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: Maxigold KF

• **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

\cdot 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



· Signal word Danger

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· Hazard statements

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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 = 0Fire = 0Reactivity = 0· HMIS-ratings (scale 0 - 4) HEALTH • Health = 0FIRE • Fire = 0**REACTIVITY O** 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% 7440-05-3 palladium 1-<10%

4 First aid measures

7440-74-6 indium

- · 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.

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1-<10%

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

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7440-74-6 indium REL () 0.1 mg/m^3 and compounds, as In $TLV() 0.1 mg/m^3$ • 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).

| Information on basic physical and General Information | chemical properties | |
|-------------------------------------------------------|-----------------------------------------------|--|
| Appearance: | | |
| Form: | Solid | |
| Color: | Yellow | |
| Odor: | Odorless | |
| Odour threshold: | Not determined. | |
| pH-value: | Not applicable. | |
| Change in condition | | |
| Melting point/Melting range: | 955–1035 °C (1751–1895 °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): | 13.9 g/cm ³ (115.996 lbs/gal) | |
| Relative density | Not determined. | |

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|------------------------------------|--------------------------------------------|--------------------|
| · Vapour density | Not applicable. | |
| \cdot Evaporation rate | Not applicable. | |
| · Solubility in / Miscibility with | | |
| Water: | Insoluble. | |
| · Partition coefficient (n-octano | / water): Not determined. | |
| · Viscosity: | | |
| Dynamic: | Not applicable. | |
| Kinematic: | Not applicable. | |
| · Solvent content: | | |
| Solids content: | 100 % | |
| \cdot 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:
- $\cdot \textit{Bioaccumulative potential No further relevant information available}.$
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes: Generally not hazardous for water

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· 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.

| 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 |
| 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

· Sara

• Section 355 (extremely hazardous substances):

None of the ingredients is listed.

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7440-22-4 silver 7440-50-8 copper

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· Section 313 (Specific toxic chemical listings):

| · 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

7440-50-8 copper

· 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



· 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.

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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)