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

- **Product identifier**
- **Trade name:** Harmony C-B 55
- **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

(Contd. on page 2)
Trade name: Harmony C-B 55

- **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:**
  - **7440-22-4** silver 25-50%
  - **7440-50-8** copper 1-<10%
  - **7440-05-3** palladium 1-<10%

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

(Contd. on page 3)
Trade name: Harmony C-B 55

- 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/m³
        - metal and soluble compounds (as Ag)
      - REL: 0.01 mg/m³
      - TLV: 0.1 mg/m³
        - metal: dust and fume
Add 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 breakthrough 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: Yellow
Odor: Odorless
Odour threshold: Not determined.

pH-value: Not applicable.

Change in condition

Melting point/Melting range: 905 – 975 °C (1661 – 1787 °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.
Trade name: Harmony C-B 55

- Vapor pressure: Not applicable.
- Density at 20 °C (68 °F): 13.6 g/cm³ (113.492 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.

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.
Trade name: Harmony C-B 55

- **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**
  - ADR, ADN, IMDG, IATA: NA3077
  - **DOT NA3077**
  - ADR, ADN, IMDG, IATA: Void
  - **Void**

- **UN proper shipping name**
  - ADR, ADN, IMDG, IATA: Void
  - **Void**

- **Transport hazard class(es)**
  - **DOT**
  - **Class**
    - Label: 9 Miscellaneous dangerous substances and articles.
    - **9**
  - **ADR, ADN, IMDG, IATA**
  - **Class**
    - Void

- **Packing group**
  - **DOT**
  - **ADR, IMDG, IATA**
  - **Class**
    - III
  - **void**

- **Environmental hazards**:
  - **Marine pollutant**: No
  - **Not applicable.**

- **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"**: -

(Contd. on page 7)
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.
    - Chemicals known to cause developmental toxicity:
      None of the ingredients is listed.
  - Carcinogenic categories
    - EPA (Environmental Protection Agency)
      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.
  - 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
    ![](image)
    - Signal word Danger
Trade name: Harmony C-B 55

- **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)