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

1.1 Product identifier

Cobalt-based alloys (powder)

Realloy C Powder
Realloy CH Powder | Realloy CH RPD
Realloy Classic Powder
Realloy BC Powder

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

Identified use:	Manufacturing of dental prostheses in dental laboratories by selective laser melting (SLM). Professional use only.
Uses advised against:	All uses other than those identified above. Supply to and use by the general public (REACH Annex XVII, entries 28–30).

1.3 Details of the supplier of the safety data sheet

Supplier:

Realloy e.K.
Moerser Straße 232
47803 Krefeld
Germany

Telephone:	+49 (0)2151-486 49 78
E-mail (competent person):	info@realloy.net
Web:	www.realloy.net

Manufacturer:

German Special Alloys GmbH
Carl-Friedrich-Benz-Str. 1b
47877 Willich
Germany – Tel. +49 (0)2154-88 09 180 – info@gs-alloys.de – www.german-special-alloys.com

1.4 Emergency telephone number

For medical advice (in German and English), available 24 hours:
+49 (0)551 192 40 (Poison Information Centre North, Göttingen, Germany)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

Resp. Sens. 1; H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin Sens. 1; H317	May cause an allergic skin reaction.
Muta. 2; H341	Suspected of causing genetic defects.
Carc. 1B; H350	May cause cancer.
Repr. 1B; H360F	May damage fertility.
Aquatic Chronic 4; H413	May cause long lasting harmful effects to aquatic life.

Classification by calculation from the cobalt content (Art. 9 CLP). The product is a fine metal powder; inhalation of dust is the main route of exposure. Based on available data, the powder is not classified as a flammable solid.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP)

Note: The labelling exemption for massive alloys (Regulation (EC) No 1272/2008, Annex I, section 1.3.4) does not apply to powders. The packaging must be labelled with the following label elements.

Hazard pictograms



GHS08

Signal word: **Danger**

Hazard-determining component for labelling: Cobalt

Hazard statements

H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H341	Suspected of causing genetic defects.
H350	May cause cancer.
H360F	May damage fertility.
H413	May cause long lasting harmful effects to aquatic life.

Precautionary statements

P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe dust/fume.
P280	Wear protective gloves/protective clothing/eye protection.
P284	[In case of inadequate ventilation] wear respiratory protection.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

Supplemental information

Text for labelling: Contains: Cobalt.

Restricted to professional users.

2.3 Other hazards

Whirled-up fine powder can form explosive dust/air mixtures. Condensate and filter residues from the SLM process are finer than the powder and may be combustible. Contact of dust with the eyes can lead to mechanical irritation.

During laser melting and during finishing of the printed parts (separating, grinding, sandblasting), metal fumes and dust containing cobalt and chromium can be formed.

Results of PBT and vPvB assessment:

The PBT/vPvB criteria of REACH Annex XIII do not apply to inorganic substances.

Endocrine disrupting properties:

The mixture does not contain substances with endocrine disrupting properties at a concentration of ≥ 0.1 %.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable.

3.2 Mixtures

Chemical characterisation: pre-alloyed metal powder. Hazardous ingredients and ingredients with occupational exposure limits:

Substance name	Identifiers	Classification (EC) 1272/2008	Content (% w/w)
Cobalt	CAS 7440-48-4 EC 231-158-0 Index 027-001-00-9	Resp. Sens. 1; H334 Skin Sens. 1; H317 Muta. 2; H341 Carc. 1B; H350 Repr. 1B; H360F Aquatic Chronic 4; H413	61 – 64
Chromium	CAS 7440-47-3 EC 231-157-5	not classified	24 – 29
Manganese	CAS 7439-96-5 EC 231-105-1	not classified	≤ 1

Full text of H statements and abbreviations: see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:	If medical advice is needed, have product container, label or this safety data sheet at hand. Take off immediately all contaminated clothing and wash it before reuse. First aider: pay attention to self-protection.
In case of inhalation (dust/fume):	Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of respiratory symptoms (e.g. asthma-like complaints) get immediate medical attention.
Following skin contact:	Wash with water and soap and rinse thoroughly. In case of skin reactions consult a physician.
After eye contact:	Flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Do not rub. Remove contact lenses, if present and easy to do. Subsequently consult an ophthalmologist.
After swallowing:	Rinse mouth and drink plenty of water. Do not induce vomiting. Get medical advice.

