

according to Regulation (EC) No. 1907/2006, Article 31

Date of issue: 10.02.2017

Version: 1

Keralloy BioStar

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

1.1 Product identifier

Tradename: Keralloy BioStar
Product description: Cobalt-chromium alloy

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: Manufacturing of dental prosthesis in dental laboratories

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier: ERNST HINRICHS Dental GmbH

 Street / mailbox:
 Borsigstr. 1

 Country code. / postal code / city:
 D - 38644 Goslar

 Phone:
 0 53 21 / 5 06 24

 Fax:
 0 53 21 / 5 08 81

E-mail / Website: info@hinrichs-dental.de / www.hinrichs-dental.de

Further information obtainable from: ERNST HINRICHS Dental GmbH

1.4 Emergency telephone number

ERNST HINRICHS Dental GmbH: +49 (0) 53 21 / 5 06 24 - 25 (Mon-Fri. 8 a.m. – 4 p.m.)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:

Skin Sens. 1 H317 May cause an allergic skin reaction.

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

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

Adverse human health and No additional information available.

environmental effects:

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008:

Labelling is not applicable according to Annex I; 1.3.4. (Metals in massive form, alloys, mixtures containing polymers, mixtures containing elastomers).

In the form in which it is marketed, the product causes no danger to health for humans through inhalation, swallowing or contact with the skin.

Processing by downstream users causing differences in the product form for which Regulation (EC) No. 1272/2008 Annex I; 1.3.4 does not apply are obliged to label.

Hazard pictograms:

Signal word: Danger Hazard-determining components of Cobalt

labelling:

Hazard statements:

H317 May cause an allergic skin reaction.

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

H413 May cause long lasting harmful effects to aquatic life.

Precautionary statements:

P273: Avoid release to the environment.

P284: In case of inadequate ventilation wear respiratory protection.

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

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

P342+P311: If experiencing respiratory symptoms: Call a doctor.
P362+P364: Take off contaminated clothing and wash it before reuse.

2.3 Other hazards

Results of PBT and vPvB assessment:

PBT: Not applicable.



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vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

Substances Not applicable

3.2 Mixtures

> Description: Alloy

| Dangerous components: | | |
|-------------------------------------|-------------------------------------------------------------|------|
| CAS: 7440-48-4 | Cobalt | 66% |
| EINECS: 231-158-0 | Skin Sens. 1, H317; Resp. Sens. 1, H334; Aquatic Chronic 4, | |
| Index: 027-001-00-9 | H413 | |
| CAS: 7440-47-3 | Chromium | 27% |
| EINECS: 231-157-5 | Not classified | |
| CAS: 7439-98-7 EINECS: 231-107-2 | Molybdenum | 6% |
| | Not classified | |
| CAS: 7440-21-3 EINECS: 215-609-9 | Silicon | < 1% |
| | Not classified | |
| CAS: 7439-96-5 EINECS: 231-105-1 | Manganese | < 1% |
| | Not classified | |
| | | |

Additional information:

For the wording of the listed risk phrases refer to section 16.

SECTION 4: First aid measures

Description of first aid measures

General information: Instantly remove any clothing soiled by the product.

Take affected persons into the open air.

After inhalation: In case of unconsciousness bring patient into stable side

position for transport. Supply fresh air.

Instantly wash with water and soap and rinse thoroughly. After skin contact:

If skin irritation continues, consult a doctor.

After eye contact: Rinse opened eye for several minutes under running water.

If symptoms persist, consult doctor.

After swallowing: Rinse mouth. Drink plenty of water as a precaution. Get

medical advice/attention.

4.2

Indication of any immediate medical

attention and special treatment needed:

acute and delayed:

Most important symptoms and effects, both May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Treat symptomatically.

