

Safety Data Sheet

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

1.1 Product identifier **GELCAST SYSTEM**

1.2. Relevant identified uses of the substance or mixture and uses advised against
 Used for making upper and lower total prosthesis with acrylic pouring technique in dental laboratories.

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

Product as sold is not classified as hazardous according to Regulation (EC) No 1272/2008.

2.2 Label elements

None for the mixture according to Regulation (EC) No. 1272/2008.

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, 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

Ingredients:

Teeth holder & canal cutter: Stainless steel

Chemical name	CAS Nr. EC-Number INDEX number	%	Classification according to EC 1272/2008	
			Hazardous class/hazardous category	Hazardous phrases
Iron	7439-89-6 231-096-4 /	> 60	/	/
Chromium	7440-47-3 231-157-5 /	18 - 20	/	/
Nickel	7440-02-0 231-111-4 028-002-00-7	10 – 12	Carc. 2 Skin Sens. 1	H351 H317
Manganese	7439-96-5 231-105-1 /	< 2	/	/

Gelcast flask: plastic

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

4.1.1 General information:

No special measures required.

After inhalation:

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No special measures required.

After skin contact:

No special measures required.

After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.

After swallowing:

Doctor consult.

4.2 Most important symptoms and effects, both acute and delayed

Refer to Section 11 – Toxicological information

4.3 Indication of any immediate medical attention and special treatment needed

Not applicable

SECTION 5: Fire Prevention Regulations

5.1 Extinguishing media

Suitable extinguishing agents:

Not limited.

Unsuitable extinguishing agents:

Not limited.

5.2 Special hazards arising from the substance or mixture

Not known

5.3 Advice for firefighters

Self-contained breathing apparatus (SBA) and full protective equipment is recommended.

SECTION 6: Accidental Substance Release Regulations

6.1 Personal precautions, protective equipment and emergency procedures

No special measures required.

6.2 Environmental precautions

No special measures required.

6.3 Methods and material for containment and cleaning up

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Collect mechanically. The product is not environmental risk.

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

Good hygienic practice

7.2 Conditions for safe storage, including any incompatibilities

Storage normal storage conditions.

7.3. Specific end use(s)

No specific end uses.

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/m³

PELOSHA (Cr, metal) = 1 mg/m³

PELOSHA (Ni, fume) = 0,5 mg/m³

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.

Protection of hands:

Protective gloves during treating and polishing.

Eye protection:

Protective goggles during treating and polishing.

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SECTION 9: Physical and chemical properties	
9.1 Information on basic physical and chemical properties	
Physical state	solid
Colour	silver
Odour	odourless
Melting point / freezing point	NA
Boiling point or initial boiling point and boiling range	NA
Flammability	NA
Lower and upper explosion limit	NA
Flash point	NA
Auto-ignition temperature	NA
Decomposition temperature	NA
pH	NA
Kinematic viscosity	NA
Solubility	NA
Partition coefficient n-octanol/water (log value)	NA
Vapour pressure	NA
Density and/or relative density	NA
Relative vapour density	NA
Particle characteristics	NA
9.2 Other information	
Powder is hygroscopic and it absorbs water.	

SECTION 10: Stability and reactivity
10.1 Reactivity
No specific test data related to reactivity available for this product.
10.2 Chemical stability
In the product form is stable under normal storage and handling conditions.
10.3 Possibility of hazardous reaction
No hazardous reaction when handled and stored according to provisions.
10.4 Conditions to avoid
None.
10.5 Incompatible materials

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Not known

10.6 Hazardous decomposition products

Not known at appropriate handling and storage.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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 toxicity:

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

Iron: LD₅₀ (rat, oral) = 1060 mg/kg

Chromium (as Cr VI): LD₅₀ (oral, rat) = 80 mg/kg

Nickel: LD₅₀ (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, TClO: 100 µg/m³ /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)

Skin corrosion/irritation:

Dusts or fumes can cause irritation with itching. Dermatitis may occur.

Serious eye damage/irritation:

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

Respiratory or skin sensitization:

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

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.

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Germ cell mutagenicity: Not classified

Carcinogenicity: Not classified

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.

Reproductive toxicity: Not classified.

STOT-single exposure: Not classified

STOT-repeated exposure:

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.

Aspiration hazard:

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.

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, 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.

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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

No data available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Smaller quantities can be disposed with household garbage.
 Bigger quantities should be disposed according to 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:

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Classification and labeling have been performed according to Regulation 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 02 issued on December 2022 in accordance with EC 1907/2006 (Commission Regulation (EU) 2015/830) and EC 1272/2008.

Revision in accordance with 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).

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 persistent 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

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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)

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.