4.2 Most important symptoms and effects, both acute and delayed

Acute: may cause allergy or asthma symptoms or breathing difficulties if dust/fume is inhaled; may cause an allergic skin reaction (contact eczema); mechanical irritation of eyes and respiratory tract by dust.
Delayed: may cause cancer; suspected of causing genetic defects; may damage fertility.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically. In case of respiratory sensitisation, avoid any further exposure.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:
Adapt extinguishing measures to the surrounding fire. For burning powder, condensate or filter residues: metal fire extinguishing powder (class D), dry sand. Cover burning powder carefully, do not whirl it up.

Unsuitable extinguishing media for safety reasons:
Water, foam, carbon dioxide (CO_2), full water jet.

5.2 Special hazards arising from the substance or mixture

In case of fire, metal oxide fumes may develop (cobalt, chromium, tungsten, molybdenum oxides). Fine dust can form explosive mixtures with air.

5.3 **Advice for firefighters**

Wear a self-contained breathing apparatus. Dispose of fire residues and contaminated extinguishing water in accordance with official regulations.

SECTION 6: Accidental release measures

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

Avoid dust formation and inhalation; do not whirl up powder. Wear personal protective equipment including respiratory protection (see section 8). Keep away from sources of ignition.

6.2 **Environmental precautions**

Do not allow dust to enter drains, surface water or ground water.

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

Collect spilled powder with an explosion-protected industrial vacuum cleaner of dust class H or pick it up wet; do not sweep dry and do not use compressed air. Place in closed, labelled containers (see section 13).

6.4 **Reference to other sections**

See sections 7, 8 and 13.

SECTION 7: Handling and storage

7.1 **Precautions for safe handling**

Obtain special instructions before use. Observe the minimisation requirement for carcinogenic, mutagenic and reprotoxic substances (Directive 2004/37/EC; in Germany GefStoffV § 10 and TRGS 910).
Open, fill, sieve and recycle powder only with local exhaust ventilation or in closed systems; avoid dust formation and dust deposits. Use the powder only in SLM systems designed for this purpose (inert gas). Keep away from sources of ignition; take measures against electrostatic charging. Handle condensate and filter residues under inert conditions or wet. Carry out finishing of the printed parts only with local exhaust ventilation (dust class H). Do not eat, drink or smoke at the workplace. Wash hands after work.

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

Keep container tightly closed in the original packaging in a dry, well-ventilated place. Protect from moisture and heat. Keep away from food, drink and animal feedingstuffs. Do not store together with acids and oxidising agents.

7.3 **Specific end use(s)**

Manufacturing of dental prostheses in dental laboratories. Observe the instructions for use of the respective alloy.

SECTION 8: Exposure controls/personal protection

8.1 **Control parameters**

Occupational exposure limit values – Germany

CAS No.	Designation	Type	Limit value
7440-48-4	Cobalt	TRGS 910: acceptance concentration	0.5 µg/m³ (R)
		TRGS 910: tolerance concentration	5 µg/m³ (R)
7440-47-3	Chromium	TRGS 900: OEL (AGW)	2 mg/m³ (I) (chromium metal and inorganic Cr(II)/Cr(III) compounds, insoluble)
7439-96-5	Manganese	TRGS 900: OEL (AGW)	0.2 mg/m³ (I), 0.02 mg/m³ (R)
–	General dust limit	TRGS 900: OEL (AGW)	10 mg/m³ (I); 1.25 mg/m³ (R)

I/E = inhalable fraction, R/A = respirable fraction.

