

Printing date 06/23/2015 Version number 6 Reviewed on 05/08/2015

1 Identification

- · Product identifier
- · Trade name: IS-85
- · 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
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

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- · 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

Ox. Sol. 2 H272 May intensify fire; oxidizer.

Skin Corr. 1C H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage.

- · Label elements
- · GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms





GHS03

GHS05

- · Signal word Danger
- · Hazard-determining components of labeling: gallium
- · Hazard statements

May intensify fire; oxidizer.

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Causes severe skin burns and eye damage.

· Precautionary statements

Keep away from heat.

Take any precaution to avoid mixing with combustibles.

Wear protective gloves / eye protection / face protection.

Wear eye protection / face protection.

Do not breathe dusts or mists.

Keep/Store away from clothing/combustible materials.

Wash thoroughly after handling.

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a poison center/doctor.

Specific treatment (see on this label).

If swallowed: Rinse mouth. Do NOT induce vomiting.

Wash contaminated clothing before reuse.

In case of fire: Use for extinction: CO2, powder or water spray.

Store locked up.

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 = 1 Fire = 3Reactivity = 0

· HMIS-ratings (scale 0 - 4)



- · 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	50-100%
7440-55-3 gallium	2.5-<10%
7440-74-6 indium	2.5-<10%
7440-31-5 tin	2.5-<10%

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7440-22-4 silver

2.5-<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.
- · 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.
- · 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.

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· 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:
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7440-74-6 indium

REL Long-term value: 0.1 mg/m³

TLV Long-term value: 0.1 mg/m³ as In

7440-31-5 tin

PEL Long-term value: 2 mg/m³

metal

REL Long-term value: 2 mg/m³ TLV Long-term value: 2 mg/m³

metal

7440-22-4 silver

PEL Long-term value: 0.01 mg/m³

REL Long-term value: 0.01 mg/m³

TLV Long-term value: 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

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Color:	White	
· Odor:	Odorless	
· Odour threshold:	Not determined.	
· pH-value:	Not applicable.	
· Change in condition		
Melting point/Melting range:	1165–1335 °C (2129–2435 °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):	11.4 g/cm³ (95.133 lbs/gal)	
· Relative density	Not determined.	
· Vapour density	Not applicable.	
· Evaporation rate	Not applicable.	
· Solubility in / Miscibility with		
Water:	Insoluble.	
· Partition coefficient (n-octanol/wat	t er): 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

- $\cdot \textit{Reactivity} \ \textit{No further relevant information available}.$
- · 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.

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- · 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.

· OSHA-Ca (Occupational Safety & Health Administration)

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.
- · 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.

· UN-Number	
$\cdot DOT$	NA3077
· ADR, ADN, IMDG, IATA	Void
· UN proper shipping name	
· ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
\cdot DOT	
· Class	9 Miscellaneous dangerous substances and articles
· Label	9
· ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
$\cdot DOT$	III

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· ADR, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex MARPOL73/78 and the IBC Code	II of 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): 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 (Envi	ronmental 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.

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· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms





GHS03

03 GHS05

· Signal word Danger

· Hazard-determining components of labeling:

gallium

· Hazard statements

May intensify fire; oxidizer.

Causes severe skin burns and eye damage.

· Precautionary statements

Keep away from heat.

Take any precaution to avoid mixing with combustibles.

Wear protective gloves / eye protection / face protection.

Wear eye protection / face protection.

Do not breathe dusts or mists.

Keep/Store away from clothing/combustible materials.

Wash thoroughly after handling.

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a poison center/doctor.

Specific treatment (see on this label).

If swallowed: Rinse mouth. Do NOT induce vomiting.

Wash contaminated clothing before reuse.

In case of fire: Use for extinction: CO2, powder or water spray.

Store locked up.

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 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 / 5
- · 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

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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)

Ox. Sol. 2: Oxidising Solids, Hazard Category 2

Skin Corr. 1C: Skin corrosion/irritation, Hazard Category 1C Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

* Data compared to the previous version altered.