

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

Version no.: 10

	he 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,	50996 Köln/ GERMANY	
country	SOSSO NOTIFY CERTAIN	
Telephone:	0 221 - 35 96 100	
Fax:	0 221 - 35 96 170	
rax:	0 221 - 33 96 170	
T. C. was billion		
Information		
department:	Alexander Schnack	
	Tel.: 0 221 - 35 96 100	
Emergency		
information:	030 19240	
Email:	info@adentatec.com	
Homepage:	www.adentatec.com	
2. Hazards identificat	ion	
	Madical davises essentian RC 2017 745 in their final state and	
	Medical devices according EG 2017-745 in their final state are	
2.1 Classification of the	excempted from the CLP legislation.	
substance or mixture		
. Classification according	The following classification is not applicable to the alloy but only	
to Regulation (EC) No	for the fumes, smokes and dusts formed during the	
1272/2008	processing and machining.	
	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.	
	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 through prolonged or repeated	
	exposure.	
	Padditional information.	
	. Additional information:	
	The specified classification and labelling relates to safe handling of	
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	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.	
Information concerning	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. This product needs not be labelled due to the calculation procedure of	
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		·		
Signal word: Dang	er			
	F F	Hazard statements H317 May cause an allergic skin reaction. H351 Suspected of causing cancer. H372 Causes damage to organs through prolonged or repeated exposure.		
	I I	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.		
	I I	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.		
	F F	P308+P313 IF exposed or concerned: Get medical advice/attention.		
	F F 6	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.		
<pre>2.3 Other hazards during treatment and processing of the alloy:</pre>		Additional information: For vapour, fume and dust created during the processing, the following also applies:		
		H372 Causes damage to organs through prolonged or repeated exposure. H412 Toxic to aquatic life with long lasting effects.		
3. Composition	n / Informa	tion about the components		
		d precautions given in the chapters 4 to 8, 10 to 12 do not only apply to the resulting dust and vapours generated when working with it.		
3.1 Chemical comp	oosition:			
Nickel chromium a	lloy			
Nickel Ni	Rest 20 - 70	CAS: 7440-02-0 % EINECS: 231-111-4 Index number: 028-002-00-7		
Chromium Cr	17 - 28	% CAS: 7440-47-3 EINECS: 231-157-5		
Silicon Si	0 - 3 %	CAS: 7440-21-3 EINECS: 231-130-8		
4. First Aid N	Measures			
4.1 Description o	of the			
IIII aIa mee				

Supply fresh air, in case of discomfort, see a doctor.

After inhalation:



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After swallowing:	Rinse out mouth and give plenty of water to drink. Seek medical advice
	in case of persistent discomfort.
After skin contact:	Wash with soap and water.
After eye contact:	Rinse eye under running water and seek medical advice.
4.2 Most important acute	No specific action required
and delayed symptoms and	No specific action required
effects:	
CIICCO.	
4.3 Information for medical	No further relevant information available.
urgent care or a specialized treatment.	
-	
5. Fire-fighting Measu	res
5.1 Extinguishing agents	Use firefighting measures that suit the environment.
J.I EXCINGUISHING AGENCS	ABC dry powder, foam or sand. NO WATER!
	nbe dry powder, round or sund. No write:
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,	Wear protective clothing. Ensure adequate ventilation
protective equipment and emergency	Dust is toxic by inhalation! Formation of dust must be avoided!
procedures:	Use breathing protection against the effects of fumes/dust/aerosol.
procedures.	OSC Dicaching proceedion against the effects of funes/dust/defosof.
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	Collect mechanically.
for containment and	
cleaning up:	
6.4 Reference to other	See section 7 for information on safe handling
sections:	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/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, German TRGS 900 (2015) 1,25 mg/m3 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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	Butyl rubber, BR Fluorocarbon rubber (Viton) Nitrile rubber, NBR Natural rubber, NR 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
9. Physical and Chemic	al Properties
9.1 Information on basic physical and chemical properties:	Tensile strength: ~530 - ~560 MPa Hardness: ~160 - ~290 HV 10 Fracture strain: >3 - ~30 % Tensile module: ~115 GPa Density: 8.2 - 8.5 g/m3 Thermal expansion coefficient: ~14 - ~16(x10^-6K^1) Melting point: ~1310 to ~1400°C Risk of explosion: The Product is not explosive. pH value: not applicable
9.2 Other information:	Form: Rod, disc, cylinder or varying geometries Colour product-specific: Metallic grey Oduor: Odourless Solubility in / miscibility with water: insoluble Flammability: non-inflammable
10. Stability and Reac	tivity
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:	not applicable not applicable not applicable not applicable not applicable Formation of metal vapor when melting
11. Information about	the Toxicology
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

