

## Safety Data Sheet according to WHS Regulations

Printing date 13.09.2022

Version number 3

Revision: 13.09.2022

Hazardous according to criteria of Australian Safety and Compensation Council.

### 1 Identification

· **Product identifier**

· **Trade name:** **Callisto CPG**

· **Relevant identified uses of the substance or mixture and uses advised against**

No further relevant information available.

· **Application of the substance / the mixture** 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

**Importer:**

Ivoclar Vivadent Pty. Ltd.

1- 5 Overseas Drive

Noble Park North VIC 3174

Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645

· **Further information obtainable from:**

Regulatory Affairs

sds@ivoclarvivadent.com

· **Emergency telephone number:** 131 126 (Poisons Information Centre - 24 hours / 7 days)

### 2 Hazard(s) Identification

· **Classification of the substance or mixture**

Ox. Sol. 2 H272 May intensify fire; oxidiser.

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin Sens. 1 H317 May cause an allergic skin reaction.

· **Label elements**

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS03 GHS08

· **Signal word** Danger

· **Hazard-determining components of labelling:**

cobalt

· **Hazard statements**

May intensify fire; oxidiser.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

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- **Precautionary statements**

Keep away from heat. - No smoking.

Take any precaution to avoid mixing with combustibles.

Avoid breathing dust/fume/gas/mist/vapours/spray.

Wear protective gloves/protective clothing/eye protection/face protection.

[In case of inadequate ventilation] wear respiratory protection.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- **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.

- **Information concerning particular hazards for human and environment:**

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.

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

### 3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**

- **Description:** Dental alloy

- **Dangerous components:**

CAS: 7440-48-4	cobalt Resp. Sens. 1, H334; Muta. 2, H341; Carc. 1B, H350; Repr. 1B, H360; Skin Sens. 1, H317	25-50%
CAS: 7440-05-3	palladium Ox. Sol. 2, H272	10-25%
CAS: 7440-47-3	chromium	10-25%
CAS: 7439-98-7	molybdenum	10-25%
CAS: 7440-33-7	tungsten	<2.5%
CAS: 7439-89-6	iron Acute Tox. 2, H300	<2.5%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 4 First Aid Measures

- **Description of first aid measures**

- **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.

Mechanical effects only.

- **After swallowing:** Seek medical treatment.

- **Information for doctor:**

- **Most important symptoms and effects, both acute and delayed** No further relevant information available.

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- **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:** Do not inhale explosion gases or combustion gases.

### 6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.
- **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.

### 7 Handling and Storage

- **Handling:**
- **Precautions for safe handling**  
Extractors are required on all machines used for thermal processing or splinter removal processes.  
For use in dentistry only.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **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 and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

· <b>Ingredients with limit values that require monitoring at the workplace:</b>	
<b>CAS: 7440-48-4 cobalt</b>	
WES	Long-term value: 0.05 mg/m <sup>3</sup>
	Sen
<b>CAS: 7440-47-3 chromium</b>	
WES	Long-term value: 0.5 mg/m <sup>3</sup>
<b>CAS: 7439-98-7 molybdenum</b>	
WES	Long-term value: 10* 5** mg/m <sup>3</sup>
	as Mo; *insoluble comp.; **soluble comp.

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**CAS: 7440-33-7 tungsten**

WES Short-term value: 10 mg/m<sup>3</sup>  
Long-term value: 5 mg/m<sup>3</sup>  
as W

- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Usual hygienic measures for dental practice and dental laboratories.
- **Respiratory protection:** 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.  
After use of gloves apply skin-cleaning agents and skin cosmetics.
- **Material of gloves**  
Mechanical processing:  
Leather gloves  
Strong material 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
Colour:	White
Odour:	Odourless
Odour threshold:	Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

Melting point/freezing point:	1185 - 1275 °C
Initial boiling point and boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Contact with combustible material may cause fire.
- **Auto-ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Not determined.
- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.
- **Vapour pressure:** Not applicable.
- **Density at 20 °C:** 9.3 g/cm<sup>3</sup>
- **Relative density** Not determined.

