

Orplid Keramik PF

Version number: SDSCH 2.0
Replaces version of: 2023-05-04 (SDSCH 1)

Revision: 2023-10-17

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

1.1 Product identifier

Trade name **Orplid Keramik PF**

Other names or synonyms Metal-ceramic alloy according to DIN EN ISO 22674 and DIN EN ISO 9693 for normally expanding ceramic materials for the fabrication of dental restorations.

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

Relevant identified uses Alloys
Alloy for manufacturing of dental prosthesis
Industrial use
Professional use

Sector of use industrial uses: uses of substances as such or in preparations at industrial sites
manufacture of fabricated metal products, except machinery and equipment
manufacture of basic metals, including alloys

Uses advised against For professional users only.

1.3 Details of the supplier of the safety data sheet

C.HAFNER GmbH + Co. KG
Maybachstr. 4
71299 Wimsheim
Germany

Telephone: +49-704490333-0
Website: www.c-hafner.de

Additional information

Manufacturer				
Country	Name	Postal code/city	Telephone	Website
Germany	C.HAFNER GmbH + Co. KG	71299 Wimsheim	+49-7044-90333-0	www.c-hafner.de

Supplier of the product				
Country	Name	Postal code/city	Telephone	Website
Germany	C.HAFNER GmbH + Co. KG	71299 Wimsheim	+49-7044-90333-0	www.c-hafner.de

e-mail (competent person) sicherheitsdatenblaetter@c-hafner.de

1.4 Emergency telephone number

Emergency information service This number is only for medical emergencies

Opening hours 24h emergency number

Country	Name	Street	Postal code/city	Telephone	Telefax
United Kingdom	NPIS UK			0344 892 0111	

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1.5 Additional relevant and available information there is no additional information

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification acc. to GHS

This mixture does not meet the criteria for classification.

2.2 Label elements

Labelling

not required

2.3 Other hazards

Inhalation of dust may cause respiratory irritation.

Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance in a concentration of $\geq 0,1\%$.

Endocrine disrupting properties

Does not contain an endocrine disruptor (EDC) in a concentration of $\geq 0,1\%$.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not relevant (mixture)

3.2 Mixtures

Description of the mixture

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms
Gold 99,99%	CAS No 7440-57-5 EC No 231-165-9	75 - < 90		
Platinum	CAS No 7440-06-4 EC No 231-116-1	10 - < 25		
Zinc	CAS No 7440-66-6 EC No 231-175-3 Index No 030-001-00-1	1 - < 5		
Tantalum	CAS No 7440-25-7 EC No 231-135-5	< 1		

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Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms
Iridium	CAS No 7439-88-5 EC No 231-095-9	< 1		

For full text of abbreviations: see SECTION 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

No special measures are necessary.

Following inhalation

Provide fresh air.

Following skin contact

Wash with plenty of soap and water.

Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and effects are not known to date.

4.3 Indication of any immediate medical attention and special treatment needed

none

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Material is not combustible under standard conditions.

Unsuitable extinguishing media

Water jet

5.2 Special hazards arising from the substance or mixture

none

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

Special protective equipment for firefighters

No special measures are necessary

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Follow emergency procedures such as the need to evacuate the danger area or to consult an expert.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

6.2 Environmental precautions

not required

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains, Take up mechanically

Advice on how to clean up a spill

Take up mechanically.

Other information relating to spills and releases

Place in appropriate containers for disposal.

6.4 Reference to other sections

Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Recommendations

- Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Use only in well-ventilated areas. Ground/bond container and receiving equipment. During thermal processing or machining, extraction measures are required on the processing machines.

- Specific notes/details

Dust deposits may accumulate on all deposition surfaces in a technical room.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Managing of associated risks

- Explosive atmospheres

Removal of dust deposits.

