

# Safety Data Sheet

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

**1.1 Product identifier** CLASP WIRE

**1.2. Relevant identified uses of the substance or mixture and uses advised against**

The product clasp wire is intended to be used as a clasp when making temporary removable partial dentures.

**1.3 Details of the supplier of the safety data sheet**

Manufacturer/Supplier:	INTERDENT d.o.o.	<i>Production:</i> INTERDENT d.o.o.
Street:	Opekarniška cesta 26	Dol 1
Country code /Postal code/City:	SI-3000 Celje	SI-3342 Gornji Grad
Telephone:	+386(0) 425-62-00	
Fax:	+368(0) 490-62-02	

**1.4 Emergency telephone number**

Emergency phone: 112 (EU)  
+386(0) 425-62-00 (Mon – Fri: 8.00 -16.00)

## **SECTION 2: Hazards Identification**

**2.1 Classification of the substance or mixture**

Stainless steel products are not classified as hazardous according to Regulation (EC) No 1272/2008.

**2.2 Label elements**

None for the mixture.

**2.3 Other hazards**

Routes of Entry/Exposure:

Stainless steel products in their solid state and under normal condition present no inhalation, ingestion or contact health hazard. Inhaling dusts, fumes or mists which may be generated during certain manufacturing procedures such as burning, melting, welding, sawing, brazing, grinding and machining may be hazardous to your health. Dusts may be irritating to the unprotected skin and eyes. Inhalation may occur if dust or fumes are generated. Skin absorption is not likely to occur but irritation may occur when in contact with the skin. Ingestion is not likely to occur.

Carcinogenicity:

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IARC, NTP, and OSHA do not list Stainless Steel alloy as a carcinogen. Chromium and nickel and their compounds are listed in NTP's 7th Annual Report on Carcinogens. NTP classifies nickel metal and certain nickel compounds as "reasonably anticipated to be carcinogens." IARC classifies nickel metal as a possible human carcinogen (Group 2B) and certain nickel compounds as known human carcinogens (Group 1).

### **SECTION 3: Composition / information on ingredients**

#### **3.1 Mixture (material: stainless steel)**

Chemical name	CAS Nr. EC-Number INDEX number	%	Classification according to EC 1272/2008	
			Hazardous class/hazardous category	Hazardous phrases
<b>Nickel</b>	7440-02-0 231-111-4 028-002-00-7	6 - 9	Carc. 2 Skin Sens. 1	H351 H317
<b>Iron</b>	7439-89-6 231-096-4 /	> 60	/	/
<b>Chromium</b>	7440-47-3 231-157-5 /	18 - 19	/	/
<b>Manganese</b>	7439-96-5 231-105-1	< 2	/	/

#### **3.2 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 instructions:*

No special measures required.

*After inhalation:*

If dust or other particles are generated during processing, it is necessary to provide adequate ventilation and respiration protection. If dust/particles have been aspirated seek for medical attention.

*After skin contact:*

Instantly wash with water and soap and rinse thoroughly.

*After eye contact:*

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Rinse open lid for several minutes under running water.

*After swallowing:*

Wash off mouth with water at first and then drink cca. 100mL of water. In case of persistent symptoms consult doctor.

### **4.2 Most important symptoms and effects, both acute and delayed**

During processing: Coughing and/ or wheezing. Difficulty in breathing. Irritation. May cause allergic skin reaction.

Refer to Section 11 – Toxicological information

### **4.3 Indication of any immediate medical attention and special treatment needed**

Notes to physician: All treatments should be based on observed signs and symptoms of distress in the patient. Consideration should be given to the possibility that overexposure to materials other than this product may have occurred.

## **SECTION 5: Fire Prevention Regulations**

### **5.1 Extinguishing media**

*Suitable extinguishing agents:*

CO<sub>2</sub>, foam, powder, water

*Unsuitable extinguishing agents:*

n.a.

### **5.2 Special hazards arising from the substance or mixture**

Not applicable for solid product. Metallic dust or fumes may be produced during welding, burning, grinding and possibly machining.

### **5.3 Advice for firefighters**

Wear a self-contained breathing apparatus and chemical protective clothing. Co-ordinate fire-fighting measures to the fire surroundings. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water. Use caution when applying carbon dioxide in confined spaces. Carbon dioxide can displace oxygen. Do not inhale explosion and combustion gases.

## **SECTION 6: Accidental Substance Release Regulations**

### **6.1 Personal precautions, protective equipment and emergency procedures**

Use personal protection equipment. Avoid causing and breathing dust. Wear breathing apparatus if exposed to vapours/dusts/aerosols.

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### 6.2 Environmental precautions

Do not allow product to enter sewage system or water.

### 6.3 Methods and material for containment and cleaning up

Dispose contaminated material according local law.

