Safety Data Sheet

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

1.1 Product identifier **LaAlloy**

1.2. Relevant identified uses of the substance or mixture and uses advised against
LaAlloy is Co-based dental alloy powder, intended for the production of fixed and removable dental restorations using SLM printing technology in dental laboratory.

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) 425-62-02	

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 is classified as hazardous according to Regulation (EC) No 1272/2008.

Hazard class	**Hazard category**	**Hazard statements**
Acute Tox.	4	H302 Harmful if swallowed.
Carc.	1B	H350i May cause cancer by inhalation.
Muta.	2	H341 Suspected of causing genetic defects.
Repr.	1B	H360Fd May damage fertility. Suspected of damaging the unborn child.
Resp. Sens.	1B	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin Sens.	1	H317 May cause an allergic skin reaction.
Aquatic Chronic	4	H413 May cause long lasting harmful effects to aquatic life.

2.2 Label elements

Signal word: DANGER

Hazard statements

H302 Harmful if swallowed.
H350i May cause cancer by inhalation.
H341 Suspected of causing genetic defects.
H360Fd May damage fertility. Suspected of damaging the unborn child.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317 May cause an allergic skin reaction.
H413 May cause long lasting harmful effects to aquatic life.

Precautionary statement
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Do not breathe dust/fume/gas/mist/vapours/spray.
P264 Wash hands thoroughly after handling.
P270 Do no eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P281 Use personal protective equipment as required
P284 Wear respiratory protection.
P330 Rinse mouth.
P363 Wash contaminated clothing before reuse.

Response:
P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

Storage:
P405 Store locked up.

Disposal
P501 Dispose of contents/container to a facility in accordance with local and national regulations.

Labelling information:
CMR: Co

2.3 Other hazards
Routes of Entry/Exposure:
Cobalt-based alloys in their 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.

SECTION3: Composition / information on ingredients

3.1 Mixtures

Chemical name	**CAS Nr. EC-Number INDEX number**	**%**	**Classification according to EC 1272/2008**	
			Hazardous class/hazardous category	Hazardous phrases
Cobalt	7440-48-4 231-158-0 027-001-00-9	60 – 67	Acute Tox. 4 Carc. 1B Muta. 2 Repr. 1B Resp. Sens. 1B Skin Sens. 1 Aquatic Chronic 4	**H302** **H350i** **H341** **H360Fd** **H334** **H317** **H413**
Chromium	7440-47-3 231-157-5	20-30	/	/
Molybdenum	7439-98-7 231-107-2	1-10	/	/
Tungsten	7440-33-7 231-143-9	1-10	/	/
Silicon	7440-21-3	< 5	/	/

	231-130-8			

3.2 Additional information
No additional information.

SECTION 4: First Aid Measures

4.1 Description of first aid measures
After inhalation:
Remove from exposure. In severe cases or if exposure has been great, obtain medical attention.

After skin contact:
Remove contaminated clothes. Instantly wash with water and soap and rinse thoroughly. If rash develops seek medical attention.

After eye contact:
Wash thoroughly with water for at least 10 minutes – obtain medical attention if irritation persists.

After swallowing:
Wash off mouth with water at first. In case of persistent symptoms consult doctor.

4.2 Most important symptoms and effects, both acute and delayed
Skin Contact: Rash may develop.
Eye Contact: Mechanical irritation.
Inhalation: Possible asthma-like symptoms.
Ingestion: No information

4.3 Indication of any immediate medical attention and special treatment needed
Skin Contact: Treat symptomatically
Eye Contact: Treat symptomatically

SECTION 5: Fire Prevention Regulations

5.1 Extinguishing media
Suitable extinguishing agents:
Use water mist, extinguishing type D powder or sand.

Unsuitable extinguishing agents:
n.a.

5.2 Special hazards arising from the substance or mixture
Avoid formation of dust cloud as this may lead to an increased risk of a dust explosion.

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.
Do not inhale explosion and combustion gases.

SECTION 6: Accidental Substance Release Regulations

6.1 Personal precautions, protective equipment and emergency procedures
6.1.1 For non-emergency personnel: Use personal protection equipment. Avoid causing and breathing dust.
6.1.2 For emergency responders: Use personal protection equipment. Avoid causing and breathing dust.

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.
6.3.1 For containment: Not applicable
6.3.2 For cleaning up:
Small spillage: Vacuum with equipment fitted with HEPA filtration.
Large spillage: Solids should be carefully transferred to salvage containers. Any residues should be treated as small spillages.

6.3.3 Other information: No Information.

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. Contaminated clothing should be removed and washed before re-use. Wash hand and face thoroughly after working with material.

7.2 Conditions for safe storage, including any incompatibilities
Technical measures and storage conditions: Should be stored in tightly closed and correctly labelled containers.
Packaging materials: Keep in the container supplied, or suitable metal, plastic or polythene container.

