

Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 12/19/2012

Version number 4

Reviewed on 12/19/2012

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

- **Product identifier**
- **Trade name: *IS-64***
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the preparation** *Manufacture of dental prothesis*
- **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 MSDS Assistance:*
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazards identification

- **Classification of the substance or mixture**
Ox. Sol. 2 H272 May intensify fire; oxidizer.

 - **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Oxidizing
Contact with combustible material may cause fire.
 - **Information concerning particular hazards for human and environment:**
Avoid breathing of grinding dust and vapours. Melted material may cause burns.
 - **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

 - **Label elements**
 - **GHS label elements**
The product is classified and labelled according to the Globally Harmonized System (GHS).
 - **Hazard pictograms**
- 

GHS03
- **Signal word** *Danger*

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- **Hazard statements**

May intensify fire; oxidizer.

- **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Take any precaution to avoid mixing with combustibles.

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

Keep/Store away from clothing/combustible materials.

In case of fire: Use for extinction: CO₂, powder or water spray.

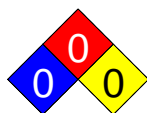
Dispose of contents/container in accordance with local/regional/national/international regulations.

- **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.

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

- **Other hazards**

- **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:**

| | | |
|-----------|-----------|---------|
| 7440-05-3 | palladium | 25-100% |
| 7440-22-4 | silver | 25-50% |
| 7440-31-5 | tin | 1-<10% |
| 7440-55-3 | gallium | 1-≤2.5% |
| 7440-74-6 | indium | 1-≤2.5% |
| 7440-06-4 | platinum | 1-≤2.5% |

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.

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- **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.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting 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.
- **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:** 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/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:**

7440-22-4 silver

| | |
|-----|---|
| PEL | 0.01 mg/m ³ metal and soluble compounds (as Ag) |
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| | |
|-----|---|
| REL | 0.01 mg/m ³ |
| TLV | 0.1 mg/m ³ metal: dust and fume |

7440-31-5 tin

| | |
|-----|------------------------------|
| PEL | 2 mg/m ³ metal |
| REL | 2 mg/m ³ |
| TLV | 2 mg/m ³ metal |

7440-74-6 indium

| | |
|-----|---|
| REL | 0.1 mg/m ³ and compounds, as In |
| TLV | 0.1 mg/m ³ |

7440-06-4 platinum

| | |
|-----|---|
| PEL | 0.002 mg/m ³ soluble salts, as Pt |
| REL | 1* 0.002** mg/m ³ *Metal **soluble salts, as Pt |
| TLV | 1* 0.002** mg/m ³ *metal **soluble salts, as Pt |

· **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.

· **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.

After use of gloves apply skin-cleaning agents and skin cosmetics.

· **Material of gloves**

Mechanical processing:

Leather gloves

Strong 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: White

· **Odor:** Odorless

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| | |
|---|--|
| · Odour threshold: | <i>Not determined.</i> |
| · pH-value: | <i>Not applicable.</i> |
| · Change in condition Melting point/Melting range: | <i>1150–1280 °C (2102–2336 °F)</i> |
| Boiling point/Boiling range: | <i>Undetermined.</i> |
| · Flash point: | <i>Not applicable.</i> |
| · Flammability (solid, gaseous): | <i>Not determined.</i> |
| · Auto 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> |
| · Vapor pressure: | <i>Not applicable.</i> |
| · Density at 20 °C (68 °F): | <i>11.2 g/cm³ (93.464 lbs/gal)</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> |
| · Solvent content: | |
| Solids content: | <i>100 %</i> |
| · Other information | <i>No further relevant information available.</i> |

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:**
- **Primary irritant effect:**
- *on the skin:* *No irritant effect.*
- *on the eye:* *No irritating effect.*
- **Sensitization:** *No sensitizing effects known.*

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- **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.

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.
- **Additional ecological information:**
- **General notes:** Generally 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 packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|-------------------------------------|--|
| · UN-Number | |
| · DOT | NA3077 |
| · ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT | |
| · Class | 9 Miscellaneous dangerous substances and articles. |
| · Label | 9 |
| · ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT | III |
| · ADR, IMDG, IATA | Void |

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- | | |
|--|-----------------|
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | - |

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
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| · Section 355 (extremely hazardous substances): |
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| None of the ingredients is listed. |
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| · Section 313 (Specific toxic chemical listings): |
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|-----------|--------|
| 7440-22-4 | silver |
|-----------|--------|

| | |
|-----------|--------|
| 7440-50-8 | copper |
|-----------|--------|

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| · TSCA (Toxic Substances Control Act): |
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| | |
|-----------|------|
| 7440-57-5 | Gold |
|-----------|------|

| | |
|-----------|--------|
| 7440-22-4 | silver |
|-----------|--------|

| | |
|-----------|--------|
| 7440-50-8 | copper |
|-----------|--------|

| | |
|-----------|----------|
| 7440-06-4 | platinum |
|-----------|----------|

| | |
|-----------|--------|
| 7440-74-6 | indium |
|-----------|--------|

| | |
|-----------|---------|
| 7439-88-5 | iridium |
|-----------|---------|

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| · Proposition 65 |
|-------------------------|

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| · Chemicals known to cause cancer: |
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|------------------------------------|
| None of the ingredients is listed. |
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| · Chemicals known to cause reproductive toxicity for females: |
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|------------------------------------|
| None of the ingredients is listed. |
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| · Chemicals known to cause reproductive toxicity for males: |
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|------------------------------------|
| None of the ingredients is listed. |
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|---|
| · Chemicals known to cause developmental toxicity: |
|---|

| |
|------------------------------------|
| None of the ingredients is listed. |
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| |
|----------------------------------|
| · Carcinogenic categories |
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|--|
| · EPA (Environmental Protection Agency) |
|--|

| | | |
|-----------|--------|--|
| 7440-22-4 | silver | |
|-----------|--------|--|

D

| | | |
|-----------|--------|--|
| 7440-50-8 | copper | |
|-----------|--------|--|

D

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|---|
| · TLV (Threshold Limit Value established by ACGIH) |
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|------------------------------------|
| None of the ingredients is listed. |
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|---|
| · NIOSH-Ca (National Institute for Occupational Safety and Health) |
|---|

| |
|------------------------------------|
| None of the ingredients is listed. |
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· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **GHS label elements**

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

· **Hazard pictograms**



GHS03

· **Signal word** *Danger*

· **Hazard statements**

May intensify fire; oxidizer.

· **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Take any precaution to avoid mixing with combustibles.

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

Keep/Store away from clothing/combustible materials.

In case of fire: Use for extinction: CO2, powder or water spray.

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

· **National regulations:**

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

The product is a medical device according to the EC-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.

· **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

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)