adentatec
competence in dental

Safety Data Sheet
-Cobalt-
According to EG 1907/2006 (REACH)

Versions-No.: 11

Valid from: 12/2021
Replaces version No. 10 from 01/2021

1. Identification of substance and company	
1.1 Trade name:	SYSTEM DURO, SYSTEM SOFT, SYSTEM NE, SYSTEM MM, SYSTEM 3, SYSTEM 1, SYSTEM MG, SYSTEM SOFT-BLANK, SYSTEM SIN
1.2 Product details:	Cobalt 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 Manufacturer:	**Adentatec GmbH**
Street:	Konrad-Adenauer-Straße 13
ZIP/city/Country.:	50996 Köln/ GERMANY
Phone:	0 221 – 35 96 100
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Information department:	Alexander Schnack Tel.: 0 221 – 35 96 100
Emergency information:	030 19240
E-Mail: Homepage:	Alexander Schnack info@adentatec.com www.adentatec.com
2. Hazards identification	
2.1 Classification of the substance or mixture . Classification according to Regulation (EC) No 1272/2008	Medical devices according EG 2017-745 in their final state are excempted from the CLP legislation. The following classification is not applicable to the alloy but only for the fumes, smokes and dusts formed during the processing and machining. Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. Skin Sens. 1 H317 May cause an allergic skin reaction. Muta. 2 H341 Suspected of causing genetic defects. Carc. 1B H350 May cause cancer. Repr. 1B H360F May damage fertility. Aquatic Chronic 4 H413 May cause long lasting harmful effects to aquatic life. **. 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 excempted 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. Labelling according to Regulation (EC) No 1272/2008 The product is classified and labelled according to the CLP regulation. . Hazard pictograms **GHS08** Signal word **DANGER** 

	Hazard-determining components of labelling: cobalt . Hazard statements H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H317 May cause an allergic skin reaction. H341 Suspected of causing genetic defects. H350 May cause cancer. H360F May damage fertility. H413 May cause long lasting harmful effects to aquatic life. . Precautionary statements P261 Avoid breathing dust. P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. P284 [In case of inadequate ventilation] wear respiratory protection. P333+P313 If skin irritation or rash occurs: Get medical advice/attention. 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.

3. Composition/Data on components

The information as to risk and precautions given in the chapters 4 to 8, 10 to 12 do not only apply to the product itself, rather to the resulting dust and vapours generated on working with it.

3.1 Chemical composition:

Co-Cr-Alloy		Chemical characterization:
Cobalt Co	Rest 50 – 70 %	CAS: 7440-48-4 EINECS: 231-158-0 Index number: 027-001-00-9
Chrome Cr	19 – 30 %	CAS: 7440-47-3 EINECS: 231-157-5
Silicone Si	0 – 2 %	CAS: 7440-21-3 EINECS: 231-130-8

4. First aid measures

4.1 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). In case of persistent symptoms consult doctor.
4.2 Important acute and delayed symptoms and effects:	No further relevant information available.
4.3 Information for the doctor:	No further relevant information available.

5. Fire fighting measures	
5.1 Suitable extinguishing aids:	Use firefighting measures that suit the environment. ABC dry powder, foam or sand. **NO WATER!**
5.2 Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases:	Metal vapors and metal oxides in the form of smoke and gas. Dusts are self-heating and can catch fire. Spontaneous combustion on contact with air. In contact with water releases flammable gases which may ignite spontaneously.
5.3 Protective equipment:	Do not inhale explosion gases or combustion gases.
6. Accidental release measures	
6.1 Person-related safety precautions: Protective equipment and to be used in emergencies procedure:	Avoid causing dust. Wear protective clothing. Ensure adequate ventilation Use breathing protection against the effects of fumes/dust/aerosol.
6.2 Measures for environmental protection:	Do not allow concentrated solutions to enter drainage system, surface or ground water.
6.3 Measures for cleaning/collecting:	Dry grinding dust by mechanical means or suckers record and disposal in appropriate containers fill, dust generation. Not use compressed air blow not.
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.
7. Handling and storage	
7.1 Information for safe handling:	Prevent formation of dust. 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 intolerances: Common storage notes:	**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 uses:	No further relevant information available.
8. Exposure controls and personal protection	
8.1 To be monitored parameter:	Particulate matter limits by TRGS 900
8.2 Limiting and monitoring exposure:	7440-48-4 Cobalt WEL (Great Britain) Long-term value: 0.1 mg/m³ as Co; Carc, Sen 7440-47-3 Chrome WEL (Great Britain) Long-term value: 0.5 mg/m³ IOELV (European Union) Long-term value: 2 mg/m³

	as Cr 7440-33-7 tungsten WEL (Great Britain) Short-term value: 10 mg/m³ Long-term value: 5 mg/m³ as W 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. Do not eat, drink or smoke while working. Avoid contact with the eyes and skin. Do not inhale dust / smoke / mist. . Breathing equipment: Use breathing protection in case of insufficient ventilation. Short term filter device: ABEK-filter 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 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 chemical properties	
9.1 Information on basic physical and chemical properties:	**Tensile strength:** ~ 400 - 900 MPa **Hardness:** ~ 270 - 450 HV 10 **Elongation:** > 2 - 16% **Young's modul:** ~ 150 - 240 GPa **density:** ~8,2 – 8,7 g/cm³ **Coefficient of thermal expansion:** ~ 14 - 16 (x10-^{6}K^{1}) **Melting point:** ~ 1250 - 1420°C **Danger of explosion:** Product is not explosive

	ph: not applicable
9.2 Other information:	**Form:** Rod, disc, cylinder or varying geometries **Colour – product specification:** Metallic bright **Smell:** Odorless **Solubility in / Miscibility with water:** Unsoluble **Inflammability:** non-flammable
10. Stability and reactivity	
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. 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 allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. . Subacute to chronic toxicity: Do not breathe dust. Harmful: possible risk of irreversible effects through inhalation. . Additional toxicological information: . CMR effects (carcinogenity, mutagenicity and toxicity for reproduction) . Germ cell mutagenicity Suspected of causing genetic defects. . Carcinogenicity May cause cancer. . Reproductive toxicity May damage fertility. . STOT-single exposure Based on available data, the classification criteria are not met. . STOT-repeated exposure Based on available data, the classification criteria are not met. . Aspiration hazard Based on available data, the classification criteria are not met.
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 Does not accumulate in organisms . 12.4 Mobility in soil No further relevant information available. . Ecotoxical effects: . 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, even in small quantities. Danger to drinking water if even extremely 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.
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. Contact manufacturer for recycling information. Must be specially treated in adherence to official regulations. . 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:	-
14.2 UN proper shipping Name:	not applicable
14.3 Transport Hazard classes:	Dental alloys are not a dangerous good under transport regulations: - Ground transport ADR/RID und GGVS/GGVE (cross-border/domestic) - Maritime transport IMDG/GGV sea - Air transport ICAO-TI und IATA-DGR
14.4 Packing Group:	not applicable
14.5 Environmental hazards:	see section 13
14.6 Special precautions:	No special precautions
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and under IBC Code:	See 14.3

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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. . 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.

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.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H341 Suspected of causing genetic defects.
H350 May cause cancer.
H360F May damage fertility.
H413 May cause long lasting harmful effects to aquatic life.
. 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
Resp. Sens. 1: Respiratory sensitisation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Muta. 2: Germ cell mutagenicity – Category 2
Carc. 1B: Carcinogenicity – Category 1B
Repr. 1B: Reproductive toxicity – Category 1B
Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4
. Sources: source ECHA: European Chemicals Agency, http://echa.europa.eu/