings and possible symptom(s): Skin sensitisation , Irritation to respiratory tract , Skin and eye irritation , May produce an allergic reaction.

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

First Aid, decontamination, treatment of symptoms. May cause sensitisation especially in sensitive humans. May cause sensitisation especially in sensitive humans.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	ABC-powder. BC-powder. alcohol resistant foam. Carbon dioxide.
Unsuitable extinguishing media	Water spray jet. Full water jet. Excess water.

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Carbon dioxide (CO₂). Carbon monoxide.

5.3. Advice for firefighters

General information

Move undamaged containers from immediate hazard area if it can be done safely. Use water spray jet to protect personnel and to cool endangered containers. Do not allow water used to extinguish fire to enter drains or waterways. Co-ordinate fire-fighting measures to the fire surroundings.

Special protective equipment for fire-fighters:

In case of fire: Wear self-contained breathing apparatus. Wear chemical resistant suit.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Remove all sources of ignition. Remove persons to safety. Wear personal protection equipment. Special danger of slipping by leaking/spilling product. See protective measures under point 7 and 8. See protective measures under point 7 and 8.

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

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

Advices on safe handling

Keep container tightly closed. When using do not eat, drink, smoke, sniff. Use only in well-ventilated areas. All work processes must always be designed so that the following is as low as possible: Inhalation Avoid contact with skin, eyes and clothes.

Precautions against fire and explosion:

Always close containers tightly after the removal of product. Use only in well-ventilated areas.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed and store in a cool, well-ventilated place. Protect against: UV radiation/sunlight. Only use the material in places where open light, fire and other flammable sources can be kept away.

Hints on joint storage

Do not store together with: Oxidizing agent . Organic peroxides . 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 exposure limit value:[ppm]	Occupational exposure limit value:[mg/m ³]	Limitation of exposure peaks:	Remark:

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

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

DNEL-/PNEC-values

DNEL value

Substance:	CAS-No.:	DNEL/DMEL
Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate	84434-11-7	worker inhalative long-term, systemic 4,93 mg/m ³ worker dermal long-term, systemic 1,4 mg/kg bw/day population inhalative long-term, systemic 0,87 mg/m ³ population dermal long-term, systemic 0,5 mg/kg bw/day population oral long-term, systemic 0,5 mg/kg bw/day
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid		worker inhalative long-term, systemic 98,7 mg/m ³ worker dermal long-term, systemic 140 mg/kg bw/day population inhalative long-term, systemic 17,4 mg/m ³ population dermal long-term, systemic 50 mg/kg bw/day population oral long-term, systemic 5 mg/kg bw/day

PNEC Value

Substance:	CAS-No.:	PNEC
Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate	84434-11-7	aquatic, freshwater 1,01 µg/l aquatic, marine water 0,101 µg/l sediment, freshwater 240 µg/kg dw sediment, marine water 24 µg/kg dw soil 47,5 µg/kg dw intermittent release, freshwater 10,1 µg/l intermittent release, marine water 1,01 µg/l

Additional information

Occupational exposure limit values : No data available, To follow: Toxicological information

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. Wear suitable protective clothing, gloves and eye/face protection.

Personal protection equipment

Wear protective gloves/protective clothing and eye/face protection. Only wear fitting, comfortable and clean protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection. Wear breathing apparatus if exposed to vapours/dusts/aerosols. Suitable respiratory protection apparatus: Combination filter device (DIN EN 141). With correct and proper use, and under normal conditions, breathing protection is not required.

Hand protection

Tested protective gloves are to be worn: DIN-/EN-Norms: EN ISO 374 Suitable material: Butyl caoutchouc (butyl rubber) , NBR (Nitrile rubber).

Eye/face protection

Eye glasses with side protection

Body protection:

Personal protection equipment . lab coat . 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:

Skin contact Inhalation

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state:

Liquid

Colour:

According to the product specification

Odour:

characteristic

Odour threshold:

-

Safety relevant basis data

	parameter	Value	unit	Remark
Melting point/freezing point:				not determined
Initial boiling point and boiling range:				not determined
Flammability:				not determined
lower flammability or explosive limits:				not determined
Upper flammability or explosive limits:				not determined
Flash point:	>	250	°C	Based on data of the components
Ignition temperature:				not determined
Decomposition temperature:				not determined
pH:		6~8		Based on data of the components
Kinematic viscosity:		1710	mPa*s	23 °C, 10/s
Water solubility (g/L):				
Partition coefficient: n-octanol/water:	Log KOW	5,30-5,62		Based on data of the components
Vapour pressure:				not determined
Density:		1,1	g/cm ³	
Relative density:				not determined
Particle properties:				not determined

9.2. Other information

Self-accelerating polymerization temperature (SAPT) : not determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Can polymerise exothermically if heated, exposed to air, sunlight or by addition of free radical initiators.

