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Safety data sheet according to 1907/2006/EC, Article 31

Version number 4 (replaces version 3) Printing date 15.05.2024 Revision: 15.05.2024

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

- · 1.1 Product identifier
 - · Trade name: Heraenium CE, EH, NF, Laser, P, Pw, Sun
- · 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 Manufacture of dental prothesis
- · 1.3 Details of the supplier of the safety data sheet
 - Manufacturer/Supplier:

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

· Informing department: E-Mail: msds@kulzer-dental.com

• 1.4 Emergency telephone number: Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
 - Classification according to Regulation (EC) No 1272/2008

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. Resp. Sens. 1

Skin Sens. 1 H317 May cause an allergic skin reaction. Muta. 2 H341 Suspected of causing genetic defects.

H350 May cause cancer. Carc. 1B H360F May damage fertility. Repr. 1B

Aquatic Chronic 4 H413 May cause long lasting harmful effects to aquatic life.

- · 2.2 Label elements
 - Labelling according to Regulation (EC) No 1272/2008

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

· Hazard pictograms



- · 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/fume/gas/mist/vapours/spray.

P280 Wear protective gloves / eye protection.

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P280 Wear protective clothing.

P284 [In case of inadequate ventilation] wear respiratory protection.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

Additional information:

Restricted to professional users.

· 2.3 Other hazards

During welding and soldering processes spatter can occur, molten metal and UV / IR heat can cause burns or fire.

Chrome:

Welding and grinding produce smoke and dust. Chromium (VI) oxide, which is classified as carcinogenic, fine dust and ozone can develop. Sodium chromate can be formed during welding.

Sodium chromate has the following classification:

Classification sodium chromate (This classification only applies to pure sodium chromate.)

H 350 May cause cancer.

H 340 May cause genetic defects.

H 360FD May damage fertility. May harm the unborn child.

H 330 Danger to life if inhaled.

H 301 Toxic if swallowed.

H 372 Causes damage to organs through prolonged or repeated exposure.

H 312 Harmful in contact with skin.

H 314 Causes severe skin burns and eye damage.

H 334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H 317 can cause allergic reactions to your skin.

H 410 Very toxic for water organisms with long-term effect.

The proportion of sodium chromate in welding fumes depends on the electrode, the material to be welded and the welding conditions. It cannot be assessed here which of the aforementioned properties the welding smoke actually has.

Note on labeling:

As alloy, the product does not need to be labeled in accordance with EC regulations or the respective national laws. Although this product does not require labeling, we recommend that you follow the safety advice

· Results of PBT and vPvB assessment

PBT: Not applicable.

· vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

· Description: -

· Dangerous components		
CAS: 7440-48-4	cobalt	≥25-≤75%
EINECS: 231-158-0	Resp. Sens. 1, H334; Muta. 2, H341; Carc. 1B, H350; Repr.	
Index number: 027_001_00_0	18 H360F	

Skin Sens. 1, H317 Aquatic Chronic 4, H413

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CAS: 7440-47-3 chromium

≥0-≤50%

EINECS: 231-157-5 substar

substance with a Community workplace exposure limit

· 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

After inhalation

Take affected persons into the open air and position comfortably

After inhalation of smoke, vapors and dust get fresh air and see a doctor.

· After skin contact

Instantly wash with water and soap and rinse thoroughly.

Seek medical treatment.

If skin irritation continues, consult a doctor.

After eye contact

Rinse opened eye for several minutes under running water.

Seek medical treatment.

Rinse opened eye for several minutes under running water. Then consult doctor.

- After swallowing Do not induce vomiting; instantly call for medical help.
- · 4.2 Most important symptoms and effects, both acute and delayed Allergic reactions
- 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

Limestone powder

Dry sand

Use fire fighting measures that suit the environment.

· For safety reasons unsuitable extinguishing agents

Water.

Extinguishing foam.

Carbon dioxide

· 5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

- 5.3 Advice for firefighters
 - · Protective equipment: Do not inhale explosion gases or combustion gases.
 - · Additional information -

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

Ensure adequate ventilation

Wear protective clothing.

6.2 Environmental precautions:

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

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Prevent material from reaching sewage system, holes and cellars.

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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SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Avoid contact with eyes and skin.

Ensure good ventilation/exhaustion at the workplace.

Ensure good ventilation/exhaustion at the workplace.

- Information about protection against explosions and fires: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
 - · Storage
 - · Requirements to be met by storerooms and containers:

Store in cool, dry place in tightly closed containers.

- Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

· 8.1 Control parameters

Components with cr	· Components with critical values that require monitoring at the workplace:			
7440-48-4 cobalt				
WEL (Great Britain)	Long-term value: 0.1 mg/m³ as Co; Carc, Sen			
7440-47-3 chromium	7440-47-3 chromium			
WEL (Great Britain)	Long-term value: 0.5 mg/m³			
AGW (European Union)	Long-term value: 2 mg/m³ as Cr			
IOELV (European Union)	Long-term value: 2 mg/m³ as Cr			

[·] Additional information: The lists that were valid during the compilation were used as basis.