### 6.4 Reference to other sections

Safe handling: see section 7. Personal protection equipment: see section 8. Disposal: see section 13.

## ***SECTION 7: Handling and storage***

### 7.1 Precautions for safe handling

Prevent formation of dust. If dust is formed, avoid breathing it. Avoid skin and eye contact. The metal powder that is formed during treatment should be suck with vacuum cleaner.

### 7.2 Conditions for safe storage, including any incompatibilities

Store away from acids and incompatible materials in tightly closed and correctly labelled containers.

### 7.3 Specific end use(s)

Product is used in dental laboratories.

## ***SECTION 8: Exposure controls/personal protection***

### 8.1 Control parameters

The OEL values for stainless steel are not defined. Because of safety reasons the PEL values for pure metal powder should be considered:

PELOSHA (Fe, fume) = 10 mg/m<sup>3</sup>

PELOSHA (Cr, metal) = 1 mg/m<sup>3</sup>

PELOSHA (Ni, fume) = 0,5 mg/m<sup>3</sup>

### 8.2 Exposure controls

#### ***Personal protective equipment***

#### ***General protection and hygienic measures:***

Consider good hygienic precaution.

#### ***Breathing equipment:***

Use dust extractor and protective mask with FFP2 filter during treating and polishing.

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*Protection of hands:*

Protective gloves during treating and polishing.

*Eye protection:*

Protective goggles during treating and polishing.

### **SECTION 9: Physical and chemical properties**

#### **9.1 Information on basic physical and chemical properties**

<b>Form</b>	solid
<b>Colour</b>	Silver-grey, metallic
<b>Odour</b>	odourless
<b>Boiling point</b>	n.a.
<b>Melting point</b>	n.a.
<b>Density at 20°C</b>	> 3g/cm <sup>3</sup>
<b>Solubility in water</b>	insoluble
<b>Flash point</b>	n.a.
<b>Explosion limits</b>	n.a.

#### **9.2 Other information**

None

### **SECTION 10: Stability and reactivity**

#### **10.1 Reactivity**

Not determined for product as a whole.

#### **10.2 Chemical stability**

Stainless Steel Alloys are stable at room temperature under normal storage and handling conditions.

#### **10.3 Possibility of hazardous reaction**

No dangerous reaction known.

#### **10.4 Conditions to avoid**

Dust-generating activities.

#### **10.5 Incompatible materials**

None.

#### **10.6 Hazardous decomposition products**

Metal oxides

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### **SECTION 11: Toxicological information**

#### **11.1 Information on toxicological effects**

*Toxicokinetics, absorption and distribution:*

Toxicological information has not been established for this product as sold. The steels contain nickel (classified as a dangerous substance). Processing of this product in operations such as high temperature (burning, welding), sawing, brazing, machining and grinding may produce fumes and/or particulates, which are to be monitored.

#### **Acute health effects:**

No LC50 or LD50 has been established for stainless steel products.

*Iron:* LD<sub>50</sub> (rat, oral) = 1060 mg/kg

*Chromium (as Cr VI):* LD<sub>50</sub> (oral, rat) = 80 mg/kg

*Nickel:* LD<sub>50</sub> (oral, rat) > 9000 mg/kg

*Eye Effects:* No known human testing.

*Skin Effects:* May cause contact dermatitis in sensitized individuals (Ni)

*Acute Inhalation Effects:* Rat, oral, LDLo: 5 mg/kg (Ni);

*Rat, unreported, LD50:* 27500 µg/kg (Cr)

*Chronic Effects:* Rat, inhalation, TLo: 100 µg/m<sup>3</sup> /24 hrs/ 17 weeks (Ni)

*Carcinogenicity:* Human Limited Evidence, IARC Group 2B (Ni);

*Known to be carcinogenic by NTP (as Cr).*

*Teratogenicity:* Rat, oral, TDLo: 158 mg/kg (Ni)

*Mutagenicity:* Hamster, morphological transformation: 400 mg/L (Ni)

*Tumorigenic:* Rat, subcutaneous, TDLo: 3000 mg/kg/6 weeks (Ni)

*Rat, intravenous, TDLo* 2160 µg/kg/6 weeks (Cr)

*Inhalation:* Excessive exposure to high concentration of dust may cause irritation to the mucous membranes of the upper respiratory tract. Dusts or fumes can cause irritation and dryness of the nose and throat, coughing, bronchitis, pneumonia, chest pain, and pulmonary edema.

*Eyes:* Excessive exposure to high concentration of dust may cause irritation to the eyes.

*Skin:* Possible sensitization by skin contact. Dusts or fumes can cause irritation with itching. Dermatitis may occur.

*Ingestion:* Ingestion of harmful amounts of this product as distributed is unlikely due to its solid insoluble form. Ingestion of dust may cause nausea or vomiting.

