1 Identification

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

2 Hazard(s) identification

- Classification of the substance or mixture
  Ox. Sol. 2  H272  May intensify fire; oxidizer.
  Skin Irrit. 2  H315  Causes skin irritation.
  Eye Irrit. 2A  H319  Causes serious eye irritation.

- Label elements
- GHS label elements
  The product is classified and labeled according to the Globally Harmonized System (GHS).

- Hazard pictograms
  
  GHS03  GHS07

- Signal word Danger
- Hazard statements
  May intensify fire; oxidizer.
  Causes skin irritation.
  Causes serious eye irritation.

(Contd. on page 2)
Trade name: IS-64

- Precautionary statements
  Keep away from heat.
  Take any precaution to avoid mixing with combustibles.
  Wear protective gloves / eye protection / face protection.
  Wear protective gloves.
  Wear eye protection / face protection.
  Keep/Store away from clothing/combustible materials.
  Wash thoroughly after handling.
  If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  Specific treatment (see on this label).
  If skin irritation occurs: Get medical advice/attention.
  If eye irritation persists: Get medical advice/attention.
  In case of fire: Use for extinction: CO2, powder or water spray.
  If on skin: Wash with plenty of water.
  Take off contaminated clothing and wash it before reuse.
  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 = 1
    Fire = 0
    Reactivity = 0
  - HMIS-ratings (scale 0 - 4)
    HEALTH
    Health = 1
    FIRE
    Fire = 0
    REACTIVITY
    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 | 50-100% |
  | 7440-22-4  | silver    | 25-50%  |
  | 7440-31-5  | tin       | 2.5-<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.
  - After eye contact:
    Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
    Mechanical effects only.
  - 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: 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 | 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 |
| 7440-31-5 tin |
| PEL | Long-term value: 2 mg/m³ |
| REL | Long-term value: 2 mg/m³ |
| TLV | Long-term value: 2 mg/m³ |
| metal |
| 7440-74-6 indium |
| REL | Long-term value: 0.1 mg/m³ |
| TLV | Long-term value: 0.1 mg/m³ |
| as In |
| 7440-06-4 platinum |
| PEL | Long-term value: 0.002 mg/m³ |
| REL | Long-term value: 1* 0.002** mg/m³ |
| TLV | Long-term value: 1* 0.002** mg/m³ |
| *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
      - Odour threshold: Not determined.
    - pH-value: Not applicable.
  - Change in condition
    - Melting point/Melting range: 1150–1280 °C (2102–2336 °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): 11.2 g/cm³ (93.464 lbs/gal)
  - Relative density: Not determined.
  - Vapour density: Not applicable.
  - Evaporation rate: Not applicable.
  - Solubility in / Miscibility with
    - Water: Insoluble.
  - Partition coefficient (n-octanol/water): Not determined.
  - 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:
  - Primary irritant effect:
    - 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.
  - 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
Trade name: IS-64

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

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):
    - 7440-22-4 silver
    - 7440-50-8 copper
  - TSCA (Toxic Substances Control Act):
    - 7440-57-5 Gold
    - 7440-22-4 silver
    - 7440-50-8 copper
    - 7440-06-4 platinum
    - 7440-74-6 indium
    - 7439-88-5 iridium
- 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.
40.1.5

- Chemicals known to cause developmental toxicity:
  None of the ingredients is listed.

- Carcinogenic categories
  
<table>
<thead>
<tr>
<th>EPA (Environmental Protection Agency)</th>
</tr>
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</table>
  | 7440-22-4 silver                     | D       
  | 7440-50-8 copper                     | D       

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

- Hazard pictograms
  GHS03  GHS07

- Signal word Danger

- Hazard statements
  May intensify fire; oxidizer.
  Causes skin irritation.
  Causes serious eye irritation.

- Precautionary statements
  Keep away from heat.
  Take any precaution to avoid mixing with combustibles.
  Wear protective gloves / eye protection / face protection.
  Wear protective gloves.
  Wear eye protection / face protection.
  Keep/Store away from clothing/combustible materials.
  Wash thoroughly after handling.
  If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  Specific treatment (see on this label).
  If skin irritation occurs: Get medical advice/attention.
  If eye irritation persists: Get medical advice/attention.
  In case of fire: Use for extinction: CO2, powder or water spray.
  If on skin: Wash with plenty of water.
  Take off contaminated clothing and wash it before reuse.
  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 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 06/23/2015 / 4
- 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)
  - Ox. Sol. 2: Oxidising Solids, Hazard Category 2
  - Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
  - Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A
- * Data compared to the previous version altered.