7.3 Specific end use(s)

See section 16 for a general overview.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

National limit values

Occupational exposure limit values (Workplace Exposure Limits)

Country	Name of agent	CAS No	Notation	Identifier	TWA [ppm]	TWA [mg/m ³]	STEL [ppm]	STEL [mg/m ³]	Ceiling-C [ppm]	Ceiling-C [mg/m ³]	Source
EU	platinum	7440-06-4		IOEL V		1					91/322/EEC
GB	platinum	7440-06-4		WEL		5					EH40/2005
GB	tantalum	7440-25-7		WEL		5		10			EH40/2005
GB	indium	7440-74-6		WEL		0.1		0.3			EH40/2005

Notation

Ceiling-C

STEL

TWA

ceiling value is a limit value above which exposure should not occur

short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)

time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours
time-weighted average (unless otherwise specified)

Relevant DNELs of components of the mixture

Name of substance	CAS No	Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
Zinc	7440-66-6	DNEL	50 mg/kg	human, oral	worker (industry)	chronic - systemic effects
Zinc	7440-66-6	DNEL	83 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Zinc	7440-66-6	DNEL	5 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects

Relevant PNECs of components of the mixture

Name of substance	CAS No	Endpoint	Threshold level	Organism	Environmental compartment	Exposure time
Zinc	7440-66-6	PNEC	14.4 µg/l	aquatic organisms	freshwater	short-term (single instance)
Zinc	7440-66-6	PNEC	7.2 µg/l	aquatic organisms	marine water	short-term (single instance)
Zinc	7440-66-6	PNEC	100 µg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Zinc	7440-66-6	PNEC	146.9 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
Zinc	7440-66-6	PNEC	162.2 mg/kg	aquatic organisms	marine sediment	short-term (single instance)

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Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
Zinc	7440-66-6	PNEC	83.1 mg/kg	terrestrial organisms	soil	short-term (single instance)

8.2 Exposure controls

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

In case of dusty working conditions wear suitable eye protection.

Skin protection

Preventive skin protection (barrier creams/ointments) is recommended.

- Hand protection

No gloves are required to handle the material as delivered. Adapt hand protection in consideration of other used substances. When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits.

- Other protection measures

Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

Respiratory protection

[In case of inadequate ventilation] wear respiratory protection.

Environmental exposure controls

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	solid
Colour	light yellow
Odour	odourless
Melting point/freezing point	1,050 – 1,165 °C at 1,013 mbar
Boiling point or initial boiling point and boiling range	not determined
Flammability	non-combustible
Lower and upper explosion limit	not determined
Flash point	not applicable
Auto-ignition temperature	not determined
Decomposition temperature	not relevant

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pH (value)	not applicable
Kinematic viscosity	not relevant
Solubility(ies)	not determined

Partition coefficient

Partition coefficient n-octanol/water (log value)	not relevant (inorganic)
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Vapour pressure	not determined
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Density and/or relative density

Density	19.1 g/cm ³ at 20 °C
Relative vapour density	information on this property is not available

Particle characteristics	no data available
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9.2 Other information

Information with regard to physical hazard classes	there is no additional information
Other safety characteristics	there is no additional information

SECTION 10: Stability and reactivity

10.1 Reactivity

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials".

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

10.5 Incompatible materials

Acids

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

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SECTION 11: Toxicological information

11.1 Information on toxicological effects

Test data are not available for the complete mixture.

Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

Classification acc. to GHS

This mixture does not meet the criteria for classification.

Acute toxicity

Shall not be classified as acutely toxic.

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity (STOT)

Shall not be classified as a specific target organ toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

11.2 Information on other hazards

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

12.2 Persistence and degradability

Data are not available.

12.3 Bioaccumulative potential

Data are not available.

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12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance in a concentration of $\geq 0,1\%$.

12.6 Endocrine disrupting properties

None of the ingredients are listed.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Waste treatment-relevant information

Recycling/reclamation of metals and metal compounds.

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packagings

Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

Relevant provisions relating to waste

List of wastes

- Product

12 01 04 non-ferrous metal dust and particles

- Product residues

12 01 03 non-ferrous metal filings and turnings

12 01 04 non-ferrous metal dust and particles

- Packagings

15 01 02 plastic packaging

Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities. Assign arising waste to a waste code according to the national list of waste.

SECTION 14: Transport information

14.1 UN number or ID number	not subject to transport regulations
14.2 UN proper shipping name	not relevant
14.3 Transport hazard class(es)	none
14.4 Packing group	not assigned
14.5 Environmental hazards	non-environmentally hazardous acc. to the dangerous goods regulations
14.6 Special precautions for user	
There is no additional information.	

