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

1.1 Product identifier

Trade name: Protocol

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

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
Ivoclar Vivadent AG
Bendererstrasse 2
FL-9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35
Fax: +423 235 33 60

Further information obtainable from:

Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein
Regulatory Affairs
sds@ivoclarvivadent.com
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.

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

Signal word: Danger

Hazard statements:

H272 May intensify fire; oxidiser.

Precautionary statements:

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.

P220 Keep远离 clothing/combustible materials.

P370+P378 In case of fire: Use for extinction: CO2, powder or water spray.
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

  - CAS: 7440-22-4
  - EINECS: 231-131-3
  - silver
  - substance with a Community workplace exposure limit

- 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:
    - 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.

- 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: The product is not flammable.

- 5.2 Special hazards arising from the substance or mixture
  - No further relevant information available.

- 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.

- 6.3 Methods and material for containment and cleaning up
  - Pick up mechanically.
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.
- 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: Not required.
  - 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

- Ingredients with limit values that require monitoring at the workplace:
  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.
  - 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.

- 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 chemical properties

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - Form: Solid
      - Colour: White
    - Odour: Odourless
    - Odour threshold: Not determined.
  - **pH-value:** Not applicable.
  - **Change in condition**
    - Melting point/Melting range: 1270–1310 °C
    - Boiling point/Boiling range: Undetermined.
  - **Flash point:** Not applicable.
  - **Flammability (solid, gaseous):** Not determined.
  - **Self-igniting:** Product is not self-igniting.
  - **Danger of explosion:** Product does not present an explosion hazard.
    - **Explosion limits:** Not determined.
    - **Vapour pressure:** Not applicable.
  - **Density at 20 °C:** 11 g/cm³
    - **Relative density**
    - **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 %
    - **9.2 Other information**
      - No further relevant information available.

### 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** No dangerous reactions known.
- **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: No irritating effect.
- Sensitisation: No sensitising effects known.
- Additional toxicological information:
  Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.

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: Generally not hazardous for water
- 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.

- European waste catalogue
  - 20 01 40 metals

- Uncleaned packaging:
  - Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

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: Void

14.4 Packing group
- ADR, IMDG, IATA: Void
SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

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.

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

* Data compared to the previous version altered.