

according to Regulation (EC) 1907/2006, Article 31

Date of issue: 11.05.2017

Date of revision: 01.09.2020 / Version: 1.1

Keralloy BioStar**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: MESA di Sala Giacomo & C.S.n.c.
Street / mailbox: Via dell' Artigianato, 35/37/39
Country code. / postal code / city: IT-25039 Travagliato / Brescia
Phone: +39 (0) 30 6863251
Fax: +39 (0) 30 6863252
E-mail / Website: info@mesaitalia.it / www.mesaitalia.it
Contact e-mail: quality@mesaitalia.it

Supplier: SILADENT Dr. Böhme & Schöps GmbH
Street / mailbox: Im Klei 26
Country code. / postal code / city: DE - 38644 Goslar
Phone: 0 53 21 / 37 79 - 0
Fax: 0 53 21 / 38 96 32
E-mail / Website: info@siladent.de / www.siladent.de

1.4 Emergency telephone number: +39 030 6863251

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 environmental effects:		No additional information available.

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:

GHS08

Signal word: Danger

Hazard-determining components of labelling: Cobalt

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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.
- vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- 3.1 Substances Not applicable
- 3.2 Mixtures
 - Description: Alloy

Dangerous components:

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

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

SECTION 4: First aid measures

4.1 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.
- After skin contact:** Instantly wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.
- After eye contact:** Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.

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After swallowing: Rinse mouth. Drink plenty of water as a precaution. Get medical advice/attention.

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

4.3 Indication of any immediate medical attention and special treatment needed: Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing agents: Metal fire powders, Sand

For safety reasons unsuitable extinguishing agents: Water, Foam, CO₂

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

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

Additional information: 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.

SECTION 6: Accidental release measures

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
Information about protection against explosions and fires: Ensure good ventilation/exhaustion at the workplace. Do not breathe dust.

Hygiene measures: Dust can form an explosive mixture with air. Avoid formation of dust.

Hygiene measures: 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

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the workplace, wash hands and other bare 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: Store in cool, dry place in tightly closed containers.
Information on mixed storage: 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/m ³
7440-47-3 Chromium	
WEL	Long-term value: 0.5 mg/m ³
7439-98-7 Molybdenum	
WEL	Long-term value: 10 mg/m ³ Short-term value: 20 mg/m ³
7440-21-3 Silicon	
WEL	Long-term value: 10 mg/m ³ inhalable dust, 4 mg/m ³ respirable dust
7439-96-5 Manganese	
WEL	Long-term value: 0.5 mg/m ³

8.2 Exposure controls:

Appropriate engineering controls: Ensure adequate ventilation so that concentrations do not exceed the applicable standard values.

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.

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

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: 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

9.1 Information on basic physical and chemical properties

General Information

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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/cm ³
Relative density:	No data available
Vapour density:	No data available
Evaporation rate:	No data available
Solubility:	Insoluble
Partition coefficient (n-octanol/water):	No data available
Viscosity:	
dynamic:	No data available
kinematic:	No data available

9.2 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	
Thermal decomposition / conditions to be avoided:	Stable under recommended storage and application conditions according to section 7. No decomposition if used according to specifications.
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.

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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. 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:	May cause long lasting harmful effects to aquatic life.
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.

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12.6 Other adverse effects No further relevant information available.

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

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

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

National regulations:

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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

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