

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

1.1. Product identifier

printodent GR-16 Xray

UFI SNNX-K48T-FT31-NXDW

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 Sens. 1, H317; Repr. 1B, H360Fd

2.2. Label elements

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

Hazard pictograms



GHS07, GHS08
Danger

Signal word:

Hazard statements:

H317 May cause an allergic skin reaction.
P360FD May damage fertility. Suspected of damaging the unborn child.

Precautionary statements:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P263 Avoid contact during pregnancy and while nursing.
P264.1 Wash hands thoroughly after handling.
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.
P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+313 IF exposed or concerned: Get medical advice/attention.
P333+313 If skin irritation or rash occurs: 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:

Hazardous component(s) for labelling: Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

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)
Annex XVII, entry: 75, 78 not relevant
Contains: SVHC substance.
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
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	01-2119972295-29-xxxx	< 03	Skin Sens. 1, H317; Repr. 1B, H360FD	M = 0 ATE (dermal) = > 2000 mg/kg bw ATE (oral) = > 5000 mg/kg bw 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. When in doubt or if symptoms are observed, get medical advice.
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. Seek medical attention if problems persist. Seek medical attention if problems persist.
After eye contact:	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention if problems persist.
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): May cause an allergic skin 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.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	Foam. ABC-powder. BC-powder. Carbon dioxide (CO ₂). Nitrogen.
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.

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). Use only antistatically equipped (spark-free) tools. 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. Dust must be exhausted directly at the point of origin.

Precautions against fire and explosion:

Always close containers tightly after the removal of product. Use only in well-ventilated areas. Usual measures for fire prevention.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed and in a well-ventilated place. Restrict access to stockrooms. Keep/Store only in original container. Always close containers tightly after the removal of product. Protect against: UV-radiation/sunlight. Heat .

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:
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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:
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DNEL-/PNEC-values

DNEL value

Substance:	CAS-No.:	DNEL/DMEL
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	worker inhalative long-term, systemic 0,822 mg/m ³ worker dermal long-term, systemic 0,233 mg/kg bw/day population inhalative long-term, systemic 0,145 mg/m ³ population dermal long-term, systemic 0,0833 mg/kg bw/day population oral long-term, systemic 0,0833 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
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	aquatic, freshwater 1,4 µg/l aquatic, marine water 0,14 µg/l sediment, freshwater 115 µg/kg dw sediment, marine water 11,5 µg/kg dw soil 22,2 µg/kg dw

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 exhaust at critical locations. Technical measures and the application of suitable work processes have priority over personal protection equipment. Dust must be exhausted directly at the point of origin.

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). dust formation: particulates filter device (DIN EN 143). 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). Thickness of the glove material, Breakthrough times and swelling properties of the material must be taken into consideration.

Eye/face protection

Wear eye/face 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

Melting point/freezing point:

parameter	Value	unit	Remark
			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:	closed crucible	113 °C	@ 1013 hPa
Ignition temperature:			not determined
Decomposition temperature:			not determined
pH:		6~8	Based on data of the components at 20°C.
Kinematic viscosity:	>	750 mPa*s	practically insoluble
Water solubility (g/L):			
Partition coefficient: n-octanol/water:	Log KOW	5,30-5,62	
Vapour pressure:			not determined
Density:		1,1 g/cm ³	at 20°C.
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

Polymerisation

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. 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
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	LC50 inhalation (Rat) 2000 mg/ kg bw LD50 oral (rat) > 5000 mg/kg bw LD50 dermal (rat) > 2000 mg/kg bw NOAEL (rat) 50 mg/kg bw/Tag NOAEL Repr.-Tox. (Rat) 60 mg/kg bw/Tag

Skin corrosion/irritation:

Frequently or prolonged contact with skin may cause dermal irritation. May cause an allergic skin reaction.

Serious eye damage/irritation:

irritant.

Respiratory or skin sensitisation:

May cause sensitization by skin contact. 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)

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:

Evidence for reproductive toxicity in experimental animals. CAS-No.: 75980-60-8, Repr. 1B

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:

The inhalation of dust/mist or aerosols causes irritation of the respiratory tract.

SECTION 12: Ecological information

12.1. Toxicity

There are no data available on the mixture itself. Data arise from reference works and literature.

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
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	EC50 (Daphnia, 48 h) 3,53 mg/L EC50 (algae, 72 h) > 2,01 mg/L EC50 (microorganisms, 3h) > 1000 mg/kg

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. Data apply to the main component. Log KOW: 5.30–5.62

12.4. Mobility in soil

There are no data available on the mixture itself. Data apply to the main component. log Koc: 3.69–3.88

12.5. Results of PBT and vPvB assessment

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

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

REGULATION (EU) 2024/590: 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.: 75, 78 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

This mixture contains the following substances of very high concern (SVHC) which are included in the Candidate List according to Article 59 of REACH: CAS No. 75980-60-8 Use restriction according to REACH annex XVII, no.: 75, 78 not applicable; 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

H317 May cause an allergic skin reaction.

360Fd May damage fertility. Suspected of damaging the unborn child.

Training advice

Observe instructions for use.

Recommended restrictions of use:

Reserved for industrial and professional use. The product should only be handled by persons over the age of 18, who were informed sufficiently about the dangerous nature or the product and about the necessary safety precautions. Do not use for private purposes (household).

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 6.2:

Revision of all sections.

Changes compared to version 6.1:

- 1.1 UFI code added.
- 3.2 Composition summarised according to CAS number.
- 3.2 Classification adapted.

Changes compared to version 6:

- 1.1 UFI code removed.

Changes compared to version 5:

- 2.2 Revised according to 3.2.
- 3.2 Composition further broken down.
- 11.1 Revised according to 3.2.
- 12.1 Revised according to 3.2.

Changes compared to version 4:

SECTION 4: 4.1 After inhalation, 4.2
SECTION 5: 5.1, 5.2, 5.3
SECTION 8: Eye protection, body protection
SECTION 10: 10.5

Key literature references and sources for data

Data arise from reference works and literature.

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