

1. IDENTIFICATION OF SUBSTANCES / PREPARATION AND COMPANY

Product Name: Croform Excel S1 Nickel Free 1kg
Product Code: 0143-1

Application: Metal Alloy for Dental Technology processing aid

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2. HAZARD IDENTIFICATION

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

Classification of the substance or mixture**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.

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.

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.

Label Elements

Medical devices according to 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.

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

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Hazard determining components of labelling:

Cobolt

Hazard Statements:

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

H317 May cause an allergic skin reaction.

H413 May cause long lasting harmful effects to aquatic life.

Precautionary Statements:

P260 Do not breathe dust.

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

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

P304+P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

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

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

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 / INFORMATION ON INGREDIENTS

Chemical characterisation: Mixtures

Description:

Cobalt-based alloy

Cobalt based alloy

Dangerous Components:

CAS: 7440-48-4 EINECS: 231-158-0 Index number: 027-001-00-9	cobalt Resp. Sens. 1, H334; Skin Sens. 1, H317; Aquatic Chronic 4, H413	50-100%
CAS: 7440-47-3 EINECS: 231-157-5	chromium substance with a Community workplace exposure limit	25-50%
CAS: 7440-21-3 EINECS: 231-130-8	silicon Flam. Sol. 2, H228	< 2.5%

SVHC - No

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

4. FIRST AID MEASURES

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). In case of persistent symptoms consult doctor.

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

Indication of any immediate medical attention and special treatment needed
No further relevant information available

5. FIRE FIGHTING MEASURES

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

Special hazards arising from the substance or mixture

Fire can cause release of :
Metal vapor and metal oxides as fumes.

Advice for firefighters

Protective equipment: Do not inhale explosion gases or combustion gases

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Avoid causing dust. Wear protective clothing.
Ensure adequate ventilation
Use breathing protection against the effects of fumes/dust/aerosol

Environmental precautions:

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

Methods and material for containment and cleaning up:

Collect mechanically.

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

Precautions 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.

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.

Specific end use(s) No further relevant information available.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Components with critical values that require monitoring at the workplace:

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

CAS No.	Designation of material	%	Type	Value	Unit
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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.

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

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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

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

Change in condition

Melting point/freezing point: 1210-1380 °C

Initial boiling point and boiling range: > 2000 °C

Flash point: not applicable

Inflammability (solid, gaseous) not applicable

Ignition temperature: not applicable

Decomposition temperature: not determined

Explosive properties: Product is not explosive.

Critical values for explosion:

Lower: not applicable

Upper: not applicable

Dust explosion class:

Oxidising properties not applicable

Steam pressure: not applicable

Density at 20 °C 8.35 g/cm³

Evaporation rate not applicable

Solubility in / Miscibility with water: Insoluble

Partition coefficient: n-octanol/water: not applicable

Viscosity:

dynamic: not applicable

kinematic: not applicable

Other information

No further relevant information available.

10. STABILITY AND REACTIVITY

Reactivity: No further relevant information available.

Chemical stability

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

Possibility of hazardous reactions: No dangerous reactions known

Conditions to avoid: No further relevant information available.

Incompatible materials: No further relevant information available.

Hazardous decomposition products: Formation of metal vapor when melting

11. TOXICOLOGY INFORMATION**Information on toxicological effects**

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

LD/LC50 values that are relevant for classification:

Oral LD50 > 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 sensitization:

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.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

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

Carcinogenicity - Based on available data, the classification criteria are not met.

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 - 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**Toxicity**

Aquatic toxicity: No further relevant information available.

Persistence and degradability: No further relevant information available.

Bioaccumulative potential: Does not accumulate in organisms

Mobility in soil No further relevant information available.

Ecotoxicological effects:

Remark: No data

Other information:

No COD, no BOD, no AOX

No VOC according to EC-directive 1999/13/EC

Additional ecological information:

General notes: Generally, not hazardous for water.

Results of PBT and vPvB assessment:

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PBT: Not applicable.
vPvB: Not applicable.

Other adverse effects: No further relevant information available.

13. DISPOSAL CONSIDERATIONS

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.

European waste catalogue

06 03 15* metallic oxides containing heavy metals 12 01 04 non-ferrous metal dust and particles

Uncleaned packaging:

Recommendation:

Empty contaminated packaging thoroughly. They can be recycled after thorough and proper cleaning. Packaging 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 packaging.

Recommended cleaning agent: Water, if necessary with cleaning agent.

14. TRANSPORT INFORMATION

UN-Number

ADR/RID/ADN, IMDG, IATA Void

UN proper shipping name

ADR/RID/ADN, IMDG, IATA Void

Transport hazard class(es)

ADR/RID/ADN, IMDG, IATA Class Void

Packing group

ADR/RID/ADN, IMDG, IATA Void

Environmental hazards: Not applicable.

Special precautions for user Not applicable.

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

15. REGULATORY INFORMATION

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.

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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).

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

16. FURTHER INFORMATION

The data given above covers exclusively the safety requirements of the product(s) and is based on our current knowledge and experience. It does not signify any warranty with regards to the products properties. This product is only supplied for specific uses in dentistry and must be used in accordance with the directions for use