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

1.1. Product identifier

Product name: Leocryl® powder.
Product Description: Polymer powder based on Poly Methyl Methacrylate.

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified Use: Professional: End use of mixtures containing for manufacturing of dental prosthesis, expanding or repairing dental prosthesis, manufacturing of dental regulators and individually formed impression trays. Polymer for self-curing orthodontic acrylic, either for spray-on or doughing technique. For further information on the utilization, visit our web site: http://www.leone.it

Uses advised against: Mixtures containing unreacted liquid monomer intended to come into contact with skins or nails.

Refer to Exposure scenario Annex for further details.

1.3. Details of the supplier of the safety data sheet

Leone s.p.a.
I – 50019 Sesto Fiorentino – Firenze - Via P. a Quaracchi, 48/50
e-mail: research@leone.it – http://www.leone.it
Tel. +39 055.30.44.1 – Fax +39 055 374808.

1.4. Emergency telephone number

+39 055.30.44.1. An answering machine is on during closing time.
www.leone.it/emergency (EU and international telephone numbers).

2. SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

According to Regulation (EC) no. 1272/2008 [CLP].
Organic peroxide Not classified

Skin sensitisation, Category 1	H317
Hazardous to the aquatic environment — Chronic Hazard, Category 2	H411

Full text of H-statements: see section 16.

Adverse physicochemical, human health and environmental effects
May cause an allergic skin reaction. Toxic to aquatic life with long lasting effects.

2.2. Label elements

Not applicable.

2.3. Other hazards

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

3. SECTION 3: Composition/information on ingredients

3.2. Mixtures

Name	Product identifier	%W/W	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Dibenzoyl peroxide; benzoyl peroxide substance with national workplace exposure limit(s) (GB)	CAS-No.: 94-36-0 EC-No.: 202-327-6	1-5	Organic Peroxides, Type B, H241 Serious eye damage/eye irritation, Category 2, H319 Skin sensitisation, Category 1, H317 Hazardous to the aquatic environment — Acute Hazard, Category 1, H400 (M=10) Hazardous to the aquatic environment — Chronic Hazard, Category 1, H410 (M=10)

Full text of H-statements: see section 16.

4. SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation: Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest.

First-aid measures after skin contact: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. If skin irritation or rash occurs: Get

	medical advice/attention. Wash contaminated clothing before reuse.
First-aid measures after eye contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	Rinse mouth. Do NOT induce vomiting. Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after inhalation	May cause an allergic skin reaction.
Symptoms/effects after skin contact	May cause an allergic skin reaction.

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

Treat symptomatically.

5. SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	Water spray. Dry powder. Foam. Carbon dioxide. Sand.
Unsuitable extinguishing media	Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire Toxic fumes may be released.

5.3. Advice for firefighters

Firefighting instructions	Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting	Do not enter fire area without proper protective equipment, including respiratory protection.

6. SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures	Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing dust, fume. Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment	Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
Emergency procedures	Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

For containment	Collect spillage.
Methods for cleaning up	Mechanically recover the product. On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away from other materials.
Other information	Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

Concerning personal protective equipment to use, see section 8. Concerning disposal elimination after cleaning, see section 13.

7. SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid breathing dust. Wear personal protective equipment. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.
Hygiene measures	Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	Store in a well-ventilated place. Keep cool. Keep only in the original container in a cool well ventilated place. Keep container closed when not in use.
Incompatible products	Strong bases. Strong acids.
Incompatible materials	Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

No additional information available.

8. SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

dibenzoyl peroxide; benzoyl peroxide (94-36-0)	
United Kingdom - Occupational Exposure Limits	
Local name	Dibenzoyl peroxide
WEL TWA (OEL TWA) [1]	5 mg/m³
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

8.1.2. Recommended monitoring procedures

No additional information available.

8.1.3. Air contaminants formed

No additional information available.

8.1.4. DNEL and PNEC

dibenzoyl peroxide; benzoyl peroxide (94-36-0)	
DNEL/DMEL (Workers)	
Long-term - systemic effects, dermal	6.6 mg/kg bodyweight/day
Long-term - local effects, dermal	0.034 mg/m³
Long-term - systemic effects, inhalation	11.75 mg/m³
DNEL/DMEL (General population)	
Long-term - systemic effects,oral	1.65 mg/kg bodyweight/day
Long-term - systemic effects, inhalation	2.9 mg/m³
Long-term - systemic effects, dermal	3.3 mg/kg bodyweight/day
PNEC (Water)	
PNEC aqua (freshwater)	0.602 µg/l
PNEC aqua (marine water)	0.602 µg/l
PNEC aqua (intermittent, freshwater)	0.602 µg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	0.338 mg/kg dwt
PNEC sediment (marine water)	0.338 mg/kg dwt
PNEC (Soil)	
PNEC soil	0.0758 mg/kg dwt
PNEC (Oral)	
PNEC oral (secondary poisoning)	6.67 mg/kg food
PNEC (STP)	
PNEC sewage treatment plant	0.35 mg/l

8.1.5. Control banding

No additional information available.