Occupational exposure limit values – European Union

CAS No.	Designation	Type	Limit value
7440-47-3	Chromium	IOELV: TWA	2 mg/m³ (metal and inorganic compounds, insoluble)
7439-96-5	Manganese	IOELV: TWA	0.2 mg/m³ (inhalable); 0.05 mg/m³ (respirable)

8.2 **Exposure controls**

Appropriate engineering controls
Follow the hierarchy of controls. Use closed SLM systems with inert gas and filter system; local exhaust ventilation when handling open powder; local exhaust ventilation with H-class filtration at finishing and sandblasting workstations.

Personal protection equipment

Respiratory protection:	When handling open powder (unpacking, filling, sieving, cleaning the SLM system) and if dust can be released: particle filter P3 (EN 143) or FFP3 mask (EN 149).
Eye protection:	Tightly fitting safety goggles (EN 166).
Hand protection:	Protective gloves against dust (EN ISO 374-1).
Body protection:	Work clothing; store separately from street clothing.

Environmental exposure controls
Filter exhaust air before release.

SECTION 9: Physical and chemical properties

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

Physical state	Solid (powder) at 20 °C
Colour	Grey
Odour	Odourless
Melting point/freezing point	Approx. 1200 – 1420 °C; the products have different melting ranges within this range
Boiling point	No data available
Flammability	Not classified as a flammable solid based on available data. Whirled-up dust can form explosive mixtures with air.
Lower and upper explosion limit	No data available
Flash point	Not applicable (solid)
Auto-ignition temperature	Not applicable
Decomposition temperature	Not applicable
pH	Not applicable (insoluble)
Kinematic viscosity	Not applicable (solid)
Solubility	Insoluble in water
Partition coefficient n-octanol/water	Not applicable (inorganic)
Vapour pressure	Not applicable (solid)
Density	8 – 9 g/cm³ at 20 °C
Relative vapour density	Not applicable (solid)
Particle characteristics	Metal powder

9.2 **Other information**

No further data available.

SECTION 10: Stability and reactivity

10.1 **Reactivity**

Reacts slowly with strong acids forming hydrogen.

10.2 **Chemical stability**

Stable under recommended storage conditions.

10.3 **Possibility of hazardous reactions**

Contact with strong acids may release hydrogen.

10.4 **Conditions to avoid**

Dust formation, whirling up of powder, sources of ignition, moisture.

10.5 **Incompatible materials**

Strong acids, strong oxidising agents.

10.6 **Hazardous decomposition products**

None when stored and handled as recommended. At melting temperature: metal oxide fumes.

SECTION 11: Toxicological information

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

The statements are derived from the properties of the single components. No toxicological data are available for the alloys as such.

Acute toxicity	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Serious eye damage/irritation	Based on available data, the classification criteria are not met.
Respiratory sensitisation	Resp. Sens. 1; H334
Skin sensitisation	Skin Sens. 1; H317
Germ cell mutagenicity	Muta. 2; H341
Carcinogenicity	Carc. 1B; H350
Reproductive toxicity	Repr. 1B; H360F
STOT – single/repeated exposure	Based on available data, the classification criteria are not met.
Aspiration hazard	Not applicable (solid).

Information on likely routes of exposure
Inhalation of dust/fume (main route), skin contact.

11.2 **Information on other hazards**

Endocrine disrupting properties: Not applicable.

SECTION 12: Ecological information

12.1 **Toxicity**

May cause long lasting harmful effects to aquatic life (Aquatic Chronic 4, derived from the cobalt content).

12.2 **Persistence and degradability**

Not applicable to inorganic substances.

12.3 **Bioaccumulative potential**

No data available.

12.4 **Mobility in soil**

Insoluble in water.

12.5 **Results of PBT and vPvB assessment**

Not applicable to inorganic substances.

12.6 **Endocrine disrupting properties**

Not applicable.