7.3 Specific end use(s)
Product used for professional use in dental laboratories.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters
Directive 98/24/EC with all amendments and supplements
Official Gazette of the Republic of Slovenia, No. 100/01, 39/05, 53/07, 102/10, 43/11 – ZVZD-1, 38/15, 78/18, 78/19, 72/21, 29/24

PEL$_{OSHA}$ (Cobalt metallic) = 0,1 mg/m^3 (mg/m3 TWA (8 hour))
PEL$_{OSHA}$ (Cobalt fume) = 0,05 mg/m^3

Chemical name: chromium – metal [CAS: 7440-47-3], inorganic chromium (II) compounds and inorganic chromium (III) compounds (insoluble)	
MV	KTV: 2 (I) mg/m^3, 8 h: 2 (I) mg/m^3 (EU^2)*
Chemical name: powder	
MV (alveolar fraction)	KTV: 2,5 mg/m^3 8 h: 1,25 mg/m^3
MV (inhalable fraction)	KTV: 20 mg/m^3 8 h: 10 mg/m^3

* **EU^2** - Limit value set by Commission Directive 2006/15/EC of 7 February 2006 establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directive 91/322/EEC and Directive 2000/39/EC (OJ L 38, 9.2.2006, p. 36).

DNEL, DMEL and PNEC values

DNEL values (worker)

Substance name **Cobalt**			**CAS** **7440-48-4**	
Route of exposure	**Exposure time**	**Effect**	**Value**	
inhalative	Long term (chronic)	local	40	µg/m³

DNEL value (consumer)

Substance name **Cobalt**	**CAS** **7440-48-4**

Route of exposure	Exposure time	Effect	Value	
oral	Long term (chronic)	systemic	9.5	µg/kg/day
inhalative	Long term (chronic)	local	6.3	µg/m³

PNEC values

Substance name Cobalt		CAS 7440-48-4	
ecological compartment	**Type**	**Value**	
water	fresh water	0.51	µg/l
water	marine water	2.36	µg/l
water	fresh water sediment	9.5	mg/kg dry weight
water	marine water sediment	9.5	mg/kg dry weight
soil	-	10.9	mg/kg dry weight
sewage treatment plant	-	0.37	mg/L

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

Substance/mixture-specific measures to prevent exposure during identified uses: CoCr powder is a heavy dust and does not travel through space. Local exhaust ventilation when handling.

Structural measures to prevent exposure: Closed processes

Organisational measures to prevent exposure: The substance/mixture should only be used by persons trained in safe use.

Technical measures to prevent exposure: Closed processes, local exhaust ventilation, local exhaust ventilation when handling.

LaAlloy is used in 3D printers. The user is in contact with the product during the changeover, dust sieving after printing. The process takes approximately 10 minutes, which means short-term use. Measured exposure in the printer room, equipped with forced ventilation of the room, without windows, without the use of suction: KTV: 0.15MV. The measurement includes the measured values of cobalt, chromium, inhalable dust fraction and alveolar dust fraction. The result is the sum of all measured values.

The following personal protective equipment is mandatory during handling:

8.2.2 Personal protection equipment*:*

General protection and hygienic measures:

Consider good hygienic precaution.

Breathing equipment:

Use dust extractor and protective mask with FFP3 filter (EN149:2001+A1:2009) Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

Protection of hands:

Protective gloves EN ISO 374-1:2017/A1:2018, nitril, type B

Eye protection:
Safety googles EN 16321-1:2022, lens: polycarbonate, transparent, curvature 7; 2C-1.2 U1 FTK CE or shield that covers the face according to EN 168:2001

Protective clothing:
Protective gown, separated from personal clothing.

8.3 Environmental exposure controls
General advice: Do not flush into surface water or sewage system.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	Solid - powder
Colour	Silver-grey, metallic
Odour	odourless
pH	No data available
Boiling point	n.a.
Density	9,03 g/cm^3 at 20°C
Solubility in water	insoluble
Flash point	No data available
Explosion limits	No data available

9.2 Other information
None

SECTION 10: Stability and reactivity

10.1 Reactivity
Not determined for product as a whole.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reaction
No data

10.4 Conditions to avoid
Dust-generating activities. Oxidizing agents.

10.5 Incompatible materials
No data

10.6 Hazardous decomposition products
No data

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
Toxicokinetic, metabolism and distribution:
For cobalt-based alloys in their solid form and under normal conditions toxicological effects are not known. Substantial uptake of cobalt may occur through the lungs following inhalation, mainly of metallic cobalt, often combined with other metals, and cobalt oxide in dust and welding fumes. During long-term, systemic cobalt exposure in humans accumulate in tissues, in particular liver and kidney, and cobalt concentration is increased in whole-blood, serum and urine.