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14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

Information for each of the UN Model Regulations

International Maritime Dangerous Goods Code (IMDG) - Additional information

Not subject to IMDG.

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Not subject to ICAO-IATA.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Relevant provisions of the European Union (EU)

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

none of the ingredients are listed

Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

Pollutant release and transfer registers (PRTR)			
Name of substance	CAS No	Remarks	Threshold for releases to air (kg/year)
Zinc	7440-66-6	(8)	200

Legend

(8) All metals shall be reported as the total mass of the element in all chemical forms present in the release

Water Framework Directive (WFD)

List of pollutants (WFD)			
Name of substance	CAS No	Listed in	Remarks
Platinum		a)	
Iridium		a)	
Zinc		a)	
Tantalum		a)	
Gold 99,99%		a)	

Legend

A) Indicative list of the main pollutants

Regulation on persistent organic pollutants (POP)

none of the ingredients are listed

National regulations (GB)

List of substances subject to authorisation (GB REACH, Annex 14) / SVHC - candidate list

none of the ingredients are listed

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Restrictions according to GB REACH, Annex 17

none of the ingredients are listed

National inventories

Country	Inventory	Status
EU	REACH Reg.	all ingredients are listed
CN	IECSC	all ingredients are listed
US	TSCA	all ingredients are listed (ACTIVE)

Legend

IECSC Inventory of Existing Chemical Substances Produced or Imported in China
REACH Reg. REACH registered substances
TSCA Toxic Substance Control Act

SECTION 16: Other information

Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)
1.1	Other names or synonyms: Metal-ceramic alloy according to DIN EN ISO 22674 and DIN EN ISO 9693 for normally expanding ceramic materials for the fabrication of dental restorations.	
1.1		Other names or synonyms: Metal-ceramic alloy according to DIN EN ISO 22674 and DIN EN ISO 9693 for normally expanding ceramic materials for the fabrication of dental restorations.
1.2	Sector(s) of use: industrial uses: uses of substances as such or in preparations at industrial sites manufacture of fabricated metal products, except machinery and equipment manufacture of basic metals, including alloys	Relevant identified uses: Alloys Alloy for manufacturing of dental prosthesis Industrial use Professional use
1.2		Sector of use: industrial uses: uses of substances as such or in preparations at industrial sites manufacture of fabricated metal products, except machinery and equipment manufacture of basic metals, including alloys
1.3	Details of the supplier of the safety data sheet: C.HAFNER GmbH + Co. KG Maybachstr. 4 71299 Wimsheim Germany Telephone: +49-704490333-0 Telefax: +49-70449033-40 e-Mail: Website: www.c-hafner.de	Details of the supplier of the safety data sheet: C.HAFNER GmbH + Co. KG Maybachstr. 4 71299 Wimsheim Germany Telephone: +49-704490333-0 Website: www.c-hafner.de
1.3		Manufacturer: change in the listing (table)
1.3		Supplier of the product: change in the listing (table)
1.3	e-mail (competent person): michael.huber@c-hafner.de (Dr. Michael Huber)	e-mail (competent person): sicherheitsdatenblaetter@c-hafner.de

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Section	Former entry (text/value)	Actual entry (text/value)
1.3	National contact: Dr .Michael Huber Telephone: +49-7231-424021-406 e-mail: Michael.huber@c-hafner.de	
1.4	Opening hours: 24h-Notrufnummer	Opening hours: 24h emergency number
1.4		Poison centre: change in the listing (table)
1.4		Opening hours: change in the listing (table)
1.5	Additional relevant and available information	Additional relevant and available information: there is no additional information
1.6	Remarks: there is no additional information	
3.2		Description of the mixture: change in the listing (table)
4.2	Most important symptoms and effects, both acute and delayed: Causes serious eye damage.	Most important symptoms and effects, both acute and delayed: Symptoms and effects are not known to date.
5.2	Special hazards arising from the substance or mixture	Special hazards arising from the substance or mixture: none
6.2	Environmental precautions: Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.	Environmental precautions: not required
7.1	- Measures to prevent fire as well as aerosol and dust generation: During thermal processing or machining, extraction measures are required on the processing machines.	- Measures to prevent fire as well as aerosol and dust generation: Use local and general ventilation. Use only in well-ventilated areas. Ground/bond container and receiving equipment. During thermal processing or machining, extraction measures are required on the processing machines.
8.1		Occupational exposure limit values (Workplace Exposure Limits): change in the listing (table)
8.1		Relevant DNELs of components of the mixture
8.1		Relevant DNELs of components of the mixture: change in the listing (table)
8.1		Relevant PNECs of components of the mixture
8.1		Relevant PNECs of components of the mixture: change in the listing (table)

