

Safety Data Sheet
according to HPR, Schedule 1

Printing date 04/27/2018

Version number 5.1

Reviewed on 04/27/2018

1 Identification

- **Product identifier**
- **Trade name: d.SIGN 53**
- **Application of the substance / the mixture** *Manufacture of dental prosthesis*
- **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 SDS Assistance:*
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard identification

- **Classification of the substance or mixture**
Oxidizing Solids – Category 2 H272 May intensify fire; oxidizer.
-
- **Label elements**
 - **GHS label elements**
The product is classified and labeled 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, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Keep away from clothing and other combustible materials.
Wear protective gloves/protective clothing/eye protection/face protection.
In case of fire: Use for extinction: CO2, powder or water spray.
Dispose of contents/container in accordance with local/regional/national/international regulations.

(Contd. on page 2)

Safety Data Sheet according to HPR, Schedule 1

Printing date 04/27/2018

Version number 5.1

Reviewed on 04/27/2018

Trade name: **d.SIGN 53**

(Contd. of page 1)

· **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)**



· **HMIS-ratings (scale 0 - 4)**



3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Dental alloy

· **Dangerous components:**

CAS: 7440-05-3	palladium	30-60% w/w
CAS: 7440-22-4	silver	25-40% w/w
CAS: 7440-31-5	tin	5-<10% w/w
CAS: 7440-74-6	indium	1-<3% w/w

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 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.

(Contd. on page 3)

Safety Data Sheet

according to HPR, Schedule 1

Printing date 04/27/2018

Version number 5.1

Reviewed on 04/27/2018

Trade name: **d.SIGN 53**

(Contd. of page 2)

- **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:**

CAS: 7440-22-4 silver

EL Short-term value: 0.03 mg/m³
Long-term value: 0.01 mg/m³
as Ag

EV Long-term value: 0.1 * 0.01** mg/m³
*metal; **water-soluble compounds (as silver)

CAS: 7440-31-5 tin

EL Long-term value: 2 mg/m³
metal

EV Long-term value: 2 * 0.1** mg/m³
*metal, oxide, inorg. compds.; **org. compds.: Skin

CAS: 7440-74-6 indium

EL Long-term value: 0.1 mg/m³
as In; ACGIH 2B

EV Long-term value: 0.1 mg/m³
as indium

- **Additional information:** The lists that were valid during the creation were used as basis.

(Contd. on page 4)

CA

Safety Data Sheet

according to HPR, Schedule 1

Printing date 04/27/2018

Version number 5.1

Reviewed on 04/27/2018

Trade name: **d.SIGN 53**

(Contd. of page 3)

- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Usual hygienic measures for dental practice and dental laboratories.
- **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
Odor threshold:	Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

Melting point/Melting range:	1180–1280 °C
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:** 10.7 g/cm³
- **Relative density** Not determined.
- **Vapor density** Not applicable.
- **Evaporation rate** Not applicable.
- **Solubility in / Miscibility with**

Water:	Insoluble.
---------------	------------

(Contd. on page 5)

CA

Safety Data Sheet

according to HPR, Schedule 1

Printing date 04/27/2018

Version number 5.1

Reviewed on 04/27/2018

Trade name: **d.SIGN 53**

(Contd. of page 4)

- | | |
|---|-----------------|
| · 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:**
- **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.
- **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.

CA

(Contd. on page 6)

Safety Data Sheet

according to HPR, Schedule 1

Printing date 04/27/2018

Version number 5.1

Reviewed on 04/27/2018

Trade name: **d.SIGN 53**

(Contd. of page 5)

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 |
| · TDG, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · TDG, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT | |
| · Class | 9 Miscellaneous dangerous substances and articles |
| · Label | 9 |
| · TDG, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT | III |
| · TDG, 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. |
| · Transport/Additional information: | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · UN "Model Regulation": | Void |

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):**

CAS: 7440-22-4 silver

CAS: 7440-50-8 copper

· **TSCA (Toxic Substances Control Act):**

CAS: 7440-57-5 Gold

(Contd. on page 7)

CA

Safety Data Sheet

according to HPR, Schedule 1

Printing date 04/27/2018

Version number 5.1

Reviewed on 04/27/2018

Trade name: d.SIGN 53

(Contd. of page 6)

CAS: 7440-22-4	silver
CAS: 7440-50-8	copper
CAS: 7440-06-4	platinum
CAS: 7440-74-6	indium
CAS: 7439-88-5	iridium

· **GHS label elements**

The product is classified and labeled 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, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Keep away from clothing and other combustible materials.

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

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 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** 04/27/2018 / 5

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

· *** Data compared to the previous version altered.**

CA