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

1.1 Product identifier

Nickel-based alloys (massive form)

Realloy N+ | Realloy N+ Blank

Realloy N

Realloy Base

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

Identified use:	Manufacturing of dental prostheses in dental laboratories (casting, milling). Professional use only.
Uses advised against:	All uses other than those identified above. Supply to and use by the general public.

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)

Skin Sens. 1; H317	May cause an allergic skin reaction.
Carc. 2; H351	Suspected of causing cancer.
STOT RE 1; H372	Causes damage to organs (lungs) through prolonged or repeated exposure (inhalation).

Classification by calculation from the nickel content (Art. 9 CLP). The alloys are supplied in massive form (ingots, blanks). The health hazards become relevant when dust, vapours or fumes are generated during processing (melting, grinding, milling, sandblasting, polishing).

2.2 Label elements

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

Note: Alloys in massive form do not require a label if they do not present a hazard to human health by inhalation, ingestion or skin contact or to the aquatic environment in the form in which they are placed on the market (Regulation (EC) No 1272/2008, Annex I, section 1.3.4). The following label elements apply to the dust, vapours and fumes generated during processing.

Hazard pictograms



GHS08

Signal word: **Danger**
Hazard-determining component for labelling: Nickel

Hazard statements

H317	May cause an allergic skin reaction.
H351	Suspected of causing cancer.
H372	Causes damage to organs (lungs) through prolonged or repeated exposure (inhalation).

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.
P302+P352	IF ON SKIN: Wash with plenty of water and soap.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.

Supplemental information
Text for labelling: Contains: Nickel.
Restricted to professional users.

2.3 Other hazards

Mechanical processing (separating, grinding, milling, sandblasting, polishing) produces metal dust. Dust contact with the eyes can lead to mechanical irritation. Inhalation of dust may cause irritation of the respiratory system. Fine grinding dust can burn.
During melting, casting, soldering and laser welding, metal fumes containing nickel and chromium oxides 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: metal alloy (massive form). Hazardous ingredients and ingredients with occupational exposure limits:

Substance name	Identifiers	Classification (EC) 1272/2008	Content (% w/w)
Nickel	CAS 7440-02-0 EC 231-111-4 Index 028-002-00-7	Skin Sens. 1; H317 Carc. 2; H351 STOT RE 1; H372	24 – 63
Chromium	CAS 7440-47-3 EC 231-157-5	not classified	21 – 25
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 get medical attention.
Following skin contact:	Wash with water and soap and rinse thoroughly. In case of skin reactions consult a physician. Burns from hot metal: cool with water, get medical attention.
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 an allergic skin reaction (contact eczema); mechanical irritation of eyes and respiratory tract by dust.
Delayed: damage to the lungs through prolonged or repeated inhalation of dust/fume; suspected of causing cancer.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically. In case of skin sensitisation, avoid any further contact.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:
The product (massive metal) is non-combustible. Adapt extinguishing measures to the surrounding fire. For burning grinding dust: metal fire extinguishing powder (class D), dry sand.

Unsuitable extinguishing media for safety reasons:
For burning metal dust: water, foam, carbon dioxide (CO_2).

5.2 Special hazards arising from the substance or mixture

In case of fire, metal oxide fumes may develop (nickel, chromium, molybdenum oxides).

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

Ingots: no special measures required. Dust: avoid dust formation and inhalation; wear personal protective equipment (see section 8).

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

Pick up ingots mechanically and reuse. Collect dust with an industrial vacuum cleaner of dust class H; 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. Keep exposure to nickel-containing dust and fume as low as possible.
Melt, cast, solder and laser weld only with fume extraction. Carry out milling, grinding, finishing and sandblasting only with local exhaust ventilation (dust class H). Avoid dust formation. Do not eat, drink or smoke at the workplace. Wash hands after work.

7.2 Conditions for safe storage, including any incompatibilities

Store in the original packaging in a dry place. Keep away from food, drink and animal feedingstuffs. Do not store together with acids.