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Section	Former entry (text/value)	Actual entry (text/value)
8.2	<p>Hand protection: Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374 and regulation (EU) Nr. 2016/425. In the case of wanting to use the gloves again, clean them before taking off and air them well. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits.</p>	<p>Hand protection: No gloves are required to handle the material as delivered. Adapt hand protection in consideration of other used substances. When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits.</p>
8.2	<p>Type of material: Leather gloves</p>	
8.2	<p>- Other protection measures: Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.</p>	<p>- Other protection measures: Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.</p>
9.2	<p>Other information: may intensify fire; oxidiser Of no significance.</p>	<p>Other information</p>
9.2	<p>Information with regard to physical hazard classes: hazard classes acc. to GHS (physical hazards): not relevant</p>	<p>Information with regard to physical hazard classes: there is no additional information</p>
10.3	<p>Possibility of hazardous reactions: Material reacts with strong acids and alkali.</p>	<p>Possibility of hazardous reactions: No known hazardous reactions.</p>
10.4	<p>Conditions to avoid</p>	<p>Conditions to avoid: There are no specific conditions known which have to be avoided.</p>
10.5	<p>Incompatible materials: Acids, Bases</p>	<p>Incompatible materials: Acids</p>
12.2	<p>Persistence and degradability</p>	<p>Persistence and degradability: Data are not available.</p>
12.2	<p>Biodegradation: The relevant substances of the mixture are readily biodegradable.</p>	
12.5	<p>Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB. Does not contain a PBT-/vPvB-substance in a concentration of $\geq 0,1\%$.</p>	<p>Results of PBT and vPvB assessment: Does not contain a PBT-/vPvB-substance in a concentration of $\geq 0,1\%$.</p>
12.6		<p>Endocrine disrupting properties: None of the ingredients are listed.</p>
13.1	<p>Waste treatment-relevant information: Recycling/reclamation of other inorganic materials.</p>	<p>Waste treatment-relevant information: Recycling/reclamation of metals and metal compounds.</p>
13.1		<p>List of wastes</p>
15.1		<p>Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)</p>
15.1		<p>Pollutant release and transfer registers (PRTR): change in the listing (table)</p>

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Section	Former entry (text/value)	Actual entry (text/value)
15.1	Water Framework Directive (WFD): none of the ingredients are listed	Water Framework Directive (WFD)
15.1		List of pollutants (WFD): change in the listing (table)
15.1		National regulations (GB)
15.1		List of substances subject to authorisation (GB REACH, Annex 14) / SVHC - candidate list: none of the ingredients are listed
15.1		Restrictions according to GB REACH, Annex 17: none of the ingredients are listed
15.1		National inventories: change in the listing (table)
15.2	Chemical safety assessment	
16		Abbreviations and acronyms: change in the listing (table)
16	Classification procedure: Health hazards. Environmental hazards. The method for classification of the mixture is based on ingredients of the mixture (additivity formula).	Classification procedure: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
91/322/EEC	Commission Directive on establishing indicative limit values by implementing Council Directive 80/1107/EEC
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EH40/2005	EH40/2005 Workplace exposure limits (http://www.nationalarchives.gov.uk/doc/open-government-licence/)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
GB REACH	The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019, SI 2019/758 (as amended)
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization

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Abbr.	Descriptions of used abbreviations
IMDG	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
IOELV	Indicative occupational exposure limit value
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
STEL	Short-term exposure limit
TWA	Time-weighted average
vPvB	Very Persistent and very Bioaccumulative
WEL	Workplace exposure limit

Key literature references and sources for data

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product. This Safety Data Sheet was created on voluntary basis. It is not necessary referring to Article 31 Regulation (EC) 1907/2006 (REACH).