1 Identification

- Product identifier
  - Trade name: BioUniversal KF

- Relevant identified uses of the substance or mixture and uses advised against
  - No further relevant information available.

- Application of the substance / the mixture
  - Dental alloy

- 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
  - The product is not classified according to the Globally Harmonized System (GHS).

- Label elements
  - GHS label elements Void
  - Hazard pictograms Void
  - Signal word Void
  - Hazard statements Void

- 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 = 2
    - Fire = 0
    - Reactivity = 0

(Contd. on page 2)
Trade name: BioUniversal KF

- HMIS-ratings (scale 0 - 4)
  - Health = 2
  - 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:
    - Alloy made of:
      - Au 74.3% (CAS: 7440-57-5), Ag 14.0% (CAS: 7440-22-4), Pd 6.0% (CAS: 7440-05-3), Zn 3.2% (CAS: 7440-66-6), In 1.0% (CAS: 7440-74-6), Pt <1.0% (CAS: 7440-06-4), Re <1.0% (CAS: 7440-15-5), Fe <1.0% (CAS: 7439-89-6), Ta <1.0% (CAS: 7440-25-7), B <1.0% (CAS: 7440-42-8)
  - Dangerous components: Void

4 First-aid measures

- Description of first aid measures
  - General information: No special measures required.
  - After inhalation: Supply fresh air; consult doctor in case of complaints.
  - After skin contact:
    - Generally the product does not irritate the skin.
    - After contact with the molten product, cool rapidly with cold water.
  - After eye contact:
    - Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
  - After swallowing: Seek immediate medical advice.
  - 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.
    - Use fire fighting measures that suit the environment.
  - 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.
Safety Data Sheet
acc. to OSHA HCS

Printing date 06/23/2015
Reviewed on 05/06/2015
Version number 2

Trade name: BioUniversal KF

- 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: Ensure good ventilation/exhaustion at the workplace.
  - 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: Not required.

- 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:
  The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- Material of gloves
  The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- 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: Safety glasses

9 Physical and chemical properties

- Information on basic physical and chemical properties
  - General Information

- Appearance:
  Form: Solid
  Color: Yellow
Trade name: BioUniversal KF

- **Odor:** Odorless
- **Odour threshold:** Not determined.
- **pH-value:** Not applicable.
- **Change in condition**
  - **Melting point/Melting range:** 910-1020 °C (1670-1868 °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):** 15.6 g/cm³ (130.182 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.
- **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.
  - **Other information (about experimental toxicology):** Non-cytotoxic
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: Smaller quantities can be disposed of with household waste.
- Uncleaned packagings:
  - Recommendation: Disposal must be made according to official regulations.

14 Transport information

- UN-Number
  - DOT, ADR, ADN, IMDG, IATA: Void
- UN proper shipping name
  - DOT, ADR, ADN, IMDG, IATA: Void
- Transport hazard class(es)
  - DOT, ADR, ADN, IMDG, IATA: Void
- Class
  - DOT, ADR, IMGD, IATA: Void
- Packing group
  - DOT, ADR, IMDG, IATA: Void
- Environmental hazards:
  - Marine pollutant: No
- Special precautions for user
  - Not applicable.
40.1.5 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": -

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): None of the ingredients is listed.
  - TSCA (Toxic Substances Control Act): None of the ingredients is listed.

- 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) None of the ingredients is listed.
  - 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 Void
  - Hazard pictograms Void
  - Signal word Void
  - Hazard statements Void

- 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 / 1

- **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)

- *Data compared to the previous version altered.*