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

1.1 Product identifier

Trade name: Universal Solder PKF

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 prothesis
Dental alloy

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 2 H411 Toxic 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

GHS09

Signal word Void

Hazard statements
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements
P273 Avoid release to the environment.
P391 Collect spillage.
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.

(Contd. on page 2)
SECTION 3: Composition/information on ingredients

- 3.2 Chemical characterisation: Mixtures
  - Description: Dental alloy
  - Dangerous components:
    - CAS: 7440-22-4 EINECS: 231-131-3 silver substance with a Community workplace exposure limit 25-50%
    - CAS: 7440-66-6 EINECS: 231-175-3 zinc powder -zinc dust (stabilized) Aquatic Acute 1, H400; Aquatic Chronic 1, H410 3-<10%
    - CAS: 7440-06-4 EINECS: 231-116-1 platinum Ox. Sol. 2, H272 2.5-<3%
  - 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.
- 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: CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- 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.

(Contd. on page 3)
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.

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: Store away from flammable substances.

7.3 Specific end use(s)
No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>7440-22-4 silver</td>
<td></td>
</tr>
<tr>
<td>WEL</td>
<td>Long-term value: 0.1 mg/m³</td>
</tr>
<tr>
<td>7440-06-4 platinum</td>
<td></td>
</tr>
<tr>
<td>WEL</td>
<td>Long-term value: 5 mg/m³</td>
</tr>
</tbody>
</table>

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).

(Contd. on page 4)
**SECTION 9: Physical and chemical properties**

- **9.1 Information on basic physical and chemical properties**
  - General Information
    - Appearance:
      - Form: Solid
      - Colour: Grey
    - Odour:
      - Odour: Odourless
      - Odour threshold: Not determined.
    - pH-value: Not applicable.
    - Change in condition
      - Melting point/Melting range: 1100 - 1165 °C
      - Boiling point/Boiling range: Undetermined.
    - Flash point: Not applicable.
    - Flammability (solid, gaseous):
      - Not determined.
    - Self-igniting:
      - Product is not self-igniting.
    - Danger of explosion:
      - Product does not present an explosion hazard.
    - Explosion limits:
      - Lower: Not determined.
      - Upper: Not determined.
    - Vapour pressure: Not applicable.
    - Density:
      - Not determined.
    - 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.
  - **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.
- **10.3 Thermal decomposition / conditions to be avoided**
  - No decomposition if used according to specifications.
- **10.4 Possibility of hazardous reactions**
  - Reacts with reducing agents.
- **10.5 Conditions to avoid**
  - No further relevant information available.
- **10.6 Incompatible materials**
  - No further relevant information available.
- **10.7 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.
- 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 2 (German Regulation) (Self-assessment): hazardous for water
  Do not allow product to reach ground water, water course or sewage system.
  Danger to drinking water if even small quantities leak into the ground.
- 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.
  - 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: 1479 OXIDIZING SOLID, N.O.S., ENVIRONMENTALLY HAZARDOUS
  - ADN, IMDG, IATA: Void
- 14.3 Transport hazard class(es)
  - ADR, ADN, IMDG, IATA: Void
Trade name: Universal Solder PKF

- 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.
- Transport/Additional information: Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
- UN "Model Regulation": UN1479, OXIDIZING SOLID, N.O.S., ENVIRONMENTALLY HAZARDOUS, 5.1, II

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
  H272 May intensify fire; oxidiser.
  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)
  Ox. Sol. 2: Oxidising Solids, Hazard Category 2
  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 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2