- · 8.2 Exposure controls
 - · Appropriate engineering controls No further data; see section 7.
 - Individual protection measures, such as personal protective equipment
 - General protective and hygienic measures

Do not eat or drink while working.

Keep away from foodstuffs, beverages and food.

Instantly remove any soiled and impregnated garments.

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

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· Breathing equipment:

ABEK-P3 (EN14387)

Filter P1.

Breathing protection recommended.

· Hand protection

For welding work: Use welding gloves (DIN 4841-4, EN 12477).

chemical protection gloves are suitable, which are tested according to EN 374

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

Check protective gloves prior to each use for their proper condition.

recommended

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Butyl rubber, BR

Nitrile rubber, NBR

Eye/face protection

eye protection (EN 166)

Tightly sealed safety glasses.

· Body protection: Light weight protective clothing

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

General Information

· Physical state

· Colour:

· Smell:

Odour threshold:

· Melting point/freezing point:

Boiling point or initial boiling point and

boiling range

· Flammability

· Lower and upper explosion limit

· Lower: · Upper:

· Flash point:

· pH

Decomposition temperature:

SADT

Solid.

Silver-coloured Odourless

Not determined.

1380 °C

>999 °C

Not determined.

Not determined.

Not determined. Not determined. Not applicable

Mixture is non-soluble (in water).

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(Contd. of page 5) · Viscosity: Kinematic viscosity Not applicable. · Kinematic viscosity · dynamic: Not applicable. Solubility · Water: Insoluble · Partition coefficient n-octanol/water (log value) Not determined. · Steam pressure: Not applicable. Vapour pressure: Density and/or relative density Density at 20 °C 8.25 g/cm³ · Relative density Not determined. · Vapour density Not applicable. · 9.2 Other information No further relevant information available. · Appearance: Solid. Form: · Important information on protection of health and environment, and on safety. Product is not selfigniting. · Self-inflammability: · Explosive properties: Product is not explosive. Not determined. · Solvent content: Solids content: 100.0 % · Change in condition · Evaporation rate Not applicable. · Information with regard to physical hazard classes Void **Explosives** Flammable gases Void · Aerosols Void Oxidising gases Gases under pressure Void Void · Flammable liquids Void · Flammable solids Void · Self-reactive substances and mixtures Void · Pyrophoric liquids Void Pyrophoric solids Void · Self-heating substances and mixtures Void · Substances and mixtures, which emit flammable gases in contact with water Void · Oxidising liquids Void Oxidising solids Void Organic peroxides Void Corrosive to metals Void

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· Desensitised explosives

Void

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- 10.2 Chemical stability
 - Conditions to be avoided: No decomposition if used and stored 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:

Strong acids

Strong oxidizers

Strong bases

· 10.6 Hazardous decomposition products:

In case of fire the following can be released:

Toxic metal oxide smoke

· Additional information: -

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
 - Acute toxicity Based on available data, the classification criteria are not met.
 - · LD/LC50 values that are relevant for classification:

	/44U-48-4 CODAIT						
	Dermal	LD50	>2,000 mg/kg (rat) (OECD 402)				
7440-47-3 chromium							
	Oral	LD50	>5,000 mg/kg (rat) (OECD 420)				
	Inhalative	LC50/4 h	>5,000 mg/kg (rat) (OECD 420) >5.41 mg/l (rat) (OECD 403)				

- · Skin corrosion/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.

- · 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.
- Additional toxicological information:
 - · Acute effects (acute toxicity, irritation and corrosivity)

Inhalation of fumes and smoke generated during welding/brazing may cause metal fume fever. Symptoms may appear after 4 - 12 hours. (Headache, dizziness, dryness, cough, nausea and fever).

· CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
Muta. 2, Carc. 1B, Repr. 1B

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· 11.2 Information on other hazards

· Endocrine disrupting properties

None of the ingredients is listed.

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.
- · 12.5 Results of PBT and vPvB assessment
 - · PBT: Not applicable.
 - vPvB: Not applicable.
- 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- 12.7 Other adverse effects
 - Additional ecological information:
 - General notes:

Do not allow product to reach ground water, water bodies or sewage system, even in small

Danger to drinking water if even extremely small quantities leak into soil.

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

Disposal must be made according to official regulations.

- · Uncleaned packagings:
 - **Recommendation:** Packaging can be reused or recycled after cleaning.

44.4.1111		
14.1 UN number or ID number ADR, ADN, IMDG, IATA	Void	
14.2 UN proper shipping name		
· ADR	Void	
· ADN, IMDG, IATA	Void	
14.3 Transport hazard class(es)		
· ADR, ADN, IMDG, IATA		
· Class	Void	



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· 14.4 Packing group · ADR, IMDG, IATA	Void	
· 14.5 Environmental hazards: · Marine pollutant:	No	
· 14.6 Special precautions for user	Not applicable.	
· 14.7 Maritime transport in bulk according instruments	y to IMO Not applicable.	
· Transport/Additional information:	-	
UN "Model Regulation":	Void	

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.
- 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

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.

· Abbreviations and acronvms:

SADT: Self Accelerating Decomposition Temperature

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

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

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Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4 · * Data compared to the previous version altered.

GB