



Material Safety Data Sheet -Nickel-

in accordance with the Regulation (EC) 1907/2006
(REACH)

Version no.: 10

Effective as of: 12/2021
Replaces version no. 09 of 01/2021

1. Identification of the substance/preparation and of the company	
1.1 Trade name:	SYSTEM KN, SYSTEM NH
1.2 Product description:	Nickel-based alloy; dental continuous casting or other casting process
Product form:	Rod, disc, cylinder or varying geometries
Purpose:	The production of crowns, bridges and dentures in dentistry
1.3 Producer:	Adentatec GmbH
Street:	Konrad-Adenauer-Straße 13
Zip code, town, country	50996 Köln/ GERMANY
Telephone:	0 221 - 35 96 100
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Information department:	Alexander Schnack Tel.: 0 221 - 35 96 100
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Email:	info@adentatec.com
Homepage:	www.adentatec.com
2. Hazards identification	
2.1 Classification of the substance or mixture . Classification according to Regulation (EC) No 1272/2008	<p>Medical devices according EG 2017-745 in their final state are exempted from the CLP legislation.</p> <p>The following classification is not applicable to the alloy but only for the fumes, smokes and dusts formed during the processing and machining.</p> <p>According to 1. ATP of 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 CLP-Regulation (EC) 1272/2008, nickel in massive form is not classified in category 3.9/1, H372.</p> <p>Skin Sens. 1 H317 May cause an allergic skin reaction.</p> <p>Carc. 2 H351 Suspected of causing cancer.</p> <p>STOT RE 1 H372 Causes damage to organs through prolonged or repeated exposure.</p> <p>. 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.</p>
Information concerning particular hazards for humans and for the environment:	This product needs not be labelled due to the calculation procedure of the "EC General Classification Directive for Preparations" in its latest valid version.
Users:	Qualified professionals (dental technicians, dentists)
Classification system:	The classification complies with the latest EU lists, but there are additional data from specialized literature and from the company.
2.2 GHS label elements:	<p>Medical devices according EG 2017-745 in their final state are exempted from the 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.</p> <p>. Labelling according to Regulation (EC) No 1272/2008 The product is classified and labelled according to the CLP regulation.</p>
 GHS08	 GHS07

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<p>After swallowing: After skin contact: After eye contact:</p> <p>4.2 Most important acute and delayed symptoms and effects:</p> <p>4.3 Information for medical urgent care or a specialized treatment.</p>	<p>Rinse out mouth and give plenty of water to drink. Seek medical advice in case of persistent discomfort. Wash with soap and water. Rinse eye under running water and seek medical advice.</p> <p>No specific action required</p> <p>No further relevant information available.</p>
5. Fire-fighting Measures	
5.1 Extinguishing agents	Use firefighting measures that suit the environment. ABC dry powder, foam or sand. NO WATER!
5.2 Special hazards emitted by the substance or composite	Metal vapours and metal oxides in the form of smoke and gas.
5.3 Advice for firefighters	Avoid inhalation of fumes!
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:	Dispose of any rests / dental scrap in an environmentally sound manner. Swarf must not 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.

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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.
7.2 Conditions for safe storage, including any incompatibilities: Advice on storage compatibility:	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.
8. Exposure Limits and Personal Safety Equipment	
8.1 Control parameter:	7440-02-0 nickel WEL (Great Britain) Long-term value: 0.5 mg/m ³ as Ni; Sk; Carc 7440-47-3 chromium WEL (Great Britain) Long-term value: 0.5 mg/m ³ IOELV (European Union) Long-term value: 2 mg/m ³ as Cr 7440-21-3 silicon WEL (Great Britain) Long-term value: 10* 4** mg/m ³ *inhalable dust **respirable dust . Ingredients with biological limit values: . CAS No. Designation of material % Type Value Unit General dust exposure limit, German TRGS 900 (2015) 1,25 mg/m ³ measured as alveolic part . 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