10.2. Chemical stability

The substance is chemically stable under recommended conditions of storage, use and temperature. Self-accelerating polymerization temperature (SAPT) : Carriage in accordance with 2.2.41.1.21 , not applicable

10.3. Possibility of hazardous reactions

Polymerization.

10.4. Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. UV-radiation/sunlight . Do not expose to temperatures exceeding 60 °C/140 °F.

10.5. Incompatible materials

Polymerization with heat evolution may occur in the presence of radical forming substances (e.g. peroxides), reducing substances, and/or heavy metal ions. Can polymerise exothermically if heated, exposed to air, sunlight or by addition of free radical initiators.

10.6. Hazardous decomposition products

In case of fire may be liberated: Carbon dioxide (CO₂). Carbon monoxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

There are no data available on the preparation/mixture itself. Data apply to the component with the highest toxicological risk.

M-factor: - **Acute toxicity (dermal):** > 2000 mg/kg
Acute toxicity (oral): > 2000 mg/kg **Acute toxicity (inhalative):** -

Acute toxicity

Substance:	CAS-No.:	Toxicological information
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid		LD50 oral (rat) > 2000 mg/kg LD50 dermal (rat) > 2000 mg/kg NOAEL Repr.-Tox. (Rat) 1000 mg/kg bw/Tag NOAEL STOT-RE (rat) 300 mg/kg/d
Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate	84434-11-7	LD50 oral (rat) > 5000 mg/kg LD50 dermal (rat) > 2000 mg/kg NOAEL (rat) 100 mg/kg bw/Tag LC50 inhalation (Rat) >= 2700 mg/l/7 h NOAEL Repr.-Tox. (Rat) 300 mg/kg bw/Tag

Skin corrosion/irritation:
irritant.

Serious eye damage/irritation:
irritant.

Respiratory or skin sensitisation:
May cause sensitization by skin contact. May cause sensitisation especially in sensitive humans. May cause sensitisation especially in sensitive humans. (based on the components)

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity:

There are no data available on the preparation/mixture itself. Based on available data, the classification criteria are not met. (based on the components) (based on the components)

Germ cell mutagenicity:

No experimental indications of genotoxicity in-vitro exist. No experimental indications of mutagenicity in-vitro exist. (based on the components)

Reproductive toxicity:

There are no data available on the preparation/mixture itself. Based on data of the components : CAS No. 84434-11-7 NOAEL: 300-1000 mg/kg bw/day

STOT-single exposure:
Based on available data, the classification criteria are not met. (based on the components)

STOT-repeated exposure:
NOAEL: 300 mg/kg bw/day (based on the components)

Aspiration hazard:
irritant.

SECTION 12: Ecological information

12.1. Toxicity

There are no data available on the mixture itself.

Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid		LC50 (fish, 96 h) > 100 mg/l LC50 (crustaceans, 48h) 6 mg/l EC50 (algae, 72 h) 100 mg/l EC50 (Daphnia, 48 h) > 100 mg/L
Ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate	84434-11-7	LC50 (fish, 96 h) 1,89 mg/L EC50 (aquatic invertebrates, 48h) 2,26 mg/l EC50 (algae, 72 h) 1,01 mg/L EC50 (microorganisms, 3h) > 1 g/L NOEC (fish, 96h) 1,29 mg/L

12.2. Persistence and degradability

There are no data available on the preparation/mixture itself. Not readily biodegradable (according to OECD criteria) (based on the components)

12.3. Bioaccumulative potential

There are no data available on the mixture itself. Log KOW: 5.30 - 5.62 (based on the components)

12.4. Mobility in soil

There are no data available on the mixture itself. Based on data of the components : log Koc: 3.69~3.88 @20 °C

12.5. Results of PBT and vPvB assessment

There are no data available on the mixture itself. The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII. (based on the components)

12.6 Endocrine disruptive effect

The substance/mixture contains no components $\geq 0.1\%$ classified as endocrine disruptors under REACH Art. 57(f), or Reg. (EU) 2017/2100 or 2018/605.

12.7. Other adverse effects

There are no data available on the mixture itself.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Appropriate disposal/Product:

Dispose of waste according to applicable legislation. Waste disposal according to directive 2008/98/EC, covering waste and dangerous waste.

Liquid, uncured resin: 08 01 11, 08 04 09;

Cured resin residues: 07 02 13, 20 01 39;

Cleaning waste: (Isopropanol, CL-1) 14 06 03; aqueous washing liquids 16 10 01.

Appropriate disposal / Package

Non-contaminated packages may be recycled.

Metal container: 15 01 04;

Plastic packaging: 15 01 02;

Special rules on packaging: 15 01 10 - Packaging that contains residues of hazardous substances or is contaminated by hazardous substances.