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· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with water:</b>	Insoluble.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <b>Solvent content:</b>	
<b>Solids content:</b>	100.0 %
· <b>Other information</b>	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**

· <b>LD/LC50 values relevant for classification:</b>
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<b>CAS: 7440-48-4 cobalt</b>
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Oral	LD50	6170 mg/kg (rat)
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- **Specific symptoms in biological assay:**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation**  
Sensitisation possible through inhalation.  
Sensitisation possible through skin contact.
- **Additional toxicological information:**  
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:  
Harmful  
Irritant

### 12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.

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- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Not hazardous for water.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 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 packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |  |  |
|--|--|
| <ul style="list-style-type: none"> <li>· <b>UN-Number</b></li> <li>· <b>ADG, ADN, IMDG, IATA</b></li> </ul>  | Void   |
| <ul style="list-style-type: none"> <li>· <b>UN proper shipping name</b></li> <li>· <b>ADG, ADN, IMDG, IATA</b></li> </ul>                            | Void   |
| <ul style="list-style-type: none"> <li>· <b>Transport hazard class(es)</b></li> <li>· <b>ADG, ADN, IMDG, IATA</b></li> <li>· <b>Class</b></li> </ul> | Void   |
| <ul style="list-style-type: none"> <li>· <b>Packing group</b></li> <li>· <b>ADG, IMDG, IATA</b></li> </ul>   | Void   |
| <ul style="list-style-type: none"> <li>· <b>Environmental hazards:</b></li> <li>· <b>Marine pollutant:</b></li> </ul>                                | No   |
| <ul style="list-style-type: none"> <li>· <b>Special precautions for user</b></li> </ul>  | Not applicable.  |
| <ul style="list-style-type: none"> <li>· <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b></li> </ul>                        | Not applicable.  |
| <ul style="list-style-type: none"> <li>· <b>Transport/Additional information:</b></li> </ul>   | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| <ul style="list-style-type: none"> <li>· <b>UN "Model Regulation":</b></li> </ul>  | Void   |

### 15 Regulatory information

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

- **Australian Inventory of Industrial Chemicals**

All ingredients are listed.

- **Standard for the Uniform Scheduling of Medicines and Poisons**

CAS: 7440-48-4 cobalt

S4

CAS: 7440-42-8 boron

S4

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· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS03    GHS08

· **Signal word** *Danger*

· **Hazard-determining components of labelling:**

cobalt

· **Hazard statements**

May intensify fire; oxidiser.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

· **Precautionary statements**

Keep away from heat. - No smoking.

Take any precaution to avoid mixing with combustibles.

Avoid breathing dust/fume/gas/mist/vapours/spray.

Wear protective gloves/protective clothing/eye protection/face protection.

[In case of inadequate ventilation] wear respiratory protection.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **Seveso category P8** OXIDISING LIQUIDS AND SOLIDS

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 50 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t

· **National regulations:**

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

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

· **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.

· **Relevant phrases**

H272 May intensify fire; oxidiser.

H300 Fatal if swallowed.

H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H341 Suspected of causing genetic defects.

H350 May cause cancer.

H360 May damage fertility or the unborn child.

· **Contact:**

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

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*IATA: International Air Transport Association*  
*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)*  
*LC50: Lethal concentration, 50 percent*  
*LD50: Lethal dose, 50 percent*  
*PBT: Persistent, Bioaccumulative and Toxic*  
*vPvB: very Persistent and very Bioaccumulative*  
*Ox. Sol. 2: Oxidizing solids – Category 2*  
*Acute Tox. 2: Acute toxicity – Category 2*  
*Resp. Sens. 1: Respiratory sensitisation – Category 1*  
*Skin Sens. 1: Skin sensitisation – Category 1*  
*Muta. 2: Germ cell mutagenicity – Category 2*  
*Carc. 1B: Carcinogenicity – Category 1B*  
*Repr. 1B: Reproductive toxicity – Category 1B*

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