classification criteria are not met.
. Serious eye damage/irritation Based on available data, the



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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 irreversibe effects through inhalation.

- . Additional toxicological information:
- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- . Germ cell mutagenicity Based on available data, the classification criteria are not met.
- . Carcinogenicity

Suspected of causing cancer.

- . 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 organs through prolonged or repeated exposure.

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

12. Information About the Ecology:

12.1 Toxicity:

12.2 Persistence and degradability:

12.3 Bioaccumulative potential:

12.4 Mobility in soil:

No results known from animal testing.

not applicable

not known

Mobility in soil No further relevant information available.

- . Ecotoxical 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 the PBT and vPvB assessment:

not, known not known

12.6 Other adverse effects:

No further relevant information available.

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.

14. Transport Information

14.1 UN number:



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1 1 1 2			
14.2	UN proper shipping		
	name:	not applicable	
14.3	Transport hazard		
	class:	Dental alloys are not a dangerous good under transport regulations: - Ground transport ADR/RID/ADN and GGVS/GGVE (cross-border/domestic) - Maritime transport IMDG/GGV sea - Air transport ICAO-TI and IATA-DGR	
14.4	Packing group:	not applicable	
14.5	Environmental		
	hazards:	See section 13	
14.6	Special precautions		
	for user:	no specific precaution required	
14.7	Transport in bulk		
	according to Annex II		
	of MARPOL73/78		
	Convention and the		
	IBC code:	see section 14.3	
15.	Regulations		
15.	Regulations		
	Safety, health and		
		. Directive 2012/18/EU	
	Safety, health and	. Directive 2012/18/EU . Named dangerous substances - ANNEX I None of the ingredients is	
	Safety, health and environmental		
	Safety, health and environmental regulations/legislati	. Named dangerous substances - ANNEX I None of the ingredients is	
	Safety, health and environmental regulations/legislati on specific for the	. Named dangerous substances - ANNEX I None of the ingredients is listed.	
	Safety, health and environmental regulations/legislati on specific for the	. Named dangerous substances - ANNEX I None of the ingredients is listed. . National regulations	
	Safety, health and environmental regulations/legislati on specific for the	 . Named dangerous substances - ANNEX I None of the ingredients is listed. . National regulations . Information about limitation of use: 	
	Safety, health and environmental regulations/legislati on specific for the	. 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.	
	Safety, health and environmental regulations/legislati on specific for the	. 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	
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16. Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product

A Chemical Safety Assessment has not been carried out.

features and shall not establish a legally valid contractual relationship.

. Relevant phrases

H228 Flammable solid.

15.2 Chemical safety

assessment:

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@adentatec.com

Abbreviations and	ADR:	Accord européen sur le transport des marchandises
definitions		dangereuses par route
	CAS:	Chemical Abstracts Service (division of the American
		Chemical Society)
	CLP:	Classification Labelling Packaging
	EINECS:	European Inventory of Existing Commercial Chemical
		Substances
	GHS:	Globally Harmonized System
	H-phrase:	Hazard statement
	IATA:	International Air Transport Association
	IATA-DGR:	Dangerous Goods Regulations by the "International Air
		Transport Association" (IATA)
	ICAO:	International Civil Aviation Organization
	ICAO-TI:	Technical Instructions by the "International Civil
		Aviation Organization" (ICAO)
	IMDG:	International Maritime Code for Dangerous Goods



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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