Acute Health Effects:
Animal data are available for cobalt:
Acute oral toxicity: Rat, oral, LD_{50}: 550 mg/kg bw (OECD 425, ECHA)
Acute dermal toxicity: Rabbit, dermal, LD_{50} >2000 mg/kg bw (OECD 402)
Acute inhalational toxicity: Dust, Rat, LC_{50} < 0.05 mg/l (4h) (OECD 436, ECHA)

Chronic Health Effects:
Skin corrosion/irritation:
Non-irritant (OECD 439, ECHA)

Serious eye damage/irritation:
Cobalt dust is a mild irritant to the eyes (OECD 437)

Respiratory or skin sensitization:
Dermatitis is a common result of dermal exposure to cobalt in humans.
Allergic sensitization and chronic bronchitis may also result from prolonged exposure to the powder.

Teratogenicity/Mutagenicity: No data available.

Reproductive toxicity: Based on available data, the classification criteria are met (ECHA).

Carcinogenicity:
IARC evaluated the carcinogenic hazards of cobalt metallic and concluded that:
• There is inadequate evidence in humans for the carcinogenicity of cobalt metal.

• There is limited evidence in experimental animals for the carcinogenicity of metal alloys containing cobalt.
In 2020, there was a radical change around the regulation of metallic Co, which in Europe has become a carcinogenic, mutagenic, or toxic-for-reproduction (CMR) substance. It now belongs to category 1B of CMR substances (carcinogenic 1B, mutagenic 2, toxic for reproduction 1B).

STOT-single exposure: No data available.

STOT-repeated exposure: No data available.

Aspiration hazard:

Delayed and immediate effects as well as chronic effects from short and long-term exposure:
Inhalation of vapours in high concentration may cause metal fume fever and may cause damage of the central nervous system in case of repeated and prolonged exposure. Repeated and prolonged exposure to high dust concentrations may lead to irritation of the respiratory tract. Inhalation of metal-containing dusts may cause acute poisoning, leading to nausea, vomiting and abdominal pain.

11.2 Information on other hazards
No other information available.

SECTION 12: Ecological information

12.1 Toxicity
Not available for the product.

Cobalt:
Toxicity to Daphnia (acute):
Daphnia magna, EC50 > 100 mg/l (48h) (OECD 202, ECHA)

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential
No data available.

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.

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SECTION 14: Transport Information

	ADR/RID	IMDG	IATA
14.1 UN number	UN 3077		
14.2 UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.		
14.3 Transport hazard class(es)			
Class	9		
Label(s)	9	9	9
			
Hazard identification	90	/	/
Tunnel restriction code	E	/	/
EmS	/	F−A+S−F	/
14.4 Packing group	III		
14.5 Environmental hazards	/	Marine pollutant	/
14.6 Special precautions for user	No special precautions known.		
14.7 Maritime transport in bulk according to IMO instruments	No information available.		

SECTION 15: Regulatory information

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

The product is classified and labelled in accordance with EC Directives 1907/2006 and 1272/2008 and respective amendments or corresponding national laws Ur.l. RS 101/2002 and Ur.l.RS 16/2008.

- Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of

Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 and Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/105/EC and 2000/21/EC
(amending Commission Regulation (EU) No 830/2015) – as amended –
Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 – with amendments and supplements
- Chemicals Act /ZKem/
- Regulation on waste (Official Gazette of the Republic of Slovenia, No. 77/22 and 113/23)
- Regulation on packaging and packaging waste (Official Gazette of the Republic of Slovenia, No. 54/21, 208/21, 44/22 – ZVO-2 and 120/22) - Decision on the publication of Annexes A and B to the European Agreement concerning the International Carriage of Dangerous Goods by Road /ADR/ - Rules on the protection of workers against risks arising from exposure to chemical substances at work (Official Gazette of the Republic of Slovenia, No. 100/01, 39/05, 53/07, 102/10, 43/11 – ZVZD-1, 38/15, 78/18 and 78/19, 72/21, 29/24) - Regulation on the implementation of the Regulation (EU) on personal protective equipment (Official Gazette of the Republic of Slovenia, No. 33/18) - List of harmonised standards for personal protective equipment (C 412 / 11.12.2015, with all amendments and supplements) - Occupational Safety and Health Act (Official Gazette of the Republic of Slovenia, No. 43/2011)

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

SECTION 16: Other information

Revision:
Version 01 issued on January 2025 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).

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
LC50 Lethal Concentration to 50 % of a test population
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.
STOT Specific Target Organ Toxicity
RE Repeated Exposure
SE Single Exposure
SVHC Substances of Very High Concern
TWA Time Weighted Average (long term 8 hours) (short term 15 minutes unless specified otherwise)
UN United Nations
vPvB Very Persistent and Very Bioaccumulative

IARC (2006); International Agency for Research on Cancer (IARC). 2006. IARC monograph on the evaluation of carcinogenic risks to humans. Volume 86. Cobalt in hard metals and cobalt sulfate, gallium arsenide, indium phosphide and vanadium pentoxide.

NTP, Report on Carcinogens. 2016. Cobalt and Cobalt Compounds that Release Cobalt Ions In Vivo. https://ntp.niehs.nih.gov/ntp/roc/monographs/cobalt_final_508.pdf

OSHA; Exposure limits and health effects.
https://www.osha.gov/dts/chemicalsampling/data/CH_229100.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.