

Printing date 23.06.2015 Version number 5 Revision: 04.05.2015

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

- · 1.1 Product identifier
- · Trade name: 4all
- $\cdot$  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 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.

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· 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: 7440-02-0 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.
- $\cdot$  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.

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#### · 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: 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

ıngreai	ients with limit values that require monitoring at the workplace:
7440-02	2-0 nickel
WEL ()	Long-term value: 0.5 mg/m³ as Ni
7440-4	7-3 chromium
WEL ()	Long-term value: 0.5 mg/m³
7440-2	1-3 silicon
WEL ()	Long-term value: 10* 4** mg/m³ *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.

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· 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	
Annaguayaa	

· Appearance: Form:

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.

Deg-ignuing.

• 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:
Relative density
Vapour density
Evaporation rate
Not applicable.
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.

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· 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 (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: 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 - 14.2 UN proper shipping name - ADR, ADN, IMDG, IATA - Void - 14.3 Transport hazard class(es) - ADR, ADN, IMDG, IATA - Class - Void

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· 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 MARPOL73/78 and the IBC Code	e <b>x II of</b> Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (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

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

 ${\it Skin Sens. 1: Sensitisation - Skin, Hazard\ Category\ 1}$ 

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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