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

1.1 Product identifier

Trade name: 4all

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 AG
Bendererstrasse 2
FL-9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN

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

Further information obtainable from:
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.
P321 Specific treatment (see on this label).
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

(Contd. on page 2)
40.1.5 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

3.2.2 Chemical characterisation: Mixtures
- Description: Dental alloy
- Dangerous components:

| CAS: 7440-02-0  | EINECS: 231-111-4 | nickel     | Carc. 2, H351; STOT RE 1, H372; Skin Sens. 1, H317 | 50-100% |
| CAS: 7440-47-3  | EINECS: 231-157-5 | chromium   | substance with a Community workplace exposure limit | 25-50%  |
| CAS: 7440-21-3  | EINECS: 231-130-8 | silicon    | Flam. Sol. 2, H228                                  | 1-<2.5% |

- 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.

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.

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

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

7440-02-0 nickel
WEL \( \text{Lung} \) Long-term value: 0.5 mg/m\(^3\)
as Ni

7440-47-3 chromium
WEL \( \text{Lung} \) Long-term value: 0.5 mg/m\(^3\)

7440-21-3 silicon
WEL \( \text{Lung} \) Long-term value: \(10^* \times 4^** \) mg/m\(^3\)
*inhalable dust **respirable dust

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: 1260–1350 °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 at 20 °C: 8.4 g/cm³
· Relative density: Not determined.
· 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.
Trade name: 4all

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: Sensitisation possible through skin contact.
- Additional toxicological information:
  - Fumes or dusts generated from cutting or grinding operations may cause respiratory irritation.
- CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)
  - Carc. 2

SECTION 12: Ecological information

12.1 Toxicity
- Aquatic toxicity: No further relevant information available.
- Persistence and degradability: No further relevant information available.
- 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.

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
### 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**

- H228 Flammable solid.
- 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)
- Flam. Sol. 2: Flammable 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

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