

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 18.04.2023

Version number 12

Revision: 18.04.2023

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

1.1 Product identifier

Trade name **Kera® N**
Kera® NH

Article number:

1004005
1004020

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

No further relevant information available.

Application of the substance / the mixture For the production of dental prostheses in the dental laboratory

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Eisenbacher Dentalwaren ED GmbH
Dr. - Konrad - Wiegand - Straße 9
63939 Wörth / Main, Germany
Tel.: 0049 9372 / 94 04 - 0
www.eisenbacher.de

Information:

product management tel.: +49 93 72 - 94 04 - 0
or by mail: info@eisenbacher.de

1.4 Emergency telephone number:

Tel.: +49 (0) 9372 9404 0, Monday to Friday 8.00 a.m. to 5.00 p.m., in German and English, also contact the local poison control centres

SECTION 2: Hazards identification

Medical devices according EG 2017-745 in their final state are exempted from the GB CLP legislation.

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

The following classification is not applicable to the alloy but only for the fumes, smokes and dusts formed during the processing and machining.

According to 1. ATP of GB CLP-Regulation (EC) 1272/2008 nickel is classified with category 3.9/1, H372. This is only relevant for nickel in a breathable form. According to annex I chapter 1.3.4 of GB CLP-Regulation (EC) 1272/2008, nickel in massive form is not classified in category 3.9/1, H372.

Skin Sens. 1 H317 May cause an allergic skin reaction.

Carc. 2 H351 Suspected of causing cancer. Route of exposure: Inhalation.

STOT RE 1 H372 Causes damage to the respiratory system through prolonged or repeated exposure. Route of exposure: Inhalation.

Additional information:

The specified classification and labelling relates to safe handling of the alloy and the manufacturing of dental prostheses and not for application in the oral cavity.

2.2 Label elements

Medical devices according EG 2017-745 in their final state are exempted from the GB CLP legislation. The following labelling is not applicable to the alloy but only for the fumes, smokes and dusts formed during the processing and machining.

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the GB CLP regulation.

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Hazard pictograms



GHS07 GHS08

Signal word Danger

Hazard-determining components of labelling:

nickel

Hazard statements

H317 May cause an allergic skin reaction.

H351 Suspected of causing cancer. Route of exposure: Inhalation.

H372 Causes damage to the respiratory system through prolonged or repeated exposure. Route of exposure: Inhalation.

Precautionary statements

P201 Obtain special instructions before use.

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

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

P264 Wash thoroughly after handling.

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

P272 Contaminated work clothing should not be allowed out of the workplace.

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

P302+P352 IF ON SKIN: Wash with plenty of water.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P321 Specific treatment (see on this label).

P314 Get medical advice/attention if you feel unwell.

P362+P364 Take off contaminated clothing and wash it before reuse.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Information pertaining to particular dangers for man and environment

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

2.3 Other hazards

For dust and metal vapors occurring during processing are also relevant:

H372: Causes damage to organs through prolonged or repeated exposure.

H412: Harmful to aquatic life with long lasting effects.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Description: Mixture of the substances listed below with harmless additions.

Dangerous components:

CAS: 7440-02-0	nickel	≥50-≤100%
EINECS: 231-111-4	Carc. 2, H351; STOT RE 1, H372; Skin Sens. 1, H317	
Index number: 028-002-00-7		
CAS: 7440-47-3	chromium	≥10-<50%
EINECS: 231-157-5	substance with a Community workplace exposure limit	
CAS: 7440-21-3	silicon	≥0-<10%
EINECS: 231-130-8	Flam. Sol. 2, H228	

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. **Additional information** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

. 4.1 Description of first aid measures

. **General information** No special measures required.

. **After inhalation** : Supply fresh air; consult doctor in case of symptoms.

. **After skin contact** : Wash with water and soap.

. **After eye contact** : Rinse opened eye for 15 minutes under running water. Then consult doctor.

. **After swallowing** :

Rinse out mouth and then drink plenty of water (approx. 500 ml).

Seek medical treatment.

. **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

. **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

SECTION 5: Firefighting measures

. 5.1 Extinguishing media

. **Suitable extinguishing agents**

Use fire fighting measures that suit the environment.

CO₂, extinguishing powder or water jet. Fight larger fires with foam.

ABC powder

Sand

. **5.2 Special hazards arising from the substance or mixture** Metal vapor and metal oxides as fumes.