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Ensure good ventilation of the work station.

8.2.2. Individual protection measures, such as personal protective equipment

Gloves. Protective clothing. Safety glasses. Avoid all unnecessary exposure.

Personal protective equipment symbol(s):

Eye and face protection

Wear eye glasses with side protection according to EN 166.

Skin and body protection:

Wear suitable protective clothing. Standard. EN 13034.

Hand protection:

Wear suitable gloves resistant to chemical penetration. The protective gloves to be used must comply with the specifications of the regulation 2016/425 and the resultant standard EN 374. penetration time (maximum wearing period): > 480 m. Suitable material: Nitrile rubber, Neoprene

Respiratory protection

Dust production: dust mask with filter type P2. Standard. EN 149

Thermal hazards

No additional information available.

8.2.3. Environmental exposure controls

Avoid release to the environment.

Other information:
Do not eat, drink or smoke during use.

9. SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid
Colour	Coloured
Odour	Typically methacrylate
Odour threshold	Not available
Melting point	150 – 230 °C
Freezing point	Not available
Boiling point	Not applicable
Flammability	Not applicable
Lower and upper explosion limit	Not applicable
Flash point	/
Auto-ignition temperature	465 °C
Decomposition temperature	Not applicable
pH	Not available
Kinematic viscosity	Not applicable
Water solubility	Negligible
Partition coefficient n-octanol/water (log value)	Not available
Vapour pressure	Not applicable
Vapour pressure at 50 °C	Not available
Density	Not applicable
Relative density	1.1 – 1.18
Relative vapour density at 20 °C	Not applicable
Particle size	Not available
Particle size distribution	Not available
Particle shape	Not available
Particle aspect ratio	Not available
Particle aggregation state	Not available
Particle agglomeration state	Not available
Particle specific surface area	Not available
Particle dustiness	Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available.

9.2.2. Other safety characteristics

Bulk density	0.6 – 0.7 g/ml
Appearance	Fine grains.
Explosive properties	Weakly to moderately explosive.
Viscosity, dynamic	Not applicable
pH solution	Not available

10. SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Het product is stabiel wanneer opgeslagen en behandeld onder aanbevolen omstandigheden.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

ignition sources. Direct sunlight.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11. SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	Not classified
Acute toxicity (dermal)	Not classified
Acute toxicity (inhalation)	Not classified

dibenzoyl peroxide; benzoyl peroxide (94-36-0)

LD50 oral rat	> 5000 mg/kg bodyweight Animal: rat, Animal sex: male
LC0, Inhalation, rat	24,3 mg/l/4h
Skin corrosion/irritation	Not classified pH: Not applicable
Additional information	Based on available data, the classification criteria are not met.
Serious eye damage/irritation	Not classified pH: Not applicable
Additional information	Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	May cause an allergic skin reaction.
Additional information	Based on available data, the classification criteria are not met
Germ cell mutagenicity	Not classified
Additional information	Based on available data, the classification criteria are not met
Carcinogenicity	Not classified
Additional information	Based on available data, the classification criteria are not met
Reproductive toxicity	Not classified
Additional information	Based on available data, the classification criteria are not met
STOT-single exposure	Not classified
Additional information	Based on available data, the classification criteria are not met
STOT-repeated exposure	Not classified
Additional information	Based on available data, the classification criteria are not met

dibenzoyl peroxide; benzoyl peroxide (94-36-0)

NOAEL (oral, rat, 90 days)	190 - 1000
NOAEL (dermal, rat/rabbit, 90 days)	833 mg/kg bodyweight/day
Aspiration hazard	Not classified
Additional information	Based on available data, the classification criteria are not met
Viscosity, kinematic	Not applicable

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

No additional information available.

11.2.2. Other information

Potential adverse human health effects and symptoms: Based on available data, the classification criteria are not met

12. SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	Toxic to aquatic life with long lasting effects
Ecology - water	Toxic to aquatic life with long lasting effects
Hazardous to the aquatic environment, short-term (acute)	Not classified
Hazardous to the aquatic environment, long-term (chronic)	Toxic to aquatic life with long lasting effects.

dibenzoyl peroxide; benzoyl peroxide (94-36-0)	
LC50 - Fish	0.0602 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri)
EC50 - Crustacea	0.11 mg/l Test organisms (species): Daphnia magna
EC50 72h - Algae	0.0422 – 0.0711 mg/l

12.2. Persistence and degradability

May cause long-term adverse effects in the environment.

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (Log Pow)	Not applicable
Bioaccumulative potential	Not established.

dibenzoyl peroxide; benzoyl peroxide (94-36-0)	
Partition coefficient n-octanol/water (Log Pow)	3.2

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available.

