

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

Version: 3 Replaces version: 2.1 Revision date: 10.01.2023 from: 09.01.2023

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

1.1. Product identifier printodent GR-13.3 model release

UFI

TTFW-F45H-1T3R-VGE7

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

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pro3dure medical GmbH This number is serviced during office hours.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS07

Warning

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: Hazard statements:

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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 east	sy 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:

-

2.3. Other hazards

-

SECTION 3: Composition / information on ingredients

3.1. Substances

not applicable

3.2. Mixtures

Mixture related information

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		60-80 %	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
Phenyl bis(2,4,6- trimethylbenzoyl)- phosphine oxide	162881-26-7		< 01 %	Skin Sens. 1, H317; Aquatic Chronic 4, H413	ATE (dermal) = 2000 mg/kg bw ATE (oral) = 2000 mg/kg bw ATE (inhalativ) = Kein Wert ermittelbar
Diphenyl(2,4,6- trimethylbenzoyl)phosphin e oxide	75980-60-8		< 01 %	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

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4.1. Description of first aid measures

General information:	Remove contaminated, saturated clothing immediately. When in doubt or if symptoms are observed, get medical advice. If unconscious place in recovery position and seek medical advice.
In case of inhalation:	Provide fresh air. In case of respiratory tract irritation, consult a physician.
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. 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

May cause sensitization by skin contact.

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

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable
extinguishing mediaABC-powder alcohol resistant foam BC-powder Carbon dioxide (CO2)Unsuitable
extinguishing mediaFull water jet Excess water Strong water jet

5.2. Special hazards arising from the substance or mixture

In case of fire: Wear self-contained breathing apparatus. Co-ordinate fire-fighting measures to the fire surroundings.

5.3. Advice for firefighters

General information

Do not inhale explosion and combustion gases. Co-ordinate fire-fighting measures to the fire surroundings.

Special protective equipment for fire-fighters:

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

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.

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

Avoid contact with skin and eyes.

Precautions against fire and explosion:

Usual measures for fire prevention.

7.2. Conditions for safe storage, including any incompatibilities Requirements for storage rooms and vessels

Keep container tightly closed 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)

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 ³]	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 ³]	peaks:	

DNEL-/PNEC-values

DNEL value Substance: CAS-No.: DNEL/DMEL Esterification products of 4,4'-isopropylidenediphenol, 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 ethoxylated and 2-methylprop-2-enoic acid population dermal short-term, systemic 1 mg/m3/24h population short-term, systemic 500 µg/m3/24h 75980-60-8 Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide 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 Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide 162881-26-7 worker inhalative long-term, systemic 21 mg/m³ worker dermal long-term, systemic 3 mg/kg bw/day population inhalative long-term, systemic 5,2 mg/m³ population dermal long-term, systemic 1,5 mg/kg bw/day population oral long-term, systemic 1,5 mg/kg bw/day

PNEC Value

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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	
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	162881-26-7	aquatic, freshwater 1 µg/l aquatic, marine water 1 µg/l sewage treatment plant 1 mg/l sediment, freshwater 0,712 mg/kg dw sediment, marine water 0,712 mg/kg dw soil 20 mg/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:

lab coat

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: Colour: Odour: Odour threshold:

Liquid yellowish characteristic

Safety relevant basis data EN - 04.2022

Melting point/freezing point: Initial boiling point and boiling range: Flammability: Iower flammability or explosive limits: Upper flammability or explosive limits: Flash point: Ignition temperature:	parameter	Value	unit	Remark
Decomposition temperature: pH: Kinematic viscosity: Water solubility (g/L): Partition coefficient: n- octanol/water: Vapour pressure: Density: Relative density: Particle properties:	<	40 m 1,1 g		

9.2. Other information

SECTION 10: Stability and reactivity

10.1. Reactivity

Sensitivity to light (photosentive).

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

Polymerization.

10.4. Conditions to avoid

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

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.

10.6. Hazardous decomposition products

none

SECTION 11: Toxicological information

11.1. Information on toxicological effects none

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

Substance:	CAS-No.:	Toxicological information
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	162881-26-7	LD50 oral (rat) > 2000 mg/kg
		LD50 dermal (rat) > 2000 mg/kg
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	41637-38-1	LD50 oral (rat) 2000 mg/kg
and 2-methylprop-2-enoic acid		LD50 dermal (rat) 2000 mg/kg

Skin corrosion/irritation:

sensitising.

Serious eye damage/irritation:

strongly irritant. Risk of serious damage to eyes.

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:

No information available.

STOT-repeated exposure:

No information available.

Aspiration hazard:

No data available

SECTION 12: Ecological information

12.1. Toxicity

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

Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	162881-26-7	LC50 (fish, 96 h) 0,09 mg/l
		LC50 (crustaceans, 48h) 1,175 mg/l
		EC50 (algae, 96 h) 0,26 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
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
		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 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.

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

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:

X X

14.4. Packing group

Packing group/ Packing Group:

14.5. Environmental hazards

ADR/RID / IMDG / ICAO-TI / IATA-DGR: Marine pollutant:

14.6. Special precautions for user

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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 none

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 No information available.

Other regulations, restrictions and prohibition regulations

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

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

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 2.1:

- 1 UFI-code added.
- 3.2 Composition adapted
- 5.1 Extinguishing agent revised
- 8 revised

Changes compared to version 1:

SECTION 4: 4.2 SECTION 5: 5.1 SECTION 6: 6.2 SECTION 7: 7.2 SECTION 12: 12.1 12.2 12.3 12.4 12.5 12.6

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 Hvaienists) 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 merchandises 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: Zubereitungsrichtline / Richtline 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 Seeschifffahrts-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, bioakkumlierbar, 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 Kurzzeitexposition (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 bioaccumulativ