Safety Data Sheet
acc. to ISO/DIS 11014

Printing date 12/14/2012 Version number 4 Reviewed on 12/14/2012

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

· **Product identifier**

· **Trade name:** **Evolution Lite**

· **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

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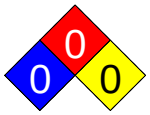
· **Hazard statements**
May intensify fire; oxidizer.
· **Precautionary statements**
Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
Take any precaution to avoid mixing with combustibles.
Wear protective gloves/protective clothing/eye protection/face protection.
Keep/Store away from 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:**		
7440-05-3	palladium	25-50%
7440-74-6	indium	1-<10%
7440-22-4	silver	1-<10%
7440-55-3	gallium	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.

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· **After swallowing:** Seek medical treatment.
· **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:**	
7440-74-6 indium	
REL ()	0.1 mg/m³ and compounds, as In
TLV ()	0.1 mg/m³

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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

· **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:	1100–1260 °C (2012–2300 °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.

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· **Density at 20 °C (68 °F):**	12.8 g/cm³ (106.816 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.
· **Mobility in soil** No further relevant information available.

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· **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
· **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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· **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

· **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)