Safety Data Sheet

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

1.1 Product identifier **I-BOND 02, I-BOND LO, I-GW**

1.2. Relevant identified uses of the substance or mixture and uses advised against
I-BOND 02 and **I-BOND LO** are used as base alloy for ceramic firing.
I-GW is base alloy for acrylic teeth.

1.3 Details of the supplier of the safety data sheet

		Production:
Manufacturer/Supplier:	INTERDENT d.o.o.	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
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:
Nickel-based alloys in their usual solid form and under normal conditions do not present an inhalation, ingestion, or contact health hazard. 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. Occupational exposure to nickel may occur by dermal contact or by inhalation of aerosols, dusts, fumes or mists containing nickel.

Carcinogenicity:
IARC, NTP, and OSHA classified nickel (metallic) as possibly carcinogenic (2B group by IARC).

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SECTION 3: Composition / information on ingredients

3.1 Mixtures

Composition range [%]					
Nickel	Chromium	Molybdenum	Silicon	Iron	Niobium, Manganese
62 - 67	22 - 26	8 - 11	0,8 - 2	0 - 1	< 1

Chemical name	**CAS Nr. EC-Number INDEX number**	**%**	**Classification according to EC 1272/2008**	
Nickel	7440-02-0 231-111-4 028-002-00-7	62 - 67	Hazardous class/hazardous category	Hazardous phrases
			Carc. 2 Skin Sens. 1	H351 H317

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

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:
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

See section 11.

4.3 Indication of any immediate medical attention and special treatment needed

n.a.

SECTION 5: Fire Prevention Regulations

5.1 Extinguishing media
Suitable extinguishing agents:
CO_2, foam, powder, water

Unsuitable extinguishing agents:
n.a.

5.2 Special hazards arising from the substance or mixture
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.

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
Nickel-based dental alloys should be stored in tightly closed and correctly labelled containers.

7.3 Specific end use(s)
Products are used in dental laboratories.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters
The OEL values for nickel-based alloys are not defined. Because of safety reasons the PEL values for pure metal powder should be considered:

PEL_{OSHA} (Nickel metallic) = 1 mg/m^3
PEL_{OSHA} (Cr, metal) = 1 mg/m^3
PEL_{OSHA} (Ni, fume) = 0,5 mg/m^3

8.2 Exposure controls
Personal protection equipment in accordance with Directive (EU) 2016/425 and List for harmonized standards for OVO-2018/C 209/03.

General protection and hygienic measures:
Provide good ventilation. Do not breath dust. Wear personal protective equipment. Do not eat, drink or smoke when working. Wash hands when stop working and during breaks.

Breathing equipment:
Use dust extractor and protective mask with FFP2 (EN149:2001+A1:2009) filter during treating and polishing.

Protection of hands:
Protective gloves during treating and polishing. Recommendation of use protection in accordance with EN 374-1:2016.

Eye protection:
Protective goggles (EN 166:2001) during treating and polishing.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	solid

Colour	Silver-grey, metallic
Odour	odourless
Boiling point	n.a.
Melting point	Cca. 1400°C
Density	7,9 -8,4 g/cm^3 at 20°C
Solubility in water	insoluble
Flash point	n.a.
Explosion limits	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
In the product form is stable under normal 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

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
Toxicokinetic, absorption and distribution:
In normal solid state and in normal industrial use nickel-based alloys are neither inhaled nor in permanent or long-term contact with the skin. The alloys contain nickel (classified as a dangerous substance) which are to be monitored. The penetration in the organism, the absorption and the elimination of nickel and its compounds depend on their physical state and largely on the route of exposure. In humans, nickel ions can be taken up via the skin, via the gastrointestinal tract or by inhalation. Occupational exposure has been shown to give rise to elevated levels of nickel in blood, urine and body tissues, with inhalation as the main route of uptake.

Acute health effects:
There is no data available for alloys. Acute effects for metallic nickel are available.
Rat, oral, LD50: 9000 mg/kg

Chronic Health Effects:
Irritation and corrosivity

Metallic nickel is not a skin or an eye irritant. Irritation of eyes, skin and respiratory tract may occur by dust and aerosols.

Sensitization:
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/cm2/week, as measured by the European Standard reference test method EN 1811, is exceeded.
Respiratory tract: Asthma in humans is rare.

Carcinogenicity:
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).
Although nickel compounds are known human carcinogens, the evidence suggests that the relatively insoluble metallic nickel is less likely to present a carcinogenic hazard than are the nickel compounds that tend to release proportionately more nickel ion.
For metallic nickel and nickel alloys there is limited evidence in humans and experimental animals. IARC classified metallic nickel and alloys in group 2B as possibly carcinogenic.

Mutagenicity and teratogenicity:
Data on the reproductive toxicity and mutagenicity of nickel and alloys in humans is limited.

11.2 Information on other hazards
No other information available.

SECTION 12: Ecological information

12.1 Toxicity
Not available for the product.

12.2 Persistence and degradability
In fresh and salt water, nickel-based 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.

12.6 Endocrine disrupting properties
No data available.

12.7 Other adverse effect
Not known

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Dispose according to the local law.

SECTION 14: Transport Information

	Land-Road/Railway (ADR/RID):	Inland waterways (ADNR):	Sea (IMDG):	Air (IATA):
14.1 UN number	No data available			
14.2 UN proper shipping name	No data available			
14.3 Transport hazard class(es)	No data available			
14.4 Packing group	No data available			
14.5 Environmental hazards	No data available			
14.6 Special precautions for user	No special precautions			

14.7 Maritime transport in bulk according to IMO instruments	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.

SECTION 16: Other information

Revision:
Version 07 issued on January 2023 in accordance with EC 1907/2006 (Commission Regulation (EU) 2015/830) and EC 1272/2008.

Revision in accordance to changes in COMMISSION REGULATION (EU) 2020/878 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

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 routs of exposure cause the hazard>.
H317: May cause an allergic skin reaction.

Legend of abbreviations:
ADR - Accord européen relatif au transport international des marchandises dangereuses par route
CAS - Chemical Abstracts Service
CLP – Classification, labeling and packaging
CMR - Carcinogenic, Mutagenic or toxic for Reproduction
DNEL - Derived No-Effect Level
EINECS European Inventory of Existing Commercial Chemical Substances

ELINCS European List of Notified Chemical Substances
EmS Emergency Schedule
GHS "Globally Harmonized System of Classification and Labelling of Chemicals"
IARC: International agency for research on cancer
IATA International Air Transport Association
IATA/DGR Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO International Civil Aviation Organization IMDG International Maritime Dangerous Goods Code PBT persistant bioaccumulative, toxic
LD50: Median lethal dose; the dose causing 50% lethality
NTP: National toxicology program
OSHA: Occupational safety and health administration
OEL: Occupational exposure limit
OSHA PELs: Permissible Exposure Limits - 8-hour TWA (time-weighted average) concentrations unless otherwise noted.
PNEC Predicted No-Effect Concentration
PPM parts per million
REACH Registration, Evaluation, Authorisation and Restriction of Chemicals
RID Règlement concernant le transport International ferroviaire des marchandises Dangereuses št. vPvB very Persistent and very Bioaccumulative (zelo obstojno in se zelo lahko kopiči v organizmih)

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

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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.