12.7 **Other adverse effects**

Do not allow dust to enter drains or surface water.

SECTION 13: Disposal considerations

13.1 **Waste treatment methods**

Product:	Waste key number: 06 04 05* = wastes containing other heavy metals. * = Evidence for disposal must be provided. Dispose of waste according to applicable legislation. Do not dispose of with household waste.
Packaging:	Dispose of waste according to applicable legislation. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

14.1 **UN number or ID number**

ADR/RID, ADN, IMDG, IATA-DGR: not applicable.

14.2 **UN proper shipping name**

ADR/RID, ADN, IMDG, IATA-DGR: not applicable.

14.3 **Transport hazard class(es)**

ADR/RID, ADN, IMDG, IATA-DGR: not applicable.

14.4 **Packing group**

ADR/RID, ADN, IMDG, IATA-DGR: not applicable.

14.5 **Environmental hazards**

Marine pollutant: no

14.6 **Special precautions for user**

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

14.7 **Maritime transport in bulk according to IMO instruments**

Not applicable.

SECTION 15: Regulatory information

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

EU regulations

Restrictions according to REACH Annex XVII, entries 28, 29, 30 (CMR substances – restricted to professional users).

REACH candidate list (SVHC) / Annex XIV: not listed

Medical device regulations
The powders are medical devices of class IIa (legacy devices according to Directive 93/42/EEC, EC certificate No. 44 235 151578; placed on the market under the transitional provisions of Art. 120 of Regulation (EU) 2017/745 (MDR) as amended by Regulation (EU) 2023/607; notified body TÜV NORD CERT GmbH, 0044). The dental prostheses made from them are custom-made devices.
Information on the cobalt content (CMR substance, Carc. 1B/Repr. 1B, > 0.1 % w/w) as well as residual risks, contraindications and incident reporting is provided in the instructions for use (MDR Annex I, sections 10.4.5 and 23.4).
The exemption of Art. 2(6)(a) REACH does not apply, as the powders are supplied to dental laboratories for further processing; this safety data sheet is therefore provided.
Directive 2004/37/EC; Directive 92/85/EEC; Directive 94/33/EC.

National regulations – Germany

Water hazard class (AwSV):	WGK 3 – self-classification according to AwSV Annex 1 No. 5 (cobalt, metallic, particle size < 1 mm: WGK 3, ID no. 8026)
Employment restrictions:	Observe employment restrictions for young people (JArbSchG § 22) and for pregnant and breastfeeding women (MuSchG §§ 11, 12).
Hazardous Substances Ordinance:	GefStoffV § 10; TRGS 910.

15.2 **Chemical safety assessment**

For this mixture a chemical safety assessment is not required.

SECTION 16: Other information

Changes from the previous version (22.04.2024)
Complete revision according to Regulation (EU) 2020/878; now in German and English. Realloy CH Powder / CH RPD added. Labelling exemption for massive alloys deleted (does not apply to powders), obsolete P statements replaced, composition limited to relevant ingredients, occupational exposure limits updated (TRGS 900/910), water hazard class (WGK 3, ID no. 8026) and medical device information added (section 15).

Classification procedure
Calculation method on the basis of the composition (Art. 9 CLP).

Wording of the H statements in sections 2 and 3

H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H341	Suspected of causing genetic defects.
H350	May cause cancer.
H360F	May damage fertility.
H413	May cause long lasting harmful effects to aquatic life.

Training advice
Employees must be instructed on the hazards and protective measures for CMR substances on the basis of operating instructions (in Germany GefStoffV § 14).

Sources
Previous version MSDS Realloy Powder (22.04.2024); instructions for use of the alloys; Regulations (EC) No 1907/2006, 1272/2008, (EU) 2020/878, 2017/745 and 2023/607 as amended.

The information in this data sheet is compiled to the best of our knowledge and corresponds to the state of knowledge at the revision date. It does not constitute a guarantee of specific product properties.