

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

1.1. Product identifier

printodent GR-13.1 model

UFI U3EW-A4CJ-WT3U-NNRX

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; Aquatic Chronic 3, H412

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.
- H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P271 Use only outdoors or in a well-ventilated area.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P273 Avoid release to the environment.
- 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.
- 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.

Special labelling of particular preparations:

none

2.3. Other hazards

none

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	01-2119980659-17-XXXX	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) = No value can be determined
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-dijyl bismethacrylate	72869-86-4	01-2120751202-68-XXXX	< 03	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) = No value can be determined
2-Propenoic acid, reaction products with pentaerythritol	1245638-61-2	01-2119490003-49	< 03	Skin Sens. 1/1A/1B, H317; Eye Dam. 1, H318; Aquatic Chronic 2, H411	M = 1 ATE (dermal) = >2000 mg/kg ATE (oral) = >2000 mg/kg ATE (inhalativ) = >5 mg/l
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) = No value can be determined
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	01-2119972295-29-xxxx	< 01	Repr. 2, H361f	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 flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist. 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. 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

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 (CO₂)
- Unsuitable extinguishing media** Full water jet Excess water Strong water jet

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

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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 excluded: 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

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
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	75980-60-8	worker inhalativ long-term, systemic 0,822 mg/m ³ worker dermal long-term, systemic 0,233 mg/kg bw/day population inhalativ 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	41637-38-1	worker inhalativ short-term, systemic 3,52 mg/m ³ worker dermal short-term, systemic 2 mg/m ³ /24h population inhalativ short-term, systemic 870 µg/m ³ population dermal short-term, systemic 1 mg/m ³ /24h population short-term, systemic 500 µg/m ³ /24h
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 inhalativ systemic 3,3 mg/m ³ worker dermal systemic 1,3 mg/kg bw /24h population inhalativ systemic 0,6 mg/m ³ population dermal systemic 0,7 mg/kg bw/24h population systemic 0,3 mg/kg bw/24h
Phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide	162881-26-7	worker inhalativ long-term, systemic 21 mg/m ³ worker dermal long-term, systemic 3 mg/kg bw/day population inhalativ long-term, systemic 5,2 mg/m ³ population dermal long-term, systemic 1,5 mg/kg bw/day population oral long-term, systemic 1,5 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
2-Propenoic acid, reaction products with pentaerythritol	1245638-61-2	aquatic, freshwater 3,2 µg/l aquatic, marine water 0 ng/l sewage treatment plant 10 mg/l sediment, freshwater 1730 µg/l sediment, marine water 173 µg/l intermittent release, freshwater 32 µg/l soil 340 µg/kg dw
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
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

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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: characteristic
Odour threshold: -

Safety relevant basis data

	parameter	Value	unit	Remark
Melting point/freezing point:				No data available
Initial boiling point and boiling range:				No data available
Flammability:				No data available
lower flammability or explosive limits:				No data available
Upper flammability or explosive limits:				No data available
Flash point:	closed crucible	113	°C	@ 1013 hPa
Ignition temperature:				No data available
Decomposition temperature:				No data available
pH:				No data available
Kinematic viscosity:		750	mPa*s	23 °C, 10/s
Water solubility (g/L):				No data available
Partition coefficient: n-octanol/water:				No data available
Vapour pressure:				No data available at 20°C.
Density:		1,1	g/cm ³	No data available
Relative density:				No data available
Particle properties:				No data available

9.2. Other information

none

SECTION 10: Stability and reactivity

10.1. Reactivity

No known hazardous reactions.

10.2. Chemical stability

The substance is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

Polymerisation

10.4. Conditions to avoid

heat. 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 mixture itself.

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

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
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	72869-86-4	LD50 oral (rat) > 5000 mg/kg LD50 dermal (rat) > 2000 mg/kg NOAEL Repr.-Tox. (Rat) 1000 mg/kg/d NOAEL STOT-RE (rat) 100 mg/kg/d
2-Propenoic acid, reaction products with pentaerythritol	1245638-61-2	LD50 oral (rat) > 2000 mg/kg LD50 dermal (rabbit) > 2000 mg/kg LC50 inhalation (rat, 4 h) > 5 mg/L
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
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

Skin corrosion/irritation:
irritant.

Serious eye damage/irritation:
irritant.

Respiratory or skin sensitisation:
There are no data available on the preparation/mixture itself.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity:
There are no data available on the preparation/mixture itself.
Germ cell mutagenicity:
There are no data available on the preparation/mixture itself.

Reproductive toxicity:

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

STOT-single exposure:

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

STOT-repeated exposure:

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

Aspiration hazard:

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

SECTION 12: Ecological information

12.1. Toxicity

There are no data available on the 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
7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	72869-86-4	LC50 (Daphnia) > 1,2 mg/L 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
2-Propenoic acid, reaction products with pentaerythritol	1245638-61-2	LC50 (fish, 96 h) 3,2 mg/l LC50 (crustaceans, 48h) 13 mg/l EC50 (algae, 96 h) 33 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
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

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

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

Can be incinerated together with household waste in compliance with applicable technical regulations following consultation with approved waste disposal management companies and authorities in charge.

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 -

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

-

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

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.

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 6.3:

- 1.1 UFI code changed.
- 2.1 Revised in accordance with 3.2.
- 2.2 Revised in accordance with 3.2.
- 3.2 Composition broken down further.
- 8.1 Revised according to 3.2.
- 11.1 Revised in accordance with 3.2.
- 12.1 Revised according to 3.2.
- 15.1 WGK corrected.

Changes compared to version 6.2:

- 12.6 Information added.
- 15.1 WGK updated.

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 broken down further.
- 11.1 Revised in accordance with 3.2.
- 12.1 Revised in accordance with 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 Government 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 transport des marchandises dangereuses par route)

AOX: Adsorbable Organic halogen compounds

Bw: Body weight

CMR: Carcinogenic, Mutagenic, toxic for Reproduction

CSR: Chemical Safety Report

DIN: Deutsches Institut für Normung (German Institute for Standardization)

DNEL: Derived No Effect Level

DPD: Dangerous Preparations Directive / Directive 1999-45-EC

DSD: Dangerous Substances Directive / Directive 67-548-EC

DU: Downstream User

EC50: Effective Concentration 50%

ECHA: European Chemicals Agency

EN: European Norm

EWC/EWL: European Waste Catalogue

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 Standards Organisation

LC50: Median Lethal Concentration

LD50: Median Lethal Dose

LEV: Local exhaust ventilation

OEL: Occupational Exposure Limit

PBT: persistent, bioaccumulative, toxic

PNEC: Predicted No Effect Concentration

PPE: Personal Protective Equipment

REACH: Registration, Evaluation and Authorization of Chemicals

RID: Transporting dangerous goods by rail (Règlement International concernant le transport de marchandises dangereuses par chemin de fer)

STEL: Short-term Exposure Limit

SVHC: Substance of Very High Concern

TLV: Threshold Limit Value

VOC: Volatile Organic Compounds

vPvB: very persistent, very bioaccumulative