. **5.3 Advice for firefighters**

. **Protective equipment:** Do not inhale explosion gases or combustion gases.

SECTION 6: Accidental release measures

. 6.1 Personal precautions, protective equipment and emergency procedures

Wear protective clothing.

Ensure adequate ventilation

Dust is toxic by inhalation! Formation of dust must be avoided!

Use breathing protection against the effects of fumes/dust/aerosol.

. **6.2 Environmental precautions:**

Do not allow concentrated solutions to enter drainage system, surface or ground water.

. **6.3 Methods and material for containment and cleaning up:** Collect mechanically.

. **6.4 Reference to other sections**

See section 7 for information on safe handling

See section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

SECTION 7: Handling and storage

. 7.1 Precautions for safe handling

Dust is toxic by inhalation! Formation of dust must be avoided!

Provide suction extractors if dust is formed.

Ensure good ventilation/exhaustion at the workplace.

Extractors are required on all machines used for thermal processing or metal removal processes.

. **Information about protection against explosions and fires:** No special measures required.

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- . **7.2 Conditions for safe storage, including any incompatibilities**
- . **Storage**
- . **Requirements to be met by storerooms and containers:** No special requirements.
- . **Information about storage in one common storage facility:** Not required.
- . **Further information about storage conditions:** Store in cool, dry conditions in well sealed containers.
- . **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- . **8.1 Control parameters**
- . **Components with critical values that require monitoring at the workplace:**

7440-02-0 nickel

WEL (Great Britain) Long-term value: 0.5 mg/m³
as Ni; Sk; Carc

7440-47-3 chromium

WEL (Great Britain) Long-term value: 0.5 mg/m³
IOELV (European Union) Long-term value: 2 mg/m³
as Cr

7440-21-3 silicon

WEL (Great Britain) Long-term value: 10* 4** mg/m³
*inhalable dust **respirable dust

- . **Ingredients with biological limit values:**

CAS No.	Designation of material	%	Type	Value	Unit
	General dust exposure limit, measured as alveolic part		German TRGS 900 (2015)	1,25	mg/m ³

- . **Additional information:** The lists that were valid during compilation were used as a basis.

- . **8.2 Exposure controls**

- . **Personal protective equipment**

- . **General protective and hygienic measures**

The usual precautionary measures should be adhered to in handling the chemicals.

Wash hands during breaks and at the end of the work.

Avoid contact with the eyes and skin.

Do not inhale dust / smoke / mist.

- . **Breathing equipment:**

Use breathing protection in case of insufficient ventilation.

Filter P3.

- . **Protection of hands:**

Protective gloves:

In case of spray contact at least protection index 2 recommended, according to more than 30 min. penetration time (EN 374).

Layer thickness of gloves at least: 0.4 mm

In case of prolonged and intensive contact protection index 6 recommended, according to more than 480 min. penetration time (EN 374).

Layer thickness of gloves at least: 0.7 mm

- . **Material of gloves**

Butyl rubber, BR

Fluorocarbon rubber (Viton)

Nitrile rubber, NBR

Natural rubber, NR

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- Chloroprene rubber, CR
- Neoprene gloves
- Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- Eye protection:** Safety glasses (DIN 58211, EN 166)
- Body protection:** Light weight protective clothing

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

- Form: Solid
- Colour: Silver-coloured
- Smell: Odourless
- Odour threshold: not applicable
- pH-value: Not applicable.
not applicable

Change in condition

- Melting point/freezing point: 1,240-1,325 °C
- Initial boiling point and boiling range: 1,390 °C

- Flash point: Not applicable
not applicable

- Inflammability (solid, gaseous) not applicable

- Auto-ignition temperature: not applicable

- Decomposition temperature: not determined

- Explosive properties: Product is not explosive.

Critical values for explosion:

- Lower: not applicable

Dust explosion class:

- Oxidising properties not applicable

- Steam pressure: Not applicable.
not applicable

- Density at 20 °C 8.2 g/cm³

- Evaporation rate not applicable

Solubility in / Miscibility with

- Water: Insoluble

- Partition coefficient: n-octanol/water: not applicable

Viscosity:

- dynamic: Not applicable.
not applicable
- kinematic: Not applicable.

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. **Solvent content:**

Solids content: 100.0 %

. **9.2 Other information** No further relevant information available.