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
7440-02-0	Nickel	TRGS 900: OEL (AGW)	0.006 mg/m³ (R) (nickel metal)
		TRGS 900: OEL (AGW)	0.03 mg/m³ (I) (nickel and nickel compounds)
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. Fume extraction at the melting/casting unit; local exhaust ventilation with H-class filtration at grinding and sandblasting workstations.

Personal protection equipment

Respiratory protection:	If dust or fume can be released (e.g. insufficient extraction): particle filter P3 (EN 143) or FFP3 mask (EN 149).
Eye protection:	Safety glasses with side shields (EN 166); when melting, tinted protective glasses / face shield.
Hand protection:	Protective gloves against dust (EN ISO 374-1); heat-resistant gloves when casting (EN 407).
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 (ingots, blanks) at 20 °C
Colour	Silver-grey, metallic
Odour	Odourless
Melting point/freezing point	Approx. 1250 – 1350 °C; the products have different melting ranges within this range
Boiling point	No data available
Flammability	Massive metal: non-combustible
Lower and upper explosion limit	Not applicable (massive form)
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	8.0 – 8.2 g/cm³ at 20 °C
Relative vapour density	Not applicable (solid)
Particle characteristics	Not applicable (massive form)

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 during processing.

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	Based on available data, the classification criteria are not met.
Skin sensitisation	Skin Sens. 1; H317
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Carc. 2; H351
Reproductive toxicity	Based on available data, the classification criteria are not met.
STOT – single exposure	Based on available data, the classification criteria are not met.
STOT – repeated exposure	STOT RE 1; H372 (lungs, inhalation)
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**

Based on available data, the classification criteria for hazards to the aquatic environment are not met (nickel in massive form). No relevant release into water is expected.

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:	Dispose of in consultation with the regional waste disposal company.
Packaging:	Dispose of emptied packaging in consultation with the regional waste disposal company.

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

REACH Annex XVII, entry 27 (nickel): concerns articles intended to come into direct and prolonged contact with the skin; not relevant for dental alloys.
REACH candidate list (SVHC) / Annex XIV: not listed

Medical device regulations

The alloys are medical devices of class IIa (legacy devices according to Directive 93/42/EEC, placed on the market under the transitional provisions of Art. 120 of Regulation (EU) 2017/745 (MDR); notified body TÜV NORD CERT GmbH, 0044). The dental prostheses made from them are custom-made devices.
Information on the nickel content (risk of allergy), residual risks, contraindications and incident reporting is provided in the instructions for use (MDR Annex I, section 23.4).
The exemption of Art. 2(6)(a) REACH does not apply, as the alloys 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 1 – self-classification according to AwSV Annex 1 No. 5 (nickel, particle size ≥ 1 mm: WGK 1, ID no. 7182)
Employment restrictions:	Observe employment restrictions for young people (JArbSchG § 22) and for pregnant and breastfeeding women (MuSchG §§ 11, 12).
Hazardous Substances Ordinance:	GefStoffV; TRGS 900.

15.2 **Chemical safety assessment**

For this mixture a chemical safety assessment is not required.

SECTION 16: Other information

Changes from the previous version (06.01.2025)

Complete revision. Classification of nickel corrected (Carc. 2, STOT RE 1, Skin Sens. 1; respiratory sensitisation and Aquatic Chronic 3 deleted), obsolete P statements (P285, P304+P341) replaced,

composition and occupational exposure limits corrected (TRGS 900), water hazard class corrected, revision according to Regulation (EU) 2020/878, 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.
H351	Suspected of causing cancer.
H372	Causes damage to organs (lungs) through prolonged or repeated exposure (inhalation).

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

Sources
Previous version SDB Realloy Ni (06.01.2025); instructions for use of the alloys; Regulations (EC) No 1907/2006, 1272/2008, (EU) 2020/878 and 2017/745 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.