

1 Identification

- **Product identifier**
- **Trade name: d.SIGN 15**
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **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: +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)**

2 Hazard(s) identification

- **Classification of the substance or mixture**
Acute Tox. 4 H302 Harmful if swallowed.
Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
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.

- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS07 GHS08

- **Signal word** *Danger*
- **Hazard-determining components of labeling:**
nickel
iron
cobalt
- **Hazard statements**
Harmful if swallowed.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.
Suspected of causing cancer.
Causes damage to organs through prolonged or repeated exposure.

Safety Data Sheet acc. to OSHA HCS

Printing date 06/23/2015

Version number 2

Reviewed on 05/07/2015

Trade name: **d.SIGN 15**

(Contd. of page 1)

· **Precautionary statements**

- Obtain special instructions before use.
- Wear protective gloves.
- Do not breathe dust/fume/gas/mist/vapors/spray.
- [In case of inadequate ventilation] wear respiratory protection.
- Wash thoroughly after handling.
- Do not eat, drink or smoke when using this product.
- Contaminated work clothing must not be allowed out of the workplace.
- Do not handle until all safety precautions have been read and understood.
- Specific treatment (see on this label).
- If experiencing respiratory symptoms: Call a poison center/doctor.
- If swallowed: Call a poison center/doctor if you feel unwell.
- Wash contaminated clothing before reuse.
- If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
- IF exposed or concerned: Get medical advice/attention.
- If skin irritation or rash occurs: Get medical advice/attention.
- Get medical advice/attention if you feel unwell.
- Rinse mouth.
- If on skin: Wash with plenty of water.
- Store locked up.
- Dispose of contents/container in accordance with local/regional/national/international regulations.

· **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)**



Health = 3
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = *3
Fire = 0
Reactivity = 0

· **Other hazards**

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

7440-02-0	nickel	50-100%
7440-47-3	chromium	≤25%
7439-98-7	molybdenum	10-<25%
7439-89-6	iron	1-<2.5%
7440-21-3	silicon	1-<2.5%

(Contd. on page 3)

Safety Data Sheet acc. to OSHA HCS

Printing date 06/23/2015

Version number 2

Reviewed on 05/07/2015

Trade name: **d.SIGN 15**

7440-48-4 cobalt

(Contd. of page 2)

0.1-<1%

4 First-aid measures

- **Description of first aid measures**
- **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **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 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to item 13.
- **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**
Prevent formation of dust.
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **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:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.

(Contd. on page 4)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 06/23/2015

Version number 2

Reviewed on 05/07/2015

Trade name: **d.SIGN 15**

· *Specific end use(s) No further relevant information available.*

(Contd. of page 3)

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:*

7440-02-0 nickel

PEL Long-term value: 1 mg/m³

REL Long-term value: 0.015 mg/m³
as Ni; See Pocket Guide App. A

TLV Long-term value: 1.5* mg/m³
elemental, *inhalable fraction

7440-47-3 chromium

PEL Long-term value: 1* 0.5** mg/m³
*metal; **inorganic compds., as Cr

REL Long-term value: 0.5* mg/m³
*metal+inorg.compds.as Cr; See Pocket Guide App. C

TLV Long-term value: 0.5 mg/m³

7439-98-7 molybdenum

PEL Long-term value: 15* mg/m³
*Total dust

TLV Long-term value: 10* 3** mg/m³
as Mo; *inhalable fraction ** respirable fraction

7440-21-3 silicon

PEL Long-term value: 15* 5** mg/m³
*total dust **respirable fraction

REL Long-term value: 10* 5** mg/m³
*total dust **respirable fraction

TLV TLV withdrawn

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

· *Exposure controls*

· *Personal protective equipment:*

· *General protective and hygienic measures:*

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Usual hygienic measures for dental practice.

· *Breathing equipment:*

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· *Protection of hands:*



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS

Printing date 06/23/2015

Version number 2

Reviewed on 05/07/2015

Trade name: d.SIGN 15

(Contd. of page 4)

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **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:** Not required.

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Solid
Color: According to product specification

· **Odor:** Odorless

· **Odour threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/Melting range: Undetermined.

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:** Not determined.

· **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:**

Organic solvents: 0.0 %

(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS

Printing date 06/23/2015

Version number 2

Reviewed on 05/07/2015

Trade name: **d.SIGN 15**

(Contd. of page 5)

Solids content: 100.0 %
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:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:** No further relevant information available.
- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

7440-02-0	nickel	2B
7440-47-3	chromium	3
7440-48-4	cobalt	2B, 2A

- **NTP (National Toxicology Program)**

7440-02-0	nickel	R
-----------	--------	---

- **OSHA-Ca (Occupational Safety & Health Administration)**

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:**
- Water hazard class 2 (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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

(Contd. on page 7)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 06/23/2015

Version number 2

Reviewed on 05/07/2015

Trade name: **d.SIGN 15**

· **Other adverse effects** No further relevant information available.

(Contd. of page 6)

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
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, ADR, ADN, IMDG, IATA Void
- **UN proper shipping name**
· DOT, ADR, ADN, IMDG, IATA Void
- **Transport hazard class(es)**
· DOT, ADR, ADN, IMDG, IATA
· Class Void
- **Packing group**
· DOT, ADR, 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":** -

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):**

7440-02-0 nickel

7440-47-3 chromium

7440-48-4 cobalt

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

7440-02-0 nickel

7440-47-3 chromium

(Contd. on page 8)

Safety Data Sheet

acc. to OSHA HCS

Printing date 06/23/2015

Version number 2

Reviewed on 05/07/2015

Trade name: d.SIGN 15

(Contd. of page 7)

7439-98-7	molybdenum
7439-89-6	iron
7440-21-3	silicon
7440-48-4	cobalt

· **Proposition 65**

· **Chemicals known to cause cancer:**

7440-02-0	nickel
7440-48-4	cobalt

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

7440-47-3	chromium	D
-----------	----------	---

· **TLV (Threshold Limit Value established by ACGIH)**

7440-02-0	nickel	A5
7440-47-3	chromium	A4
7439-98-7	molybdenum	A3
7440-48-4	cobalt	A3

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

7440-02-0	nickel
-----------	--------

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07 GHS08

· **Signal word Danger**

· **Hazard-determining components of labeling:**

nickel
iron
cobalt

· **Hazard statements**

Harmful if swallowed.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.
Suspected of causing cancer.
Causes damage to organs through prolonged or repeated exposure.

· **Precautionary statements**

Obtain special instructions before use.
Wear protective gloves.
Do not breathe dust/fume/gas/mist/vapors/spray.

(Contd. on page 9)

Safety Data Sheet acc. to OSHA HCS

Printing date 06/23/2015

Version number 2

Reviewed on 05/07/2015

Trade name: d.SIGN 15

(Contd. of page 8)

[In case of inadequate ventilation] wear respiratory protection.

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

Contaminated work clothing must not be allowed out of the workplace.

Do not handle until all safety precautions have been read and understood.

Specific treatment (see on this label).

If experiencing respiratory symptoms: Call a poison center/doctor.

If swallowed: Call a poison center/doctor if you feel unwell.

Wash contaminated clothing before reuse.

If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.

IF exposed or concerned: Get medical advice/attention.

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

Get medical advice/attention if you feel unwell.

Rinse mouth.

If on skin: Wash with plenty of water.

Store locked up.

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** 06/23/2015 / 1

· **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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

Acute Tox. 4: Acute toxicity, Hazard Category 4

Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1

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.**