

## 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: 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

Telephone +49 (0)2374 920050-10

Telefax: +49 (0)2374 920050-50

#### Supplier

pro3dure medical GmbH

Am Burgberg 13  
D 58642 Iserlohn

Telephone +49 (0)2374 920050-10

Telefax: +49 (0)2374 920050-50

#### 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

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. 1/1A/1B, H317; STOT SE 3, H335

### 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.  
H335 May cause respiratory irritation.

**Precautionary statements:**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
P264 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 IF ON SKIN: Wash with plenty of water/soap.  
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.  
P312 Call a POISON CENTER/doctor if you feel unwell.  
P321 Specific treatment (see information 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 according to official regulations.

**Special labelling of particular preparations:**

Provide fresh air. Seek medical attention if problems persist.

## 2.3. Other hazards

-

## 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
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid	41637-38-1		80-100	Skin Irrit. 2, H315; Skin Sens. 1/1A/1B, H317; Eye Irrit. 2, H319; STOT SE 3, H335	ATE (dermal) = 2000 ATE (oral) = 2000 ATE (inhalativ) = Kein Wert ermittelbar
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8		< 03	Repr. 2, H361; Skin Sens. 1/1A/1B, H317; Aquatic Chronic 2, H411	M = 0 ATE (dermal) = 2000 ATE (oral) = 5000 ATE (inhalativ) = 2000

(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 Take off immediately all contaminated clothing.

**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, rinse immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Seek medical attention if problems persist.  
**After ingestion:** Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. Consult an ophthalmologist.

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

May cause sensitization by skin contact.

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

First Aid, decontamination, treatment of symptoms.

---

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

**Suitable extinguishing media** ABC-powder alcohol resistant foam BC-powder Carbon dioxide (CO<sub>2</sub>) Sand  
**Unsuitable extinguishing media** Water spray jet Excess water Full water jet

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

In case of fire may be liberated: Carbon dioxide (CO<sub>2</sub>). 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. Use water spray jet to protect personnel and to cool endangered containers.

##### 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

Wear personal protection equipment. Remove persons to safety. Remove all sources of ignition. Provide adequate ventilation.

#### 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

-

---

### SECTION 7: Handling and storage

## 7.1. Precautions for safe handling

### Advices on safe handling

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

### 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.

### 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/m³]	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/m³]	Limitation of exposure peaks:	Remark:
------------	----------	---------	---	---	-------------------------------	---------

### 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 short-term, systemic 3,52 mg/m³ worker dermal short-term, systemic 2 mg/m³/24h population inhalative short-term, systemic 870 µg/m³ population dermal short-term, systemic 1 mg/m³/24h population short-term, systemic 500 µg/m³/24h
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	worker inhalative long-term, systemic 0,822 mg/m³ worker dermal long-term, systemic 0,233 mg/kg bw/day population inhalative long-term, systemic 0,145 mg/m³ population dermal long-term, systemic 0,0833 mg/kg bw/day population oral long-term, systemic 0,0833 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

none

## 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**

Only wear fitting, comfortable and clean protective clothing.

**Respiratory protection**

With correct and proper use, and under normal conditions, breathing protection is not required. Respiratory protection necessary at: insufficient ventilation. Suitable respiratory protection apparatus: Protective respiration apparatus not using surrounding air (breathing apparatus) (DIN EN 133).

**Hand protection**

Tested protective gloves are to be worn: DIN-/EN-Norms: EN ISO 374 Suitable material: Butyl rubber.

**Eye/face protection**

Eye glasses with side protection

**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:**

Skin contact Inhalation

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

**Appearance**

<b>Physical state:</b>	Liquid
<b>Colour:</b>	diverse
<b>Odour:</b>	fruity
<b>Odour threshold:</b>	No data available

**Safety relevant basis data**

	parameter	Value	unit	Remark
<b>Melting point/freezing point:</b>				No data available
<b>Initial boiling point and boiling range:</b>				No data available
<b>Flammability:</b>				No data available
<b>lower flammability or explosive limits:</b>				No data available
<b>Upper flammability or explosive limits:</b>				No data available
<b>Flash point:</b>				No data available
<b>Ignition temperature:</b>				No data available
<b>Decomposition temperature:</b>				No data available

pH:		No data available
Kinematic viscosity:	500 Pa*s	at 20°C.
Water solubility (g/L):		
Partition coefficient: n-octanol/water:		No data available
Vapour pressure:		No data available
Density:	1,1 g/mL	at 20°C.
Relative density:		No data available
Particle properties:		No data available

## 9.2. Other information

none

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

### 10.2. Chemical stability

With proper storage and handling the product is stable.

### 10.3. Possibility of hazardous reactions

Polymerization.

### 10.4. Conditions to avoid

heat. frost. UV-radiation/sunlight.

### 10.5. Incompatible materials

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.

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

#### Acute toxicity

Substance:	CAS-No.:	Toxicological information
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
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid	41637-38-1	LD50 oral (rat) 2000 mg/kg LD50 dermal (rat) 2000 mg/kg

#### Skin corrosion/irritation:

Frequently or prolonged contact with skin may cause dermal irritation.

#### Serious eye damage/irritation:

irritant.

**Respiratory or skin sensitisation:**

May cause sensitisation especially in sensitive humans.

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

Carcinogenicity:

No information available.

Germ cell mutagenicity:

No information available.

Reproductive toxicity:

No information available.

**STOT-single exposure:**

No information available.