SECTION 5: Firefighting measures

Extinguishing media

4.3

Suitable extinguishing agents: Metal fire powders, Sand For safety reasons unsuitable Water, Foam, CO₂ extinguishing agents:

5.2 Special hazards arising from the substance No additional information available.

or mixture:

5.3 Advice for firefighters Do not inhale explosion gases or combustion gases.

Protective equipment: Wear self-contained breathing apparatus.

Additional information: Dispose of fire debris and contaminated firefighting water in

accordance with official regulations.

Collect contaminated firefighting water separately. It must

not enter drains.



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6.1 Personal precautions, protective equipment and emergency procedures:

Wear protective equipment. Keep unprotected persons away. Ensure adequate ventilation. Use breathing protection

against the effects of dust.

6.2 Environmental precautions:

Do not allow to enter drainage system, surface or ground water. Inform respective authorities in case product reaches

water or sewage system.

6.3 Methods and material for containment and

cleaning up:

Take up mechanically and collect in suitable container for

disposal. Send for recovery or disposal in suitable

containers.

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.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace. Do not

breathe dust.

Information about protection against

explosions and fires: Hygiene measures:

Dust can form an explosive mixture with air. Avoid formation

of dust.

When handling the product, ensure good industrial hygiene

and adequate safety precautions. Do not eat, drink or smoke at work. Before eating, drinking, smoking and leaving the workplace, wash hands and other bares areas with mild soap and water. Do not wear contaminated clothing outside

the workplace.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions: St

Store in cool, dry place in tightly closed containers. Keep away from food, drink and animal feedingstuffs. Do

not store together with explosive substances.

Storage class: 10-13

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

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Components with critical values that require monitoring at the workplace:

7440-48-4 Cobalt

WEL Long-term value: 0.1 mg/m³

Information on mixed storage:

7440-47-3 Chromium

WEL Long-term value: 0.5 mg/m³

7439-98-7 Molybdenum

WEL Long-term value: 10 mg/m³

Short-term value: 20 mg/m³

7440-21-3 Silicon

WEL Long-term value: 10 mg/m³ inhalable dust, 4 mg/m³ respirable dust

7439-96-5 Manganese

WEL Long-term value: 0.5 mg/m³

8.2 Exposure controls:

Appropriate engineering controls: Ensure adequate ventilation so that concentrations do not

exceed the applicable standard values.



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Personal protective equipment:

Protection of hands: Wear suitable gloves. The glove material has to be

impermeable and resistant to the product/ the substance/

the preparation.

Latex, Nitrile rubber (> 0.1 mm). Material of gloves:

The exact break through time has to be found out by the Penetration time of glove material:

manufacturer of the protective gloves and has to be

observed.

Eye protection: Tightly sealed safety glasses (EN 166).

Breathing equipment: In case of dust formation or inadequate ventilation wear

respiratory protection. Breathing apparatus with filter P. Not

necessary if room is well-ventilated.

Body protection: Protective work clothing.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

General Information

Appearance: Solid Physical state: Solid Colour: Metallic

Odour: No data available Odour threshold: No data available pH: No data available

Melting point/Freezing point 1436 °C

Boiling point/Boiling range: No data available Flash point: Not applicable Flammability (solid, gas): No data available.

Auto-ignition temperature: Product is not self-igniting.

Decomposition temperature: No data available Oxidising properties No data available

Explosive properties: Product is not explosive. However, during processing

formation of explosive dusts is possible.

Explosive Limits:

Lower: No data available Upper: No data available Vapour pressure at 20 °C: No data available

Density at 20 °C: 8.5 g/cm3

Relative density: No data available Vapour density: No data available Evaporation rate: No data available

Solubility: Insoluble No data available

Partition coefficient (n-octanol/water):

Viscosity:

No data available

kinematic: No data available

Other information No further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity Under normal conditions of use no dangerous reactions

known.

10.2 Chemical stability

dynamic:

Thermal decomposition / conditions to be

avoided:

Stable under recommended storage and application conditions according to section 7. No decomposition if used

according to specifications.

