

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/13/2019

Version number 1

Reviewed on 09/12/2019

1 Identification

- **Product identifier**
- **Trade name:** **Porta Aurium 2, Auropal KF**
- **Application of the substance / the mixture**
Dental alloy
Manufacture of dental prosthesis
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285

- Ivoclar Vivadent Inc.
1-6600 Dixie Road
Mississauga, Ontario
L5T 2Y2
Canada
Phone: +1 905 670 8499
Fax: +1 905 670 3102
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666

- General SDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).

- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:**
Alloys do not require a label, providing they do not present a hazard to human health by inhalation, ingestion or contact with skin or to the aquatic environment in the form in which they are placed on the market.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**
- | | | |
|------------|---|----------------|
| HEALTH | 0 | Health = 0 |
| FIRE | 0 | Fire = 0 |
| REACTIVITY | 0 | Reactivity = 0 |

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- **Other hazards** Avoid breathing of grinding dust and vapours. Melted material may cause burns.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization:** Mixtures
- **Description:** Dental alloy

- **Dangerous components:**

CAS: 7440-22-4	silver	25-50%
CAS: 7440-05-3	palladium	2.5-10%
CAS: 7440-74-6	indium	2.5-10%

4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:**
Grinding dust: Supply fresh air; consult doctor in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** After contact with the molten product, cool rapidly with cold water.
- **After eye contact:**
Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** Seek medical treatment.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** The product is not flammable.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:**
No special measures required.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

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· Protective Action Criteria for Chemicals

· PAC-1:

CAS: 7440-22-4	silver	0.3 mg/m ³
CAS: 7440-05-3	palladium	6 mg/m ³
CAS: 7440-74-6	indium	0.3 mg/m ³

· PAC-2:

CAS: 7440-22-4	silver	170 mg/m ³
CAS: 7440-05-3	palladium	66 mg/m ³
CAS: 7440-74-6	indium	3.3 mg/m ³

· PAC-3:

CAS: 7440-22-4	silver	990 mg/m ³
CAS: 7440-05-3	palladium	400 mg/m ³
CAS: 7440-74-6	indium	20 mg/m ³

7 Handling and storage

· Handling:

· Precautions for safe handling

Only adequately trained personnel should handle this product.

For use in dentistry only.

Extractors are required on all machines used for thermal processing or splinter removal processes.

· Information about protection against explosions and fires: No special measures required.

· Conditions for safe storage, including any incompatibilities

· Storage:

· Requirements to be met by storerooms and receptacles: Store only in the original receptacle.

· Information about storage in one common storage facility: Not required.

· Further information about storage conditions: None.

· Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

· Additional information about design of technical systems: No further data; see item 7.

· Control parameters

· Components with limit values that require monitoring at the workplace:

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.

At this time, the remaining constituent has no known exposure limits.

CAS: 7440-22-4 silver

PEL Long-term value: 0.01 mg/m³

REL Long-term value: 0.01 mg/m³

TLV Long-term value: 0.1 mg/m³
metal: dust and fume

CAS: 7440-74-6 indium

REL Long-term value: 0.1 mg/m³
as In

TLV Long-term value: 0.1 mg/m³
as In

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- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Usual hygienic measures for dental practice and dental laboratories.
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
- **Breathing equipment:** Use respiratory protective device against the effects of fumes/dust/aerosol.
- **Protection of hands:** Protective gloves should always be worn during mechanical and thermal processing.
- **Material of gloves**
Thermal processing:
Heat protection gloves
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:**
Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Solid
Color:	Yellow
Odor:	Odorless
Odor threshold:	Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

Melting point/Melting range:	910 - 1110 °C (1670-2030 °F)
Boiling point/Boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Not determined.
- **Auto igniting:** Product is not selfigniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.
- **Vapor pressure:** Not applicable.
- **Density at 20 °C (68 °F):** 13.7 - 14.2 g/cm³ (114.327-118.499 lbs/gal)
- **Relative density** Not determined.
- **Vapor density** Not applicable.
- **Evaporation rate** Not applicable.
- **Solubility in / Miscibility with**

Water:	Insoluble.
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- **Partition coefficient (n-octanol/water):** Not determined.

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· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
Solids content:	100 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.
- **Carcinogenic categories**

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
- **DOT, ADR/RID/ADN, ADN, IMDG, IATA** Void
- **UN proper shipping name**
- **DOT** Void
- **ADR/RID/ADN, ADN, IMDG, IATA** Void
- **Transport hazard class(es)**
- **DOT, ADR/RID/ADN, ADN, IMDG, IATA**
- **Class** Void
- **Packing group**
- **DOT, ADR/RID/ADN, IMDG, IATA** Void
- **Environmental hazards:** Not applicable.
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.
- **Transport/Additional information:** Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
- **UN "Model Regulation":** Void

15 Regulatory information

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

- **SARA**

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

CAS: 7440-22-4 silver

- **TSCA (Toxic Substances Control Act):**

CAS: 7440-22-4 silver

CAS: 7440-05-3 palladium

CAS: 7440-74-6 indium

- **Hazardous Air Pollutants**

None of the ingredients is listed.

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· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

CAS: 7440-22-4 silver

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· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **GHS label elements** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to the Directive 93/42/EEC.

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Date of preparation / last revision** 09/13/2019 / -

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit