

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

Printing date 23.06.2015

Version number 8

Revision: 05.05.2015

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

- **1.1 Product identifier**
- **Trade name: .650 Fine Gold Solder**
- **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**
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.
- **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** Void
- **Signal word** Void
- **Hazard statements**
H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**
P273 Avoid release to the environment.
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.
- **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: 7440-50-8 | copper | 10-<25% |
| EINECS: 231-159-6 | substance with a Community workplace exposure limit | |

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| | | |
|-------------------|-----------------------------------------------------|---------|
| CAS: 7440-22-4 | silver | 10-<25% |
| EINECS: 231-131-3 | substance with a Community workplace exposure limit | |
| CAS: 7440-66-6 | zinc powder -zinc dust (stabilized) | 0.3-<1% |
| EINECS: 231-175-3 | Aquatic Acute 1, H400; Aquatic Chronic 1, H410 | |

· **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**
- **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.
If skin irritation continues, consult a doctor.
- **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.
- **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.
Do not allow to enter sewers/ surface or ground water.
- **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.
- **Information about fire - and explosion protection:** No special measures required.

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- **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:**

7440-50-8 copper

| | |
|-----|---------------------------------------------------------------------------------------------------------------------------|
| WEL | Short-term value: 2** mg/m ³ Long-term value: 0.2* 1** mg/m ³ *fume **dusts and mists (as Cu) |
|-----|---------------------------------------------------------------------------------------------------------------------------|

7440-22-4 silver

| | |
|-----|----------------------------------------|
| WEL | Long-term value: 0.1 mg/m ³ |
|-----|----------------------------------------|

- **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.
Wash hands before breaks and at the end of work.
Keep away from foodstuffs, beverages and feed.
- **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).

SECTION 9: Physical and chemical properties

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

| | |
|----------------|---------------|
| Form: | Solid |
| Colour: | Gold coloured |
| Odour: | Odourless |

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| · Odour threshold: | <i>Not determined.</i> |
| · pH-value: | <i>Not applicable.</i> |
| · Change in condition | |
| Melting point/Melting range: | <i>785 - 835 °C</i> |
| Boiling point/Boiling range: | <i>Undetermined.</i> |
| · Flash point: | <i>Not applicable.</i> |
| · Flammability (solid, gaseous): | <i>Not determined.</i> |
| · Self-igniting: | <i>Product is not selfigniting.</i> |
| · Danger of explosion: | <i>Product does not present an explosion hazard.</i> |
| · Explosion limits: | |
| Lower: | <i>Not determined.</i> |
| Upper: | <i>Not determined.</i> |
| · Vapour pressure: | <i>Not applicable.</i> |
| · Density: | <i>Not determined.</i> |
| · Relative density | <i>Not determined.</i> |
| · Vapour density | <i>Not applicable.</i> |
| · Evaporation rate | <i>Not applicable.</i> |
| · Solubility in / Miscibility with water: | <i>Insoluble.</i> |
| · Partition coefficient (n-octanol/water): | <i>Not determined.</i> |
| · Viscosity: | |
| Dynamic: | <i>Not applicable.</i> |
| Kinematic: | <i>Not applicable.</i> |
| · 9.2 Other information | <i>No further relevant information available.</i> |

SECTION 10: Stability and reactivity

- **10.1 Reactivity** *No further relevant information available.*
- **10.2 Chemical stability** *Stable under normal handling and storage conditions.*
- **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:**
- **Primary irritant effect:**
- **on the skin:** *No irritant effect.*
- **on the eye:** *Mechanical effects only.*
- **Sensitisation:** *No sensitising effects known.*

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- **Additional toxicological information:**
Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.

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:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **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.
 - **European waste catalogue**
- | | |
|----------|--------|
| 20 01 40 | metals |
|----------|--------|
- **Uncleaned packaging:**
 - **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|---------------------------------------------------------------------------------------|-----------------|
| · 14.1 UN-Number | |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · 14.4 Packing group | |
| · ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |

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- | | |
|--------------------------------------------|--------------------------------------------------------------------------------|
| · Transport/Additional information: | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · UN "Model Regulation": | - |

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**
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
- **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
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
Aquatic Acute 1: Hazardous to the aquatic environment - Acute Hazard, Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1
Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3
- *** Data compared to the previous version altered.**

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