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10.3 Possibility of hazardous reactions Possible hydrogen formation upon contact with acids.

10.4 Conditions to avoid None, if handled according to intended use.

10.5 Incompatible materials Acids.

10.6 Hazardous decomposition products

No dangerous decomposition products known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity: Not classified

Based on available data, the classification criteria are not

met.

Skin corrosion/irritation: Not classified

Based on available data, the classification criteria are not

met.

Serious eye damage/irritation: Not classified

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: Not classified

Based on available data, the classification criteria are not

met.

Carcinogenicity: Not classified

Based on available data, the classification criteria are not

met.

Reproductive toxicity: Not classified

Based on available data, the classification criteria are not

met.

Specific target organ toxicity (single

exposure):

Not classified

Based on available data, the classification criteria are not

met.

Specific target organ toxicity (repeated

exposure):

Not classified

Based on available data, the classification criteria are not

met.

Aspiration hazard: Not classified

Based on available data, the classification criteria are not

met.

Potential adverse human health effects

and symptoms:

Inhalation of vapours in high concentration may cause metal

fume fever and may cause damage of the central nervous system in case repeated and prolonged exposure.

May cause long lasting harmful effects to aquatic life.

Repeated and prolonged exposure to high dust

concentrations may lead to irritation of the respiratory tract. Inhalation of metal-containing dusts may cause acute poisoning, leading to nausea, vomiting and abdominal pain.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

12.2 Persistence and degradability:

12.3 Bioaccumulative potential:

12.4 Mobility in soil:

12.5 Results of PBT and vPvB assessment

PBT: vPvB: Not applicable.

Not applicable.

12.6 Other adverse effects

No further relevant information available.



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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation: Disposal must be made according to official regulations. Do

not dispose of with domestic waste. Do not allow product to

reach sewage system.

| European waste catalogue | | |
|--------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|--|
| 18 00 00 | WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE) | |
| 18 01 00 | wastes from natal care, diagnosis, treatment or prevention of disease in humans | |
| 18 01 06* | chemicals consisting of or containing dangerous substances | |

Waste code:

The waste code number according to the Ordinance on the European Waste Catalogue (AVV) depends on the waste producer and can therefore vary for any given product. The waste code number is therefore to be gleaned separately from each waste producer.

SECTION 14:Transport information

14.1 UN number

ADR, IMDG, IATA: Not regulated for transport

14.2 UN proper shipping name

ADR, IMDG, IATA: Not applicable

14.3 Transport hazard class(es)

ADR, IMDG, IATA

Class: Not applicable Danger labels: Not applicable

14.4 Packing group

ADR, IMDG, IATA: Not applicable

14.5 Environmental hazards No Marine pollutant: No

Special marking: No supplementary information available

14.6 Special precautions for user Not applicable Kemler Number: Not applicable EMS Number: Not applicable

EMS Number: Not applicable 14.7 Transport in bulk according to Annex II of Not applicable

Marpol and the IBC Code

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations:

Other regulations, limitations and

prohibitive regulations:

15.2 Chemical safety assessment A Chemical Safety Assessment of the product 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.

The data given here only applies when product used for proper application(s). The product is not sold as suitable for other applications - usage in such may cause risks not mentioned in this sheet. Do not use for other application(s) without seeking advice from manufacturer.

Adjustments compared to earlier versions

Section 1-16 New edition, complete revision



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Relevant phrases

H317: May cause an allergic skin reaction

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

H413: May cause long lasting harmful effects to aquatic life

Abbreviations and acronyms:

ADR: Accord européen sur le transport 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
CAS: Chemical Abstracts Service (division of the American Chemical Society)
Aquatic Chronic 4: Hazardous to the aquatic environment — Chronic Hazard, Category 4

Resp. Sens. 1: Sensitisation — Respiratory, category 1

Skin Sens. 1: Sensitisation — Skin, category 1