SECTION 10: Stability and reactivity

. **10.1 Reactivity**

No further relevant information available.

No further relevant information available.

. **10.2 Chemical stability**

. **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

. **10.3 Possibility of hazardous reactions** No dangerous reactions known

. **10.4 Conditions to avoid** No further relevant information available.

. **10.5 Incompatible materials:** No further relevant information available.

. **10.6 Hazardous decomposition products:** Formation of metal vapor when melting

SECTION 11: Toxicological information

. **11.1 Information on toxicological effects**

. **Acute toxicity** Based on available data, the classification criteria are not met.

. **LD/LC50 values that are relevant for classification:**

Components	Type	Value	Species
Product	LD50: oral	> 2000 mg/kg	rat

. **Primary irritant effect:**

. **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 or skin sensitisation**

May cause an allergic skin reaction.

. **Subacute to chronic toxicity:**

Do not breath dust.

Toxic: possible risk of irreversible effects through inhalation.

. **Additional toxicological information:**

. **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**

Suspected of causing cancer. Route of exposure: Inhalation.

. **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

. **Carcinogenicity**

Suspected of causing cancer. Route of exposure: Inhalation.

. **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**

Causes damage to the respiratory system through prolonged or repeated exposure. Route of exposure: Inhalation.

. **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

. **12.1 Toxicity**

. **Aquatic toxicity:** No further relevant information available.

. **12.2 Persistence and degradability** No further relevant information available.

. **12.3 Bioaccumulative potential** No further relevant information available.

. **12.4 Mobility in soil** No further relevant information available.

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- . **Ecotoxicological effects:**
- . **Remark:** No data
- . **Other information:**
No COD, no BOD, no AOX
No VOC (0%) according to EC-directive 1999/13/EC
- . **Additional ecological information:**
- . **General notes:**
Do not allow product to reach ground water, water bodies or sewage system.
Danger to drinking water if even small quantities leak into soil.
- . **12.5 Results of PBT and vPvB assessment**
- . **PBT:** Not applicable.
- . **vPvB:** Not applicable.
- . **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- . **13.1 Waste treatment methods**
- . **Recommendation**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Must be specially treated in adherence to official regulations.
Contact manufacturer for recycling information.
- . **Uncleaned packaging:**
- . **Recommendation:**
Empty contaminated packagings thoroughly. They can be recycled after thorough and proper cleaning.
Packagings that cannot be cleaned are to be disposed of in the same manner as the product.
Dispose of packaging according to regulations on the disposal of packagings.
- . **Recommended cleaning agent:** Water, if necessary with cleaning agent.

SECTION 14: Transport information

- | | |
|--|---|
| . 14.1 UN-Number | Void |
| . ADR/RID/ADN, IMDG, IATA | Void |
| . 14.2 UN proper shipping name | Void |
| . ADR/RID/ADN, IMDG, IATA | Void |
| . 14.3 Transport hazard class(es) | Void |
| . ADR/RID/ADN, IMDG, IATA | Void |
| . Class | Void |
| . 14.4 Packing group | Void |
| . ADR/RID/ADN, IMDG, IATA | Void |
| . 14.5 Environmental hazards: | Not applicable. |
| . 14.6 Special precautions for user | Not applicable. |
| . 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| . Transport/Additional information: | Not dangerous according to the above regulations. |
| . UN "Model Regulation": | Void |

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SECTION 15: Regulatory information

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

. Directive 2012/18/EU

. **Named dangerous substances - ANNEX I** None of the ingredients is listed.

. National regulations

. Information about limitation of use:

Employment restrictions concerning young persons must be observed.

Employment restrictions concerning pregnant and lactating women must be observed.

. Other regulations, limitations and prohibitive regulations

The general dust exposure limit of 1.25 mg/m³, measured as alveolic part has to be observed (German TRGS 900, 2015).

. **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

. Relevant phrases

H228 Flammable solid.

H317 May cause an allergic skin reaction.

H351 Suspected of causing cancer.

H372 Causes damage to organs through prolonged or repeated exposure.

52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

. **Contact:** info@eisenbacher.de

. Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Sol. 2: Flammable solids – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Carc. 2: Carcinogenicity – Category 2

STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

. **Sources:** source ECHA: European Chemicals Agency, <http://echa.europa.eu/>

. * **Data compared to the previous version altered.**