# Safety Data Sheet

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

# Orplid Keramik 2

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 2**

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<br>7440-57-5<br><br>EC No<br>231-165-9 | 75 – < 91 | | |
| Platinum | CAS No<br>7440-06-4<br><br>EC No<br>231-116-1 | 10 – < 25 | | |
| Indium | CAS No<br>7440-74-6<br><br>EC No<br>231-180-0 | 1 – < 5 | STOT RE 1 / H372 | |
| Iron | CAS No<br>7439-89-6<br><br>EC No<br>231-096-4 | < 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

## 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 |
| GB | platinum | 7440-06-4 | | WEL | | 5 | | | | | 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 |
| 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 |

Relevant PNECs of components of the mixture

| Name of substance | CAS No | End-point | Threshold level | Organism | Environmental compartment | Exposure time |
|---|---|---|---|---|---|---|
| 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) |

### 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 | yellow |
| Odour | odourless |
| Melting point/freezing point | 1,030 – 1,100 °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 | 19.1 $^{g}/_{cm^3}$ 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.

#### 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

**Water Framework Directive (WFD)**

List of pollutants (WFD)

| Name of substance | CAS No | Listed in | Remarks |
|---|---|---|---|
| Iron | | a) | |
| Platinum | | 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:<br>Does not contain an endocrine disruptor (EDC) in a concentration of ≥ 0,1%. | Endocrine disrupting properties:<br>Does not contain an endocrine disruptor (ED) in a concentration of ≥ 0,1%. |
| 3.2 | | Description of the mixture:<br>change in the listing (table) |
| 8.2 | Respiratory protection:<br>[In case of inadequate ventilation] wear respiratory protection. | Respiratory protection:<br>[In case of inadequate ventilation] wear respiratory protection. P3 (filters at least 99,95 % of airborne particles, colour code: White). |
| 16 | | Abbreviations and acronyms:<br>change in the listing (table) |

### 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 |

| Abbr. | Descriptions of used abbreviations |
|---|---|
| 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 |
| 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.