Safety Data Sheet

acc. to Regulation (EC) No. 1907/2006 (REACH)

Orplid Keramik 3

Version number: SDSCH 3.0
Replaces version of: 2023-10-17 (SDSCH 2)

Revision: 2024-01-26

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

1.1 Product identifier

Trade name: **Orplid Keramik 3**

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	

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

Section	Hazard class	Category	Hazard class and category	Hazard statement
3.9	specific target organ toxicity - repeated exposure	2	STOT RE 2	H373

For full text of abbreviations: see SECTION 16.

The most important adverse physicochemical, human health and environmental effects

Delayed or immediate effects can be expected after short or long-term exposure.

2.2 Label elements

Labelling

- Signal word warning

- Pictograms

GHS08

- Hazard statements

H373 May cause damage to organs (lung) through prolonged or repeated exposure (if inhaled).

- Precautionary statements

P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P314 Get medical advice/attention if you feel unwell.
P501 Dispose of contents/container to industrial combustion plant.

- Hazardous ingredients for labelling Indium

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 ≥ 0,1%.

Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) in a concentration of ≥ 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 – < 91		
Platinum	CAS No 7440-06-4 EC No 231-116-1	5 – < 10		
Palladium	CAS No 7440-05-3 EC No 231-115-6	1 – < 5		
Indium	CAS No 7440-74-6 EC No 231-180-0	1 – < 5	STOT RE 1 / H372	
Silver 99.9 % (Massive Form, Particle Size > 1mm)	CAS No 7440-22-4 EC No 231-131-3	< 1		
Iridium	CAS No 7439-88-5 EC No 231-095-9	< 1		
Copper massive	CAS No 7440-50-8 EC No 231-159-6 Index No 029-024-00-X	< 1		

Name of substance	Specific Conc. Limits	M-Factors	ATE	Exposure route
Copper massive	-	-	300 $^{mg}/_{kg}$ 2,000 $^{mg}/_{kg}$	oral dermal

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

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

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

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.

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/m³]	STEL [ppm]	STEL [mg/m³]	Ceiling-C [ppm]	Ceiling-C [mg/m³]	Source
EU	platinum	7440-06-4		IOELV		1					91/322/EEC
EU	silver	7440-22-4		IOELV		0.1					2000/39/EC

Country	Name of agent	CAS No	Notation	Identifier	TWA [ppm]	TWA [mg/m³]	STEL [ppm]	STEL [mg/m³]	Ceiling-C [ppm]	Ceiling-C [mg/m³]	Source
GB	platinum	7440-06-4		WEL		5					EH40/2005
GB	silver	7440-22-4		WEL		0.01					EH40/2005
GB	copper	7440-50-8	dm	WEL		1		2			EH40/2005
GB	copper	7440-50-8	fume	WEL		0.2					EH40/2005
GB	indium	7440-74-6		WEL		0.1		0.3			EH40/2005

Notation

Ceiling-C	ceiling value is a limit value above which exposure should not occur
dm	as dusts and mists
fume	as fume
STEL	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)
TWA	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	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
Indium	7440-74-6	DNEL	6.3 µg/m³	human, inhalatory	worker (industry)	chronic - local effects
Indium	7440-74-6	DNEL	0.12 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Silver 99.9 % (Massive Form, Particle Size > 1mm)	7440-22-4	DNEL	0.1 mg/m³	human, inhalatory	worker (industry)	chronic - systemic effects
Copper massive	7440-50-8	DNEL	20 mg/m³	human, inhalatory	worker (industry)	acute - systemic effects
Copper massive	7440-50-8	DNEL	137 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Copper massive	7440-50-8	DNEL	273 mg/kg bw/day	human, dermal	worker (industry)	acute - systemic effects

Relevant PNECs of components of the mixture

Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
Palladium	7440-05-3	PNEC	0.027 µg/l	aquatic organisms	freshwater	short-term (single instance)
Palladium	7440-05-3	PNEC	0.003 µg/l	aquatic organisms	marine water	short-term (single instance)
Palladium	7440-05-3	PNEC	1.46 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)

Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
Palladium	7440-05-3	PNEC	0.274 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
Palladium	7440-05-3	PNEC	0.027 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
Palladium	7440-05-3	PNEC	0.012 mg/kg	terrestrial organisms	soil	short-term (single instance)
Indium	7440-74-6	PNEC	40.6 µg/l	aquatic organisms	freshwater	short-term (single instance)
Indium	7440-74-6	PNEC	40.6 µg/l	aquatic organisms	marine water	short-term (single instance)
Indium	7440-74-6	PNEC	51.6 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Indium	7440-74-6	PNEC	5,051 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
Indium	7440-74-6	PNEC	5,051 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
Indium	7440-74-6	PNEC	7.3 mg/kg	terrestrial organisms	soil	short-term (single instance)
Silver 99.9 % (Massive Form, Particle Size > 1mm)	7440-22-4	PNEC	0.04 µg/l	aquatic organisms	freshwater	short-term (single instance)
Silver 99.9 % (Massive Form, Particle Size > 1mm)	7440-22-4	PNEC	0.86 µg/l	aquatic organisms	marine water	short-term (single instance)
Silver 99.9 % (Massive Form, Particle Size > 1mm)	7440-22-4	PNEC	0.025 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Silver 99.9 % (Massive Form, Particle Size > 1mm)	7440-22-4	PNEC	438.1 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
Silver 99.9 % (Massive Form, Particle Size > 1mm)	7440-22-4	PNEC	438.1 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
Silver 99.9 % (Massive Form, Particle Size > 1mm)	7440-22-4	PNEC	1.41 mg/kg	terrestrial organisms	soil	short-term (single instance)
Copper massive	7440-50-8	PNEC	6.3 µg/l	aquatic organisms	freshwater	short-term (single instance)
Copper massive	7440-50-8	PNEC	5.2 µg/l	aquatic organisms	marine water	short-term (single instance)
Copper massive	7440-50-8	PNEC	230 µg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Copper massive	7440-50-8	PNEC	87 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
Copper massive	7440-50-8	PNEC	676 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
Copper massive	7440-50-8	PNEC	65 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. P3 (filters at least 99,95 % of airborne particles, colour code: White).

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	1,085 – 1,200 °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
pH (value)	not applicable
Kinematic viscosity	not relevant
Solubility(ies)	not determined

Partition coefficient

Partition coefficient n-octanol/water (log value)	not relevant (inorganic)

Vapour pressure	not determined

Density and/or relative density

Density	18.1 $^{g}/_{cm^3}$ at 20 °C
Relative vapour density	information on this property is not available

Particle characteristics	no data available

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

See below "Conditions to avoid".

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.

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

Acute toxicity

Shall not be classified as acutely toxic.

Acute toxicity estimate (ATE) of components

Name of substance	CAS No	Exposure route	ATE
Copper massive	7440-50-8	oral	300 $^{mg}/_{kg}$
Copper massive	7440-50-8	dermal	2,000 $^{mg}/_{kg}$

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)

Specific target organ toxicity - single exposure

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

Specific target organ toxicity - repeated exposure

May cause damage to organs (lung) through prolonged or repeated exposure (if inhaled).

Hazard category	Target organ	Exposure route
2	lung	if inhaled

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.

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 ≥ 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.

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)
Copper massive	7440-50-8	(8)	100

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
Palladium		a)	
Palladium		a)	
Platinum		a)	

List of pollutants (WFD)

Name of substance	CAS No	Listed in	Remarks
Iridium		a)	
Silver 99.9 % (Massive Form, Particle Size > 1mm)		a)	
Copper massive		a)	
Gold 99,99%		a)	
Indium		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

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)
2.3	Endocrine disrupting properties: Does not contain an endocrine disruptor (EDC) in a concentration of ≥ 0,1%.	Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) in a concentration of ≥ 0,1%.
3.2		Description of the mixture: change in the listing (table)
8.2	Respiratory protection: [In case of inadequate ventilation] wear respiratory protection.	Respiratory protection: [In case of inadequate ventilation] wear respiratory protection. P3 (filters at least 99,95 % of airborne particles, colour code: White).
11.1		Acute toxicity estimate (ATE) of components: change in the listing (table)
16		Abbreviations and acronyms: change in the listing (table)

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2000/39/EC	Commission Directive establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC
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)
ATE	Acute Toxicity Estimate
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)
ED	Endocrine disruptor
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
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
STOT RE	Specific target organ toxicity - repeated exposure
TWA	Time-weighted average

Abbr.	Descriptions of used abbreviations
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).

List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H372	Causes damage to organs (lung) through prolonged or repeated exposure (if inhaled).
H373	May cause damage to organs (lung) through prolonged or repeated exposure (if inhaled).

Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.