

Safety Data Sheet
in accordance with HSNO

Printing date 29.01.2020

Version number 2

Revision: 29.01.2020

1 Identification of the substance or mixture and of the supplier

- **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
- **Importer:**
Ivoclar Vivadent Ltd.
12 Omega St, Rosedale, Auckland
New Zealand
Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclarvivadent.com
- **Emergency telephone number:** 0800 764 766 (National Poison Centre - 24 hours / 7 days)

2 Hazards identification

- **Classification of the substance or mixture**
Acute Tox. 4 H302 Harmful if swallowed.
Acute Tox. 5 H333 May be harmful 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 labelled according to the Globally Harmonised System (GHS).
- **Hazard pictograms**


 GHS07 GHS08
- **Signal word** Danger
- **Hazard-determining components of labelling:**
nickel
iron
cobalt
- **Hazard statements**
Harmful if swallowed.
May be harmful if inhaled.
May cause an allergic skin reaction.
Suspected of causing cancer.
Causes damage to organs through prolonged or repeated exposure.

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- **Precautionary statements**

Obtain special instructions before use.

Do not breathe dust/fume/gas/mist/vapours/spray.

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

IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

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.

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

3 Composition/Information on ingredients

- **Chemical characterisation: Mixtures**

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

- **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	10-25%
CAS: 7439-98-7 EINECS: 231-107-2	molybdenum	10-25%
CAS: 7439-89-6 EINECS: 231-096-4	iron Acute Tox. 2, H300; Acute Tox. 3, H311; Acute Tox. 3, H331	<2.5%
CAS: 7440-21-3 EINECS: 231-130-8	silicon Flam. Sol. 2, H228; Acute Tox. 5, H303	<2.5%
CAS: 7440-48-4 EINECS: 231-158-0	cobalt Resp. Sens. 1, H334; Skin Sens. 1, H317; Aquatic Chronic 4, H413	<2.5%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

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.

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5 Fire fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **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 fire - and explosion protection:** 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.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

CAS: 7440-02-0 nickel

WES Long-term value: 0.005* mg/m³
sen; elemental or metallic; *resp.dust

CAS: 7440-47-3 chromium

WES Long-term value: 0.5 mg/m³

CAS: 7439-98-7 molybdenum

WES Long-term value: 5* 10** mg/m³
as Mo; *soluble compds.; **insoluble compds.

CAS: 7440-21-3 silicon

WES Long-term value: 10 mg/m³

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CAS: 7440-48-4 cobalt

WES Long-term value: 0.02 mg/m³
dust, fume: bio, sen, suspected carcinogen

· **Additional information:** The lists valid during the making 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 and dental laboratories.

· **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· **Protection of hands:**



Protective gloves

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

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

Colour:

According to product specification

· **Odour:**

Odourless

· **Odour threshold:**

Not determined.

· **pH-value:**

Not applicable.

· **Change in condition**

Melting point/freezing point:

Undetermined.

Initial boiling point and boiling range: Undetermined.

· **Flash point:**

Not applicable.

· **Flammability (solid, gas):**

Not determined.

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· Auto-ignition temperature:	<i>Product is not selfigniting.</i>
· Explosive properties:	<i>Product does not present an explosion hazard.</i>
· Explosion limits:	
Lower:	<i>Not determined.</i>
Upper:	<i>Not determined.</i>
· Vapour pressure:	<i>Not applicable.</i>
· Density:	<i>Not determined.</i>
· Relative density	<i>Not determined.</i>
· Vapour density	<i>Not applicable.</i>
· Evaporation rate	<i>Not applicable.</i>
· Solubility in / Miscibility with water:	<i>Insoluble.</i>
· Partition coefficient: n-octanol/water:	<i>Not determined.</i>
· Viscosity:	
Dynamic:	<i>Not applicable.</i>
Kinematic:	<i>Not applicable.</i>
· Solvent content:	
Organic solvents:	<i>0.0 %</i>
Solids content:	<i>100.0 %</i>
· Other information	<i>No further relevant information available.</i>

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**
- **Skin corrosion/irritation** *No irritant effect.*
- **Serious eye damage/irritation** *No irritating effect.*
- **Respiratory or skin sensitisation** *Sensitisation possible through skin contact.*
- **Additional toxicological information:** *No further relevant information available.*
- **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
Carc. 2

12 Ecological information

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

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- **Behaviour 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 (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.*
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
*Must not be disposed 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 packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|--|
| <ul style="list-style-type: none"> · UN-Number · ADR/RID/ADN, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · UN proper shipping name · ADR/RID/ADN, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · Transport hazard class(es) · ADR/RID/ADN, ADN, IMDG, IATA · Class | Void |
| <ul style="list-style-type: none"> · Packing group · ADR/RID/ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · Environmental hazards: · Marine pollutant: | No |
| <ul style="list-style-type: none"> · Special precautions for user | Not applicable. |
| <ul style="list-style-type: none"> · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| <ul style="list-style-type: none"> · Transport/Additional information: | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| <ul style="list-style-type: none"> · UN "Model Regulation": | Void |

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15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **New Zealand Inventory of Chemicals**

CAS: 7440-02-0	nickel
CAS: 7440-47-3	chromium
CAS: 7439-98-7	molybdenum
CAS: 7439-89-6	iron
CAS: 7440-21-3	silicon
CAS: 7440-48-4	cobalt

· **HSNO Approval numbers**

CAS: 7440-02-0	nickel	HSR003031
CAS: 7440-47-3	chromium	HSR002943
CAS: 7439-98-7	molybdenum	HSR003029
CAS: 7440-21-3	silicon	HSR001306
CAS: 7440-48-4	cobalt	HSR003639

· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Danger

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

nickel

iron

cobalt

· **Hazard statements**

Harmful if swallowed.

May be harmful 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.

Do not breathe dust/fume/gas/mist/vapours/spray.

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

IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

Store locked up.

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

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to the Directive 93/42/EEC.

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· **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.

· **Relevant phrases**

H228 Flammable solid.

H300 Fatal if swallowed.

H303 May be harmful if swallowed.

H311 Toxic in contact with skin.

H317 May cause an allergic skin reaction.

H331 Toxic if inhaled.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H351 Suspected of causing cancer.

H372 Causes damage to organs through prolonged or repeated exposure.

H413 May cause long lasting harmful effects to aquatic life.

· **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

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Sol. 2: Flammable solids – Category 2

Acute Tox. 2: Acute toxicity – Category 2

Acute Tox. 4: Acute toxicity – Category 4

Acute Tox. 5: Acute toxicity – Category 5

Acute Tox. 3: Acute toxicity – Category 3

Resp. Sens. 1: Respiratory sensitisation – Category 1

Skin Sens. 1: Skin sensitisation – Category 1

Carc. 2: Carcinogenicity – Category 2

STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4