12.6. Endocrine disrupting properties

No additional information available

12.7 Other adverse effects

Additional information: Avoid release to the environment

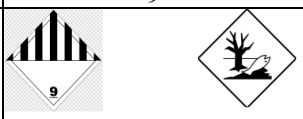
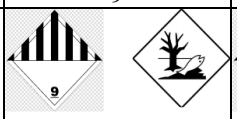
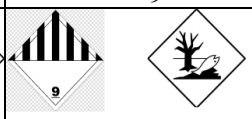
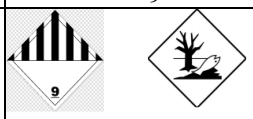
13. SECTION 13: Disposal considerations

In Italy dispose of according to Legislative Decree of April 3 2006 no. 152 "Regulations on environmental subject", application of European Directives on environmental protection, and subsequent modifications and integrations including those of Decree-Law No. 153 of 17 October 2024.

13.1. Waste treatment methods

Regional legislation (waste)	Disposal must be done according to official regulations.
Waste treatment methods	Dispose of contents/container in accordance with licensed collector's sorting instructions.
Product/Packaging disposal recommendations	Dispose in a safe manner in accordance with local/national regulations
Ecology - waste materials	Avoid release to the environment.

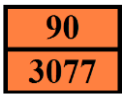
14. SECTION 14: Transport information

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
UN 3077	UN 3077	UN 3077	UN 3077	UN 3077
14.2. UN proper shipping name				
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide; benzoyl peroxide)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide; benzoyl peroxide)	Environmentally hazardous substance, solid, n.o.s. (dibenzoyl peroxide; benzoyl peroxide)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide; benzoyl peroxide)	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide; benzoyl peroxide)
Transport document description				
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide; benzoyl peroxide), 9, III, (-)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide; benzoyl peroxide), 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s. (dibenzoyl peroxide; benzoyl peroxide), 9, III	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide; benzoyl peroxide), 9, III	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide; benzoyl peroxide), 9, III
14.3. Transport hazard class(es)				
9 	9 	9 	9 	9 
14.4. Packing group				
III	III	III	III	III
14.5. Environmental hazards				
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes	Dangerous for the environment: Yes	Dangerous for the environment: Yes	Dangerous for the environment: Yes
No supplementary information available				

14.6. Special precautions for user

Overland transport

Classification code (ADR)	M7
Special provisions (ADR)	274, 335, 375, 601
Limited quantities (ADR)	5kg
Excepted quantities (ADR)	E1
Packing instructions (ADR)	P002, IBC08, LP02, R001
Special packing provisions (ADR)	PP12, B3
Mixed packing provisions (ADR)	MP10
Portable tank and bulk container instructions (ADR)	T1, BK1, BK2, BK3
Portable tank and bulk container special provisions (ADR)	TP33
Tank code (ADR)	SGAV, LGBV
Vehicle for tank carriage	AT
Transport category (ADR)	3
Special provisions for carriage - Packages (ADR)	V13

Special provisions for carriage - Bulk (ADR)	VC1, VC2
Special provisions for carriage - Loading, unloading and handling (ADR)	CV13
Hazard identification number (Kemler No.)	90
Orange plates	
Tunnel restriction code (ADR)	-
EAC code	2Z

Transport by sea

Special provisions (IMDG)	274, 335, 966, 967, 969
Limited quantities (IMDG)	5 kg
Excepted quantities (IMDG)	E1
Packing instructions (IMDG)	LP02, P002
Special packing provisions (IMDG)	PP12
IBC packing instructions (IMDG)	IBC08
IBC special provisions (IMDG)	B3
Tank instructions (IMDG)	BK1, BK2, BK3, T1
Tank special provisions (IMDG)	TP33
EmS-No. (Fire)	F-A
EmS-No. (Spillage)	S-F
Stowage category (IMDG)	A
Stowage and handling (IMDG)	SW23

Air transport

PCA Excepted quantities (IATA)	E1
PCA Limited quantities (IATA)	Y956
PCA limited quantity max net quantity (IATA)	30kgG
PCA packing instructions (IATA)	956
PCA max net quantity (IATA)	400kg
CAO packing instructions (IATA)	956
CAO max net quantity (IATA)	400kg
Special provisions (IATA)	A97, A158, A179, A197, A215
ERG code (IATA)	9L

Inland waterway transport

Classification code (ADN)	M7
Special provisions (ADN)	274, 335, 375, 601
Limited quantities (ADN)	5 kg
Excepted quantities (ADN)	E1
Carriage permitted (ADN)	T* B**
Equipment required (ADN)	PP, A***
Number of blue cones/lights (ADN)	0
Additional requirements/Remarks (ADN)	* Only in the molten state. ** For carriage in bulk see also 7.1.4.1. ** * Only in the case of transport in bulk.