#### **Chronic Health Effects:**

*Sensitization:*

During processing: may cause sensitization by inhalation and skin contact. Dermatitis and allergic sensitization have been reported.

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*Skin effects:* The most common health effect of metallic nickel in humans is an allergic skin reaction in those who are sensitive to nickel. Nickel may cause allergic contact dermatitis. Alloys containing nickel are classified for skin sensitization when the release rate of 0,5 µg Ni/cm<sup>2</sup>/week, as measured by the European Standard reference test method EN 1811, is exceeded.

*Respiratory tract:* Chronic exposure to certain metals in Stainless Steel alloys may cause non-progressive pulmonary fibrosis or chronic bronchitis when overexposed to elevated dust or fume concentrations. Other symptoms include shortness of breath, cough, chest tightness, and wheezing without impairment.

*Carcinogenicity:*

IARC, NTP and OSHA do not list steel products as carcinogens. Nickel and certain nickel compounds have been listed by NTP as being reasonably anticipated to be carcinogens. Nickel is not regulated as a carcinogen by OSHA (29 CFR 1910 Subpart Z). IARC has listed nickel compounds within group 1 (there is sufficient evidence for carcinogenicity in humans). For metallic nickel there is limited evidence in humans and experimental animals. IARC classified metallic nickel and alloys in group 2B as possibly carcinogenic.

*Mutagenicity and teratogenicity:*

No data available for stainless steel alloys.

### **SECTION 12: Ecological information**

#### **12.1 Toxicity**

Not available for the product.

#### **12.2 Persistence and degradability**

In fresh and salt water, stainless steel alloys will eventually form metal oxides and precipitate in sediments.

#### **12.3 Bioaccumulative potential**

There is little tendency for bioaccumulation along food chain. Alloy may persist in the environment for long periods based upon the corrosive resistance, insolubility in water, and non-biodegradable properties.

#### **12.4 Mobility in soil**

Not available for the product.

#### **12.5 Results of PBT and vPvB assessment**

The substances in the mixture do not meet the PBT/vPvB criteria according to EC 1907/2006 REACH, annex XIII.

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**12.6 Other adverse effect**

Not known

**SECTION 13: Disposal consideration**
**13.1 Waste treatment methods**

Dispose according to the local law.

12 01 02 ferrous metal dust and particles

**SECTION 14: Transport Information**

	Land-Road/Railway (ADR/RID):	Inland waterways (ADNR):	Sea (IMDG):	Air (IATA):
<b>14.1 UN number</b>	No data available			
<b>14.2 UN proper shipping name</b>	No data available			
<b>14.3 Transport hazard class(es)</b>	No data available			
<b>14.4 Packing group</b>	No data available			
<b>14.5 Environmental hazards</b>	No data available			
<b>14.6 Special precautions for user</b>	No special precautions			
<b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	No data available			

Not a dangerous product within the meaning of the transport regulations.

**SECTION 15: Regulatory information**
**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
*EU Label Information:*

Classification and labeling have been performed according to Regulative 1272/2008.

*EU Hazard Symbol and Indication of Danger:*

According to Regulation EC 1272/2008 this product is not classified.

**15.2 Chemical safety assessment**

Chemical safety assessments for substances in this mixture were not carried out.



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### **SECTION 16: Other information**

*Revision:*

Version 06 issued on September 2021 in accordance with EC 1907/2006 (Commission Regulation (EU) 2015/830) and EC 1272/2008.

*Full text of phrase codes used in this safety data sheet:*

H351: Suspected of causing cancer <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

H317: May cause an allergic skin reaction.

*Legend of abbreviations:*

IARC: International agency for research on cancer

NTP: National toxicology program

OSHA: Occupational safety and health administration

OEL: Occupational exposure limit

LD<sub>50</sub>: Median lethal dose; the dose causing 50% lethality

OSHA PELs: Permissible Exposure Limits - 8-hour TWA (time-weighted average) concentrations unless otherwise noted.

*References:*

IARC: <https://monographs.iarc.fr/ENG/Monographs/vol100C/mono100C-10.pdf>

<http://monographs.iarc.fr/ENG/Monographs/vol49/mono49.pdf>

NTP: <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/nickel.pdf>

OSHA; Exposure limits and health effects.

[https://www.osha.gov/dts/chemicalsampling/data/CH\\_256200.html](https://www.osha.gov/dts/chemicalsampling/data/CH_256200.html)

*Disclaimer of expressed and implied warranties:*

The information contained in the safety data sheet is correct to the best of our knowledge at the date of issue. It is intended as a guide for the safe use, handling, disposal, storage and transportation and is not intended as warranty or as a specification. The information relates only to the product specified and may not be suitable for combinations with other materials or in processes other than those specifically described herein.