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

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

SECTION 14: Transport information

14.1. UN number

UN No.: -

14.2. UN proper shipping name

Land transport (ADR/RID)

-
-

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

-
-

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 quantity (LQ): -

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Remark No bulk transport by sea is intended.

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:

Substance / mixture / product / ingredients not listed

Regulation (EC) No. 1005/2009 on substances that lead to the depletion of the ozone layer:
not applicable , Substance / mixture / product / ingredients not listed

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

Regulation (EC) No 850/2004 [POP-Regulation]:
REGULATION (EU) 2019/102: Substance / mixture / product / ingredients not listed

Regulation (EU) No 649/2012 on the export and import of dangerous chemicals:

Substance / mixture / product / ingredients not listed

Use restriction according to REACH annex XVII, no.:

Use restriction according to REACH annex XVII, no.: not relevant not applicable

National regulations

Observe in addition any national regulations!

Restrictions of occupation

Observe restrictions to employment for juvenils 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.

Other regulations, restrictions and prohibition regulations

Use restriction according to REACH annex XVII, no.: 75, 78 not relevant ; CA Proposition 65 :
Substance(s) not listed. ; RoHS Directive 2011/65/EU : not relevant

15.2. Chemical Safety Assessment

For this preparation a chemical safety assessment has been carried out. -

For this substance a chemical safety assessment has not been carried out.

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.

Training advice

Observe instructions for use.

Recommended restrictions of use:

Reserved for industrial and professional use. According to directive 94/33/EC, juveniles are only allowed to handle this product as long as all effects of dangerous substances are prevented. Do not use for private purposes (household). refer to chapter 1.

Further remarks:

The information provided in this Safety Data Sheet is based on our current knowledge at the time of publication. It is intended to offer guidance for the safe handling of the product mentioned herein during storage, processing, transport, and disposal. These details are not transferable to other products. If the product is blended, mixed, or processed with other materials, or subjected to any treatment, the information in this Safety Data Sheet may not apply to the resulting new material, unless explicitly stated otherwise.

Documentation of changes:

Changes compared to version 2:

- 2 Update in accordance with 3
- 3 Update in accordance with CLP classification
- 8 Updated
- 9 Updated
- 10 Updated
- 11 Updated
- 12 Updated
- 13 Addition of waste codes

Changes compared to version 1.2:

All SECTIONS: Revision and update of content

Key literature references and sources for data

Information comes from reference works, the literature or safety data sheets of the components.

Abbreviations and acronyms

AC: Article category
ACGIH: American Conference of Governmental Industrial Hygienists
ADN: European agreement concerning the international carriage of dangerous goods by inland waterways (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
ADR: European agreement concerning the international carriage of dangerous goods by road (Accord européen relatif au transport international des marchandises dangereuses par route)
AGW: Occupational exposure limit
AOX: Adsorbable organically bound halogens
Bw/KG: Body weight
CAS: Chemical Abstracts Service
CMR: Substances classified as carcinogenic, mutagenic or toxic for reproduction
CSR: Chemical safety report
DIN: German Institute for Standardization (Deutsches Institut für Normung)
DNEL: Derived no-effect level
DPD: Dangerous Preparations Directive (Richtlinie 1999/45/EC)
DSD: Dangerous Substances Directive (Richtlinie 67/548/EWG)
DU: Downstream user
EC50: Effective concentration 50%
ECHA: European Chemicals Agency
EN: European standard
EWC/EWL: European Waste Catalogue
GHS: Globally harmonized system of classification and labelling of chemicals
IATA: International Air Transport Association
IBC: Intermediate bulk container
ICAO: International Civil Aviation Organization
IMDG Code: International Maritime Dangerous Goods Code
IMO: International Maritime Organization
ISO: International Organization for Standardization
LC50: Lethal concentration 50%
LD50: Lethal dose 50%
LEV: Local exhaust ventilation
LOAEL: Lowest observed adverse effect level
LOEL: Lowest observed effect level
MAK: Maximum workplace concentration (Maximale Arbeitsplatzkonzentration – DFG)
n.a.: Not applicable
n.b.: Not determined
NOAEC: No observed adverse effect concentration
NOAEL: No observed adverse effect level
NOEC: No observed effect concentration
OEL: Occupational exposure limit
PBT: Persistent, bioaccumulative and toxic
PNEC: Predicted no-effect concentration
POP: Persistent organic pollutant
PPE/PSA: Personal protective equipment
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
RID: Regulations concerning the international carriage of dangerous goods by rail (Règlement international concernant le transport des marchandises dangereuses par chemin de fer)
STEL: Short-term exposure limit
SVHC: Substance of very high concern
TLV: Threshold limit value
UN: United Nations
VOC: Volatile organic compounds
vPvB: Very persistent and very bioaccumulative
dw: Dry weight