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	<p>Butyl rubber, BR Fluorocarbon rubber (Viton) Nitrile rubber, NBR Natural rubber, NR Chloroprene rubber, CR Neoprene gloves</p> <p>. 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.</p> <p>. Eye protection: Safety glasses (DIN 58211, EN 166) . Body protection: Light weight protective clothing</p>
9. Physical and Chemical Properties	
9.1 Information on basic physical and chemical properties:	<p>Tensile strength: ~530 - ~560 MPa</p> <p>Hardness: ~160 - ~290 HV 10</p> <p>Fracture strain: >3 - ~30 %</p> <p>Tensile module: ~115 GPa</p> <p>Density: 8.2 - 8.5 g/m³</p> <p>Thermal expansion coefficient: ~14 - ~16 (x10⁻⁶K⁻¹)</p> <p>Melting point: ~1310 to ~1400°C</p> <p>Risk of explosion: The Product is not explosive.</p> <p>pH value: not applicable</p>
9.2 Other information:	<p>Form: Rod, disc, cylinder or varying geometries</p> <p>Colour product-specific: Metallic grey</p> <p>Oduor: Odourless</p> <p>Solubility in / miscibility with water: insoluble</p> <p>Flammability: non-inflammable</p>
10. Stability and Reactivity	
<p>10.1 Reactivity: 10.2 Chemical stability: 10.3 Possibility of hazardous reactions: 10.4 Conditions to avoid: 10.5 Incompatible materials: 10.6 Hazardous decomposition products:</p>	<p>not applicable not applicable not applicable not applicable not applicable Formation of metal vapor when melting</p>
11. Information about the Toxicology	
11.1 Information on toxicological effects	<p>Acute toxicity Based on available data, the classification criteria are not met.</p> <p>LD/LC50 values that are relevant for classification:</p> <p>. Components Type Value Species Product LD50: oral > 2000 mg/kg rat</p> <p>. 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</p>

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<p>14.2 UN proper shipping name:</p> <p>14.3 Transport hazard class:</p> <p>14.4 Packing group:</p> <p>14.5 Environmental hazards:</p> <p>14.6 Special precautions for user:</p> <p>14.7 Transport in bulk according to Annex II of MARPOL73/78 Convention and the IBC code:</p>	<p>not applicable</p> <p>Dental alloys are not a dangerous good under transport regulations:</p> <ul style="list-style-type: none"> - Ground transport ADR/RID/ADN and GGVS/GGVE (cross-border/domestic) - Maritime transport IMDG/GGV sea - Air transport ICAO-TI and IATA-DGR <p>not applicable</p> <p>See section 13</p> <p>no specific precaution required</p> <p>see section 14.3</p>
15. Regulations	
<p>15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:</p> <p>15.2 Chemical safety assessment:</p>	<p>. Directive 2012/18/EU</p> <p>. Named dangerous substances - ANNEX I None of the ingredients is listed.</p> <p>. National regulations</p> <p>. Information about limitation of use:</p> <p>Employment restrictions concerning young persons must be observed. Employment restrictions concerning pregnant and lactating women must be observed.</p> <p>. 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).</p> <p>A Chemical Safety Assessment has not been carried out.</p>
16. Other information	
<p>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.</p> <p>. Relevant phrases</p> <p>H228 Flammable solid.</p> <p>H317 May cause an allergic skin reaction.</p> <p>H351 Suspected of causing cancer.</p> <p>H372 Causes damage to organs through prolonged or repeated exposure.</p> <p>52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.</p> <p>. Contact: info@adentatec.com</p>	
<p>Abbreviations and definitions</p>	<p>ADR: Accord européen sur le transport des marchandises dangereuses par route</p> <p>CAS: Chemical Abstracts Service (division of the American Chemical Society)</p> <p>CLP: Classification Labelling Packaging</p> <p>EINECS: European Inventory of Existing Commercial Chemical Substances</p> <p>GHS: Globally Harmonized System</p> <p>H-phrase: Hazard statement</p> <p>IATA: International Air Transport Association</p> <p>IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)</p> <p>ICAO: International Civil Aviation Organization</p> <p>ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)</p> <p>IMDG: International Maritime Code for Dangerous Goods</p>

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	LC50:	Lethal concentration, 50 percent
	LD50:	Lethal dose, 50 percent
	P-phrase:	Precautionary statement
	PBT:	Provider Backbone Transport
	RID:	Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
	vPvB:	very persistent very bioaccumulating