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

- · 1.1 Product identifier
- · Trade name: Super Solder Ceramic Solder
- · 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

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

Skin Sens. 1 H317 May cause an allergic skin reaction.

Carc. 2 H351 Suspected of causing cancer.

STOT RE 1 H372 Causes damage to organs through prolonged or repeated exposure.

- · 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







GHS03

GHS07

GHS0

- · Signal word Danger
- · Hazard-determining components of labelling:

nickel

· Hazard statements

H272 May intensify fire; oxidiser.

H317 May cause an allergic skin reaction.

H351 Suspected of causing cancer.

H372 Causes damage to organs through prolonged or repeated exposure.

· Precautionary statements

P201 Obtain special instructions before use.

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P221 Take any precaution to avoid mixing with combustibles.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P405 Store locked up.

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.

SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
- · Description: Dental alloy

· Dangerous components:						
CAS: 7440-05-3 EINECS: 231-115-6	palladium	Self-heat. 2, H252; Ox. Sol. 2, H272	50-100%			
CAS: 7440-02-0 EINECS: 231-111-4	nickel	Carc. 2, H351; STOT RE 1, H372; Skin Sens. 1, H317	25-50%			
CAS: 7440-22-4 EINECS: 231-131-3	silver	substance with a Community workplace exposure limit	3-<10%			

[·] 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:

Rinse with water.

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.

- · After swallowing: Seek medical treatment.
- 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: Use fire extinguishing methods suitable to surrounding conditions.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.

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- · 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.

See Section 13 for disposal information.

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.

- · Information about fire and explosion protection: No special measures required.
- · 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 reducing agents.
- · Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters

$\cdot I$	ngredients	with lim	it values i	that require	e monitoring	at the	workplace:

7440-02-0 nickel

WEL Long-term value: 0.5 mg/m³

as Ni

7440-22-4 silver

WEL Long-term value: 0.1 mg/m³

- · 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.

Do not inhale dust / smoke / mist.

- 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.

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· 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).

SECTION 9: Physical and ch	content properties
9.1 Information on basic physical a	and chemical properties
General Information	
Appearance:	
Form:	Solid
Colour:	Grey
Odour:	Odourless Not determined.
Odour threshold:	
pH-value:	Not applicable.
Change in condition	
Melting point/Melting range:	1085 - 1180 °C
Boiling point/Boiling range:	Undetermined.
Flash point:	Not applicable.
Flammability (solid, gaseous):	Not determined.
Self-igniting:	Product is not selfigniting.
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/wat	er): Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.

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SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability Stable under normal handling and storage conditions.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions Reacts with reducing agents.
- · 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- · 10.6 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.

 $\cdot \textit{CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)}\\$

Carc. 2

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.

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· 14.1 UN-Number	
· ADR, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name	
· ADR, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	Void
· 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 Anne	x II of
MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transpo (ADR, IMDG, IATA).
· UN ''Model Regulation'':	_

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · National regulations:
- $\cdot \textit{Other regulations, limitations and prohibitive regulations}$

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

H252 Self-heating in large quantities; may catch fire.

H272 May intensify fire; oxidiser.

H317 May cause an allergic skin reaction.

H351 Suspected of causing cancer.

H372 Causes damage to organs through prolonged or repeated exposure.

· 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)

Self-heat. 2: Self-Heating Substances and Mixtures, Hazard Category 2

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

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

Carc. 2: Carcinogenicity, Hazard Category 2

STOT RE 1: Specific target organ toxicity - Repeated exposure, Hazard Category 1