

according to 1907/2006/EC, Article 31 (Reach)

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Keralloy N**1. Identification of the Substance / Preparation and Company:**

Identification of the substance or preparation:

Commercial product name: Keralloy N
 Application of the substance: Metal alloy for dental technology
 Company / Manufacturer: SILADENT Dr. Böhme & Schöps GmbH
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2. Hazards Identification**2.1 Classification of the substance or mixture**

Hazard statements:

Classification in accordance with (EC) n° 487/2013 (ATP 4 CLP). and (EC) n° 605/2014 (ATP 6 CLP):

H334: May cause allergy or asthma symptom or breathing difficulties if inhaled.

H317: May cause an allergic skin reaction.

H413: May cause long lasting harmful effects to aquatic life.

Precautionary statements:

Classification in accordance with (EC) n° 487/2013 (ATP 4 CLP). and (EC) n° 605/2014 (ATP 6 CLP):

P102 Keep out of reach of children;

P202 Do not handle until all safety precautions have been read and understood.

P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

P501 Dispose of content/ container according to the relevant current rules.

2.2 Labelling Information:

In the form in which is marketed, the product causes no danger to health for humans through inhalation, swallowing or contact with the skin. There is therefore no obligation to label the product in accordance with:

(EC) n° 487/2013 (ATP 4 CLP)

(EC) n° 605/2014 (ATP 6 CLP)

2.3 Other hazards:

If the product from in the as-supplied state is changed through further processing (e.g. through grinding, polishing, electrical discharge machining, welding or melting) and dust or vapours are produced, there may be danger from hazardous components in the product.

PBT assessment: No data available

vPvB assessment: No data available

3. Composition/ information on ingredients**3.1 Description** The product is not a substance but an alloy which contains:

Ingredients:	CAS number EINESCS number	%
Nickel (Ni) max P102 Keep out of reach of children; P202 Do not handle until all safety precautions have been read and understood; P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray. P270 Do not eat, drink or smoke when using this product; P280 Wear protective gloves/ protective clothing/ eye protection/ face protection; P501 Dispose of contents/ container according to the relevant current rules. 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	CAS-No. 7440-02-0 EC-No. 231-111-4	63

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Chromium (Cr)	CAS-No. 7440-47-3 EC-No. 231-157-5	25
Molybdenum (Mo)	CAS-No. 7439-98-7 EC-No. 231-107-2	9
Silicon (Si)	CAS-No. 7440-21-3 EC-No. 215-609-9	2
Niobium (Nb)	CAS-No. 7440-03-1 EC-No. 231-113-5	1

4 First aid measures

After inhalation:	If large amount is inhaled or under an asthma attack, remove to fresh air and contact a doctor.
After skin contact:	Wash off contaminated areas with water or remove contaminated clothing and have a shower. Wash clothing before reuse. Avoid prolonged or repeated skin contact.
After eye contact:	Irrigate with water for at least 15 minutes.
After swallowing:	If a large amount is ingested induce vomiting only if the person is conscious and contact a doctor.

5. Fire Fighting measures:

Coherent form of Nickel-Chrome alloys run no risk of fire or explosion. At the contrary, if the material is fine divided (powder) it can explode at open air.	
Suitable extinguishing media:	Metal fire powder, sand.
Unsuitable extinguishing media:	Water, Foam, CO ₂ , Dry chemicals.
Special hazards caused by the material, its product of combustion or flue gases:	Intoxication, see point 11.
Special protective equipment for fire-fighters:	Use of aqualung and fully protective garment.

6. Accidental release measures:

Personal precautions:	Avoid dust formation. Avoid breathing dust.
Environmental precautions:	In case of dust being formed, provide for adequate aeration. Collect contaminated water separately. Do not discharge into the drains/ surface, waters/ groundwater. Do not discharge into the subsoil/ soil.
Methods and material for containment and cleaning up:	Treat the material as prescribed under heading "disposal considerations".

7. Handling and Storage:

7.1 Handling:	No special measures necessary.
7.2 Storage:	No special measures necessary.

8. Exposure controls / Personal protection:

Respiratory protection	If solid Nickel-Chrome alloy forms are converted in manufacturing processes to particulates, maintain working environment below the recommended limits by use of appropriate ventilation (Cr<0,050 mg/m ³) if ventilation is not adequate, then respiratory protection should be used.
Protection of hands	Protective gloves to be used.
Eye protection	Safety goggles with side-shields (EN 166) to be used.
Skin and body protection	Suitable protective clothing to be used.

9. Physical and chemical properties:

State at the supply:	Solid
Colour at the supply:	Silver-coloured
Odour at the supply:	Odourless

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Melting range at atmospheric pressure:	No data available
Boiling range at atmospheric pressure:	>1200 °C
PH at the supply:	Not applicable
Flash point:	Not applicable
Flammability:	Not applicable
Self-flammability:	Not applicable
Danger of explosion:	Not applicable
Fire supporting:	Not applicable
Steam pressure at standard temperature:	Not Known
Absolute density at standard condition:	8,5 g/cm ³
Solubility at standard condition:	Insoluble in water..
Liposolubility:	Insoluble
Coefficient of distribution: n-octanol / water:	Not applicable

10. Stability and Reactivity:

Condition to be avoided:	Not applicable
Substances to be avoided:	Perchlorates, ammonium nitrate, hydrazine, alkali, oxidizing, acids.
Necessary/ existing stabilizer:	Not applicable
Dangerous exothermic reactions:	Not applicable
Change of state of aggregation:	Not applicable
Dangerous decomposition products or contact with water:	Not applicable

11. Toxicological Information:

Under normal handling and use, exposure to massive forms of Nickel-Chrome alloys presents few health hazards. If however, massive forms are converted to particulates then both acute and chronic health hazards are possible.	
After inhalation:	Rare cases of asthma have been reported to have occurred in individuals exposed to some forms of particulates. Effects on respiratory tract and gastrointestinal disorder may occur.
After skin contact:	Exposure to Nickel-Chrome alloys may cause dermatitis or other allergic reactions in sensitive individuals.
After eye contact:	Irritation due to mechanical causes. Some workers exposed to aerosol of electrolysis reports eye irritation.
After swallowing:	Nickel-Chrome alloys are scarcely absorbed by the intestine, acute dose; however, may cause abdominal pains, vomit, anuria, uraemia. If the material is absorbed for long period, kidney harm may occur.

12. Ecological Information:

Toxicity:	No data available.
Persistence and degradability:	No data available.
Bioaccumulative potential:	No data available.
Mobility in soil:	No data available.
Results of PBT and vPvB assessment:	No data available.
Other adverse effects:	No data available.
Other information	No data available.

13. Disposal Considerations:

- 13.1 The processing scrap must be disposed of as special waste in accordance with the EC directives 91/156/EC on waste, 91/689/EC on hazardous waste and 94/62/EC on packaging and packaging waste and in compliance with national legislation in force on the subject.

14. Transport Information:

According to the laws, dental alloys are not considered as dangerous goods.

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15. Regulatory Information:

National legislation and European legislation.

This product is a medical device according to European Normative 93/42/EC.

16. Further Information:

Sources of key data used to compile the data sheet:

Regulation 67/548/EC or 99/45/EC in the corresponding relevant version in force. Regulation EC n. 1907/2006 (REACH), 1272/2008 (CLP) in the corresponding relevant version in force.

EC Directives 2000/39/EC, 2006/15/EC, 2009/161/EC.

These information are based on our present state of knowledge. However it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.