

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

Version: 2.1 Revision date: 09.01.2023
Replaces version: 2 from: 02.08.2022

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

1.1. Product identifier

FLOW Denture

UFI 0P10-552P-VT3Y-2YC7

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

Telephone +49 (0)2374 920050-10

Am Burgberg 13 **Telefax:** +49 (0)2374 920050-50

D 58642 Iserlohn

Supplier

Ackuretta Technologies Private Ltd.

11493 Tainei City Neibu District

11493, Taipei City, Neihu District, **Telephone** +(886) 2 7737 8330 Section 1, Neihu Rd, No. 322, 6F

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 Telephone +49 (0)2374 920050-10

This number is serviced during office hours.

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

GHS07

Signal word: Warning

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 ea	sy to do. Continue rinsing.
P312	Call a POISON CENTER/doctor if you feel unwell.
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.

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Special labelling of particular preparations:

2.3. Other hazards

P501

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

Dispose of contents/container according to official regulations.

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		50-70 %	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
7,7,9(or 7,9,9)-trimethyl- 4,13-dioxo-3,14-dioxa- 5,12-diazahexadecane- 1,16-diyl bismethacrylate	72869-86-4	01- 2120751202-68- XXXX	20-30 %	Skin Sens. 1/1A/1B, H317; Aquatic Chronic 2, H411	M = 0 ATE (dermal) = 2000 mg/kg bw ATE (oral) = 5000 mg/kg bw ATE (inhalativ) = Kein Wert ermittelbar
3,6,9- trioxaundecamethylenedi methacrylate	109-17-1		10-20 %	Skin Irrit. 2, H315; Eye Irrit. 2, H319	M = 0 ATE (dermal) = 3000 mg/kg bw ATE (oral) = 5000 mg/kg bw ATE (inhalativ) = Kein Wert ermittelbar
Diphenyl(2,4,6- trimethylbenzoyl)phosphin e oxide	75980-60-8		< 02 %	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: 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 After contact with skin, wash immediately with plenty of water and soap. In case

contact: 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.

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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 ABC-powder alcohol resistant foam BC-powder Carbon dioxide (CO2) Sand

extinguishing media

Unsuitable Water spray jet Excess water Full water jet

extinguishing media

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. 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

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

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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

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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	Occupational	Limitation of	Remark:
			exposure limit	exposure limit	exposure	
			value:[ppm]	value:[mg/m³]	peaks:	

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

Substance:	CAS-No.:	Sc	ource:	Occupational	Occupational	Limitation of	Remark:
				exposure limit	exposure limit	exposure	
				value:[ppm]	value:[mg/m³]	peaks:	

DNEL-/PNEC-values DNEL value

Substance:	CAS-No.:	DNEL/DMEL
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 systemic 3,3 mg/m³ worker dermal systemic 1,3 mg/kg bw /24h population inhalative systemic 0,6 mg/m³ population dermal systemic 0,7 mg/kg bw/24h population systemic 0,3 mg/kg bw/24h
3,6,9-trioxaundecamethylenedimethacrylate	109-17-1	worker inhalative long-term, systemic 48,5 mg/m³ worker dermal long-term, systemic 13,9 mg/kg bw/day population inhalative long-term, systemic 14,5 mg/m³ population dermal long-term, systemic 8,33 mg/kg bw/day population oral long-term, systemic 8,33 mg/kg bw/day
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
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

PNEC Value

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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	aquatic, freshwater 0,01 µg/l aquatic, marine water 0,001 µg/l sewage treatment plant 3,61 µg/l sediment, freshwater 4,56 µg/kg dw sediment, marine water 0,46 µg/kg dw soil 0,91 µg/kg dw
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

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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

Physical state: Liquid
Colour: diverse
Odour: fruity

Odour threshold: No data available

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Safety relevant basis data	parameter	Value	unit	Remark
Melting point/freezing point: Initial boiling point and boiling	F			No data available No data available
range: Flammability:				No data available
lower flammability or explosive limits:				No data available
Upper flammability or explosive limits:				No data available
Flash point:				No data available
Ignition temperature:				No data available
Decomposition temperature:				No data available
pH:				No data available
Kinematic viscosity:		500	Pa*s	at 20°C.
Water solubility (g/L):				
Partition coefficient: n-				No data available
octanol/water:				
Vapour pressure:			, ,	No data available
Density:		1,1	g/mL	at 20°C.
Relative density:				No data available
Particle properties:				No data available

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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 or 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

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Acute toxicity (inhalative): Acute toxicity (oral): 2000 mg/kg

Acute toxicity

Substance:	CAS-No.:	Toxicological information
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
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
3,6,9-trioxaundecamethylenedimethacrylate	109-17-1	LD50 dermal (rat) > 3000 mg/kg
		LD50 oral (rat) > 5000 mg/kg
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		LD50 dermal (rat) > 2000 mg/kg
		NOAEL ReprTox. (Rat) 1000 mg/kg/d
		NOAEL STOT-RE (rat) 100 mg/kg/d

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
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
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
3,6,9-trioxaundecamethylenedimethacrylate	109-17-1	EC50 Daphnia (Daphnia magna) 48 h 381 mg/l
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-	72869-86-4	LC50 (Daphnia) > 1,2 mg/l
diazahexadecane-1,16-diyl bismethacrylate		EC50 (algae, 72 h) > 0,68 mg/l
		LC50 (fish, 96 h) 101 mg/L
		EC50 (Daphnia, 48 h) > 12 mg/L
		NOEC (algae, 72h) 21 mg/l

12.2. Persistence and degradability

There are no data available on the mixture itself.

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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.

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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:

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14.5. Environmental hazards	Vaa	Na
ADR/RID / IMDG / ICAO-TI / IATA-DGR: Marine pollutant:	Yes	No X X
14.6. Special precautions for user Land transport (ADR/RID) transport category: Special provisions:	tunnel restricti Limited quantit	
Sea transport (IMDG) EmS-No: - Special provisions: - Limited	d quantity (LQ): -	
14.7. Transport in bulk according to An Remark -	nex II of MARPO	OL 73/78 and the IBC Code
SECTION 15: Regulatory information		
15.1. Safety, health and environmental substance or mixture EU legislation Information on Regulation (EC) No 166/2006 Transfer Register:		·
Regulation (EC) No. 1005/2009 on substance	es that lead to the	depletion of the ozone layer:
Regulation (EC) No. 648/2004 (Detergents r	egulation)	
Regulation (EC) No 850/2004 [POP-Regulation -	ion]:	
Regulation (EU) No 649/2012 on the export	and import of dang	erous 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 prohibit	ion regulations	
15.2. Chemical Safety Assessment For this preparation a chemical safety assessment For this substance a chemical safety assessment		

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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

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.

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Documentation of changes:

Changes compared to version 5.1:

- 1.1 UFI-code added.
- documentation of changes added.

Changes compared to version 5:

1.1 UFI-code removed.

Changes compared to version 4:

- 1.1 UFI-code added.
- 1.4 Company name added.
- 2.2 Classification revised.
- 3.2 Composition further broken down.
- 4.2 Symptoms added.
- 5.1 Extinguishing media revised.
- 7.2 Storage instructions expanded.
- 8.1 Extended according to 3.2.
- 11.1 Extended according to 3.2.
- 12.1 Extended according to 3.2.16 Documentation of changes introduced.

Key literature references and sources for data

Data arise from reference works and literature.

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Abbreviations and acronyms

AC: Artikelkategorie (Article Category)

ACGIH: Rat für Arbeitsschutz und Gefahrstoffe, Amerika (American Conference of Government Industrial Hygienists)

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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)

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