**STOT-repeated exposure:**

No information available.

**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 preparation/mixture itself.

#### Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
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
Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid	41637-38-1	LC50 (fish, 96 h) 100 mg/l LC50 (crustaceans, 48h) 6 mg/l EC50 (algae, 72 h) 100 mg/l

### 12.2. Persistence and degradability

There are no data available on the mixture itself.

### 12.3. Bioaccumulative potential

There are no data available on the mixture itself.

### 12.4. Mobility in soil

There are no data available on the mixture itself.

### 12.5. Results of PBT and vPvB assessment

There are no data available on the mixture itself.

### 12.6 Endocrine disruptive effect

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

### 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. Must not be disposed together with household garbage.

**Appropriate disposal / Package**

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

**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 -

---

## 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:

-

Regulation (EC) No. 1005/2009 on substances that lead to the depletion of the ozone layer:

-

Regulation (EC) No. 648/2004 (Detergents regulation)

-

Regulation (EC) No 850/2004 [POP-Regulation]:

-

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

-

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

-

### National regulations

Observe in addition any national regulations!

### Restrictions of occupation

none

### Other regulations, restrictions and prohibition regulations

-

## 15.2. Chemical Safety Assessment

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

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.
H335	May cause respiratory irritation.seri

### Training advice

Observe instructions for use.

### Recommended restrictions of use:

refer to chapter 1.

### Further remarks:

The information provided in this safety data sheet is correct to the best of our knowledge at the time of printing. The information is intended to provide guidance on the safe handling of the product specified in this safety data sheet during storage, processing, transport and disposal. The information is not transferable to other products. Insofar as the product is mixed, blended or processed with other materials or undergoes treatment, the information in this safety data sheet cannot be transferred to the new material thus produced, unless expressly stated otherwise.

**Documentation of changes:**

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: Artikelkategorie (Article Category)  
ACGIH: Rat für Arbeitsschutz und Gefahrstoffe, Amerika (American Conference of Government Industrial Hygienists)  
ADN: Europäisches Übereinkommen über die internationale Beförderung gefährlicher Güter auf Binnengewässern (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)  
ADR: Europäisches Übereinkommen über die internationale Beförderung gefährlicher Güter auf der Straße (Accord européen relatif transport des marchandises dangereuses par route)  
AGW: Arbeitsplatzgrenzwert  
AOX: Adsorbierbare organisch gebundene Halogene (Adsorbable Organic halogen compounds)  
Bw: Körpergewicht (Body weight)  
CMR: Stoffe klassifiziert als Krebserzeugend, Mutagen oder Reproduktionstoxisch (Carcinogenic, Mutagenic, toxic for Reproduction)  
CSR: Stoffsicherheitsbericht (Chemical Safety Report)  
DIN: Deutsches Institut für Normung / Deutsche Industrienorm  
DNEL: Grenzwert, unterhalb dessen der Stoff keine Wirkung ausübt (Derived No Effect Level)  
DPD: Zubereitungsrichtlinie / Richtlinie 1999-45-EC (Dangerous Preparations Directive)  
DSD: Stoffrichtlinie / Richtlinie 67-548-EC (Dangerous Substances Directive)  
DU: Nachgeschalteter Anwender (Downstream User)  
EC50: Wirksame Konzentration 50% (Effective Concentration 50%)  
ECHA: Europäische Chemikalienagentur  
EN: Europäische Norm  
EWC/EWL: Europäischer Abfallartenkatalog (European Waste Catalogue)  
IATA: Verband für den internationalen Lufttransport (International Air Transport Association)  
IBC: Großpackmittel (Intermediate Bulk Container)  
ICAO: Internationale Zivilluftfahrt-Organisation (International Civil Aviation Organization)  
IMDG Code: Gefahrgutvorschriften für den internationalen Seetransport (International Maritime Dangerous Goods Code)  
IMO: Internationale Seeschiffahrts-Organisation (International Maritime Organization)  
ISO: Internationale Normungsorganisation (International Standards Organisation)  
LC50: Lethale (Tödliche) Konzentration 50%  
LD50: Lethale (Tödliche) Dosis 50%  
LEV: Lokale Absaugung (Local exhaust ventilation)  
MAK: Maximale Arbeitsplatzkonzentration – DFG  
n.a.: nicht anwendbar  
n.b.: nicht bestimmt  
OEL: Arbeitsplatzgrenzwert (Occupational Exposure Limit)  
PBT: persistent, bioakkumulierbar, giftig (persistent, bioaccumulative, toxic)  
PNEC: Abgeschätzte Nicht-Effekt-Konzentration (Predicted No Effect Concentration)  
PPE/PSA: Persönliche Schutzausrüstung (Personal Protective Equipment)  
REACH: Registrierung, Bewertung und Zulassung von Chemikalien (Registration, Evaluation and Authorization of Chemicals)  
RID: Gefahrgutvorschriften für den Transport mit der Eisenbahn (Règlement International concernant le transport de marchandises dangereuses par chemin de fer)  
STEL: Grenzwert für Kurzzeiteexposition (Short-term Exposure Limit)  
SVHC: Stoff sehr hoher Besorgnis (Substance of Very High Concern)  
TLV: Arbeitsplatzgrenzwert (Threshold Limit Value)  
VOC: Flüchtige organische Kohlenwasserstoffe (Volatile Organic Compounds)  
vPvB: sehr persistent, sehr bioakkumulierbar (very persistent, very bioaccumulative)