

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 23.06.2015

Version number 3

Revision: 06.05.2015

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

- **1.1 Product identifier**
- **Trade name: Callisto CPG**
- **1.2 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
- **1.3 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
- **Further information obtainable from:**  
Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein  
Regulatory Affairs  
sds@ivoclarvivadent.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
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.  
Aquatic Chronic 4 H413 May cause long lasting harmful effects to aquatic life.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.

· **Hazard pictograms**



GHS03    GHS08

- **Signal word** Danger
- **Hazard-determining components of labelling:**  
cobalt
- **Hazard statements**  
H272 May intensify fire; oxidiser.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H317 May cause an allergic skin reaction.  
H413 May cause long lasting harmful effects to aquatic life.

- **Precautionary statements**  
P210            Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P221            Take any precaution to avoid mixing with combustibles.  
P261            Avoid breathing dust/fume/gas/mist/vapours/spray.  
P280            Wear protective gloves/protective clothing/eye protection/face protection.  
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

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P501 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.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

· **Description:** Dental alloy

· **Dangerous components:**

CAS: 7440-48-4 EINECS: 231-158-0	cobalt Resp. Sens. 1, H334; Skin Sens. 1, H317; Aquatic Chronic 4, H413	25-50%
CAS: 7440-05-3 EINECS: 231-115-6	palladium Self-heat. 2, H252; Ox. Sol. 2, H272	10-<25%
CAS: 7440-47-3 EINECS: 231-157-5	chromium substance with a Community workplace exposure limit	10-<25%
CAS: 7440-33-7 EINECS: 231-143-9	tungsten substance with a Community workplace exposure limit	1-<2.5%

· **Additional information:** For the wording of the listed risk phrases refer to section 16.

### SECTION 4: First aid measures

· **4.1 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.

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

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

### SECTION 5: Firefighting measures

· **5.1 Extinguishing media**

· **Suitable extinguishing agents:** The product is not flammable.

· **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

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- **5.3 Advice for firefighters**
- **Protective equipment:** Do not inhale explosion gases or combustion gases.

### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 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.

### SECTION 7: Handling and storage

- **7.1 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.
- **7.2 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.
- **7.3 Specific end use(s)** No further relevant information available.

### SECTION 8: Exposure controls/personal protection

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

#### · 8.1 Control parameters

- **Ingredients with limit values that require monitoring at the workplace:**

#### 7440-47-3 chromium

WEL Long-term value: 0.5 mg/m<sup>3</sup>

#### 7440-33-7 tungsten

WEL Short-term value: 3\* 10\*\* mg/m<sup>3</sup>Long-term value: 1\* 5\*\* mg/m<sup>3</sup>

\*soluble, \*\*insoluble compounds, as W

- **Additional information:** The lists valid during the making were used as basis.

#### · 8.2 Exposure controls

- **Personal protective equipment:**
- **General protective and hygienic measures:** Usual hygienic measures for dental practice.
- **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:

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*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).***SECTION 9: Physical and chemical properties**· **9.1 Information on basic physical and chemical properties**· **General Information**· **Appearance:**

· <b>Form:</b>	Solid
· <b>Colour:</b>	White
· <b>Odour:</b>	Odourless
· <b>Odour threshold:</b>	Not determined.

· **pH-value:** Not applicable.· **Change in condition**

· <b>Melting point/Melting range:</b>	1185 - 1275 °C
· <b>Boiling point/Boiling range:</b>	Undetermined.

· **Flash point:** Not applicable.· **Flammability (solid, gaseous):** Contact with combustible material may cause fire.· **Self-igniting:** Product is not selfigniting.· **Danger of explosion:** Not determined.· **Explosion limits:**

· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.

· **Vapour pressure:** Not applicable.

· <b>Density at 20 °C:</b>	9.3 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.

· **Solubility in / Miscibility with water:** Insoluble.· **Partition coefficient (n-octanol/water):** Not determined.· **Viscosity:**

· <b>Dynamic:</b>	Not applicable.
· <b>Kinematic:</b>	Not applicable.

· **Solvent content:**· **Solids content:** 100.0 %· **9.2 Other information** No further relevant information available.**SECTION 10: Stability and reactivity**· **10.1 Reactivity** No further relevant information available.· **10.2 Chemical stability** Stable under normal handling and storage conditions.

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

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**

· <b>LD/LC50 values relevant for classification:</b>	
<b>7440-48-4 cobalt</b>	
Oral	LD50 6170 mg/kg (rat)

- **Primary irritant effect:**

- **on the skin:** No irritant effect.

- **on the eye:** No irritating effect.

- **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

### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**

- **Recommendation**

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

- |                                   |        |
|-----------------------------------|--------|
| · <b>European waste catalogue</b> |        |
| 20 01 40                          | metals |

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

### SECTION 14: Transport information

· <b>14.1 UN-Number</b>	
· <b>ADR, ADN, IMDG, IATA</b>	Void
· <b>14.2 UN proper shipping name</b>	
· <b>ADR, ADN, IMDG, IATA</b>	Void
· <b>14.3 Transport hazard class(es)</b>	
· <b>ADR, ADN, IMDG, IATA</b>	
· <b>Class</b>	Void
· <b>14.4 Packing group</b>	
· <b>ADR, IMDG, IATA</b>	Void
· <b>14.5 Environmental hazards:</b>	
· <b>Marine pollutant:</b>	No
· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· <b>UN "Model Regulation":</b>	-

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
The product is a medical device according to the Directive 93/42/EEC.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 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**  
H252 Self-heating in large quantities; may catch fire.  
H272 May intensify fire; oxidiser.  
H317 May cause an allergic skin reaction.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H413 May cause long lasting harmful effects to aquatic life.

- **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  
IATA: International Air Transport Association  
GHS: Globally Harmonised System of Classification and Labelling of Chemicals  
EINECS: European Inventory of Existing Commercial Chemical Substances

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*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**Self-heat. 2: Self-Heating Substances and Mixtures, Hazard Category 2**Ox. Sol. 2: Oxidising Solids, Hazard Category 2**Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1**Skin Sens. 1: Sensitisation - Skin, Hazard Category 1**Aquatic Chronic 4: Hazardous to the aquatic environment - Chronic Hazard, Category 4***\* Data compared to the previous version altered.**

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