Rail transport

Classification code (RID)	M7
Special provisions (RID)	274, 335, 375, 601
Limited quantities (RID)	5kg
Excepted quantities (RID)	E1
Packing instructions (RID)	P002, IBC08, LP02, R001
Special packing provisions (RID)	PP12, B3
Mixed packing provisions (RID)	MP10
Portable tank and bulk container instructions (RID)	T1, BK1, BK2, BK3
Portable tank and bulk container special provisions (RID)	TP33
Tank codes for RID tanks (RID)	SGAV, LGBV
Transport category (RID)	3
Special provisions for carriage – Packages (RID)	W13
Special provisions for carriage – Bulk (RID)	VC1, VC2
Special provisions for carriage - Loading, unloading and handling (RID)	CW13, CW31

Colis express (express parcels) (RID)	CE11
Hazard identification number (RID)	90

14.7. Maritime transport in bulk according to IMO instruments
Not applicable.

15. SECTION 15: Regulatory information
15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
Regulation (EC) no. 1272/2008 (Classification, labeling and packaging of substances and mixtures) and subsequent amendments, amending and repealing Directive 67/548/EEC and 1999/45/EC, and amending Regulation (EC) no. 1907/2006.
Directive 2009/161/EU (third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC).
This product is CE marked in accordance with the essential safety and performance requirements of Annex I of the European regulation on medical devices.
15.2. Chemical safety assessment
No chemical safety assessment has been carried out.

16. SECTION 16: Other information
This safety data sheet has been prepared in accordance with REACH Regulation (EC) 1907/2006 as amended by Regulation (EU) 2020/878.
The safety data sheet has been written according to relevant European provisions, on the basis of information received by the supplier of the mixture.
The product is intended for orthodontic and odontological use only. The use of the product has to be restricted to skilled and licensed professionals. The information relates only to specific product designated and is not intended as a warranty of quality.
Leone disclaims any responsibility arising out of the use of the information here furnished, or of the handling, the application or the manufacture of the product here described. The final user is called to verify the application and completeness of the information herein in relationship to the specific use and reliability of the rules and local applicable dispositions.
The present information does not imply any liberty to break patent rights.

Previous safety data sheet no. R02-7E dated 31/01/2023 is to be considered obsolete. In comparison to the preceding revision, meaningful changes have not been effected but only adjustments to the European provisions which regulate the compilation of safety data sheets.
Certain subsections of some sections are omitted because, as permitted by Annex II, Part B of Regulation (EU) 2020/878, they are not applicable.
This safety data sheet is subject to revision. Visit our web site www.leone.it for an updated version of the present sheet.

Hazard and precautionary statements
H241 Heating may cause a fire or explosion.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H411 - Toxic to aquatic life with long lasting effects.
P261 - Avoid breathing dust.
P280 - Wear protective gloves.
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.
P273 - Avoid release to the environment.
P391 - Collect spillage.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Legend
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS No.: numerical identifier that uniquely identifies a chemical substance, assigned by the Chemical Abstract Service.
CLP: Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008.
DMEL: Derived Minimal Effect level.
DNEL: Derived-No Effect Level.
EAC: Emergency Action Code. Identifies emergency actions in the event of an accident during the transport of dangerous goods.
EC-Number: EINECS and ELINCS Number (see also EINECS and ELINCS).

EC50: 50 % effective concentration. Corresponds to the concentration of a tested substance capable of causing 50 % effect changes (e.g. on growth) during a specified time interval.
EN: European Standard.
EN 166: Personal eye-protection – Specifications.
EN 13034: Protective clothing against liquid chemicals.
EN 374: Protective gloves against dangerous chemicals and micro-organisms.
EN 149: Respiratory protective devices - Filtering half masks against dust - Requirements, testing, marking
IATA: International Air Transport Association.
IMDG Code : International Maritime Dangerous Goods Code.
IMO: International Maritime Organization.
LC50: Lethal Concentration 50: lethal concentration of substance for 50% of organisms of a certain population during a certain exposure period.
LD50 Lethal Dose 50: the dose required to kill half the members of a tested population after a specified test duration.
NOAEL: No-Observed Adverse Effect Level.
OEL: Occupational Exposure Limit.
PBT: Persistent, Bioaccumulative And Toxic Substances.
PNEC: Predicted No-Effect Concentration.
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006.
RID: Regulations concerning the International Carriage of Dangerous Goods by Rail.
STOT: Specific target organ toxicity.
STP: Waste Water Treatment Plant.
TWA: Time-weighted average concentration of a chemical agent in the air within the breathing zone of a worker for an 8-hour working day.
vPvB: Very Persistent And Very Bioaccumulative Substances.
WEL: Workplace Exposure Limit.