

Printing date 23.06.2015 Version number 7 Revision: 08.05.2015

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

- · 1.1 Product identifier
- Trade name: High Fusing White Gold Solder (HFWG)
- \cdot 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

· 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

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





GHS07

GHS08

· Signal word Danger

· Hazard-determining components of labelling:

nickel

· Hazard statements

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.

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

P260 Do not breathe dust/fume/gas/mist/vapours/spray. P308+P313 IF exposed or concerned: Get medical advice/attention.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

(Contd. on page 2)

Printing date 23.06.2015 Version number 7 Revision: 08.05.2015

Trade name: High Fusing White Gold Solder (HFWG)

(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.

- · 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 compone | ents: | | |
|-------------------------------------|-------|--|---------|
| CAS: 7440-02-0 EINECS: 231-111-4 | | Carc. 2, H351; STOT RE 1, H372; Skin Sens. 1, H317 | 10-<25% |

· 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.

- · 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: 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.

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.

(Contd. on page 3)

Printing date 23.06.2015 Version number 7 Revision: 08.05.2015

Trade name: High Fusing White Gold Solder (HFWG)

(Contd. of page 2)

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: 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:

7440-02-0 nickel

WEL Long-term value: 0.5 mg/m³ as Ni

- · 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.

· Eve 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

(Contd. on page 4)

Printing date 23.06.2015 Version number 7 Revision: 08.05.2015

Trade name: High Fusing White Gold Solder (HFWG)

| | | (Contd. of page |
|--------------------------------------|---|-----------------|
| Colour: | White | |
| · Odour: | Odourless | |
| Odour threshold: | Not determined. | |
| pH-value: | Not applicable. | |
| Change in condition | | |
| Melting point/Melting range: | 880–910 °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 | t er): 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.

(Contd. on page 5)

 Printing date 23.06.2015
 Version number 7
 Revision: 08.05.2015

Trade name: High Fusing White Gold Solder (HFWG)

(Contd. of page 4)

- · Sensitisation: No sensitising effects known.
- · Additional toxicological information:

Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.

· 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.

· European waste catalogue

20 01 40 metals

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

| · 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 | |

Printing date 23.06.2015 Version number 7 Revision: 08.05.2015

Trade name: High Fusing White Gold Solder (HFWG)

| · 14.6 Special precautions for user | Not applicable. |
|--|---|
| · 14.7 Transport in bulk according to Anne MARPOL73/78 and the IBC Code | ex II of Not applicable. |
| · Transport/Additional information: | Product is not classified as a dangerous good for transpor (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:
- · 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

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)

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

* Data compared to the previous version altered.

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