

## Keralloy BioStar

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

- 1.1. Product identifier
- Product form: Mixture
- Tradename: Keralloy BioStar
- Product description: Non precious milling alloy based on cobalt for metal ceramic
- UFI: -
- 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 Italia S.r.l.
- Street / mailbox: Via dell' Artigianato, 35/37
- 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](mailto:info@mesaitalia.it) / [www.mesaitalia.it](http://www.mesaitalia.it)
- Contact e-mail: [quality@mesaitalia.it](mailto:quality@mesaitalia.it)
- Supplier: SILADENT Dr. Böhme & Schöps GmbH
- Street / mailbox: Im Klei 26
- Country code. / postal code / city: DE - 38644 Goslar
- Phone: +49 (0) 53 21 / 37 79 – 0
- Fax: +49 (0) 53 21 / 38 96 32
- E-mail / Website: [info@siladent.de](mailto:info@siladent.de) / [www.siladent.de](http://www.siladent.de)
- 1.4. Emergency telephone number: +39 (0)30 6863251 (8:00 – 17:00 h)

### SECTION 2: Hazards identification

- 2.1. Classification of the substance or mixture
- Classification according to Regulation (EC) No 1272/2008 [CLP]:
- |                   |       |  |
|-------------------|-------|--|
| 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. |
| 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.                    |

Special hazards information for human and environment: No information available.

#### 2.2. Label elements

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

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. There is therefore no obligation to label the product in accordance with: Regulation 1272/2008 (CLP: annex I; 1.3.4.: "Metals in massive form, alloys, mixtures containing polymers, mixtures containing elastomers").

If the product form in the as-supplied state is changed through further processing (e.g. through grinding, polishing, electrical discharge machining, welding or melting) and dust or vapours are produced, there may be danger from hazardous components in product.

Hazard pictograms (CLP):



GHS08

Signal word (CLP):

Danger



according to Regulation (EU) 2020/878

Date of issue: 03.04.2013

Printing date: 02.02.2024

Date of revision: 15.01.2024 Version/replaced Version 7.0/6.0

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Hazard-determining components of labelling: Cobalt

Hazard statements (CLP):

- 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.

Precautionary statements (CLP):

- P273: Avoid release to the environment.  
 P280: Wear protective gloves, protective clothing, eye protection, face protection.  
 P308+P313: IF exposed or concerned: Get medical advice/attention.  
 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 No) 7440-48-4 (EC No) 231-158-0	Cobalt (Co)	66 %
	H302 acute tox 4, H334 resp sens 1B, H317 skin sens 1, H350i carc 1b, H361f repr 2, H413 aquatic chronic 4	
(CAS No) 7440-47-3 (EC No) 231-157-5	Chromium (Cr)	27 %
	Not classified	
(CAS No) 7439-98-7 (EC No) 231-107-2	Molybdenum (Mo)	6 %
	Not classified	
(CAS No) 7440-21-3 (EC No) 231-130-8	Silicone (Si)	Traces
	Not classified	

**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. IF exposed or concerned: Get medical advice/attention.

After inhalation:

In case of unconsciousness bring patient into stable side position for transport. Supply fresh air. If experiencing respiratory symptoms: Call a doctor.

After skin contact:

Instantly wash with water and soap and rinse thoroughly.  
 If skin irritation or rash occurs: Get medical advice/attention.

After eye contact:

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

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.  
 Suspected of causing genetic defects. May cause cancer.

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according to Regulation (EU) 2020/878

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- 4.3. Indication of any immediate medical attention and special treatment needed:
- May damage fertility.  
Treat symptomatically.

### SECTION 5: Firefighting measures

- 5.1. Extinguishing media  
Suitable extinguishing agents: Metal fire powders, sand  
Unsuitable extinguishing agents: Water, foam, CO<sub>2</sub>
- 5.2. Special hazards arising from the substance or mixture: No additional information available.
- 5.3. Advice for firefighters: Do not inhale explosion gases or combustion gases.  
Protection during firefighting: 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: Ensure adequate ventilation. Evacuate unnecessary personnel. Use personal protective equipment as required. Avoid dust formation. 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: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Ensure good ventilation of the work station. In case of insufficient ventilation, use respiratory protection. Do not inhale dust. Wear personal protective equipment. Dust can form an explosive mixture with air. Avoid formation of dust.
- Information about protection against explosions and fires: 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 bare areas with mild soap and water. Do not wear contaminated clothing outside the workplace.
- Hygiene measures:
- 7.2. Conditions for safe storage, including any incompatibilities  
Storage conditions: Store cool and dry in tightly closed containers. Store locked up.  
Storage incompatibility: Keep away from food, drinks and feedingstuff. Do not store together with explosive substances.  
Storage class: LGK 10-13
- 7.3. Specific end use(s): No further relevant information available.

### SECTION 8: Exposure controls/personal protection

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### 8.1. Control parameters

(ACGIH/14 - AIDII/14)	CAS No.	Name	TLV - TWA	TLV - STEL	Critical effects
	7440-48-4	Cobalt	0.1 mg/m <sup>3</sup> OSHA USA 0.05 mg/m <sup>3</sup> NIOSH USA	-	-
	7439-98-7	Molybdenum	10 mg/m <sup>3</sup> (inhalable fraction) 3 mg/m <sup>3</sup> (respirable fraction)	-	-
	7440-21-3	Silicon	10 mg/m <sup>3</sup> (inhalable fraction) 3 mg/m <sup>3</sup> (respirable fraction)	-	-
	7440-47-3	Chromium	0.5 mg/m <sup>3</sup>	-	-

### 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.

Environmental exposure controls:

Avoid release to the environment.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state:	Solid
Colour:	Metallic
Odour:	No data available
Melting point/Freezing point:	1470 °C
Boiling point or initial boiling point and boiling range:	No data available
Flammability:	No data available
Lower and upper explosion limit:	Not applicable
Flash point:	Not applicable
Auto-ignition temperature:	Product is not self-igniting.
Decomposition temperature:	No data available
pH:	No data available
Kinematic viscosity:	Not applicable
Solubility:	Water: Not miscible.
Partition coefficient n-octanol/water (log value):	Not applicable
Vapour pressure:	No data available
Density and/or relative density:	8.4 g/cm <sup>3</sup> (20 °C)
Relative vapour density:	Not applicable
Particle characteristics:	No data available

### 9.2. Other information

Explosive properties:

Product is not explosive. However, during processing formation of explosive dusts is possible.

## SECTION 10: Stability and reactivity

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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. Strong oxidising agents.
10.6. Hazardous decomposition products:	Metal oxides.

### SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008	
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:	Suspected of causing genetic defects.
Carcinogenicity:	May cause cancer.
Reproductive toxicity:	May damage fertility.
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.
11.2. Information on other hazards	
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	
Acute aquatic toxicity:	Not classified
Chronic aquatic toxicity:	May cause long lasting harmful effects to aquatic life.
12.2. Persistence and degradability:	No further information available.
12.3. Bioaccumulative potential:	No further information available.
12.4. Mobility in soil:	No further information available.
12.5. Results of PBT and vPvB assessment	
PBT:	Not applicable.
vPvB:	Not applicable.

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12.6. Endocrine disrupting properties: No further information available.

12.7. Other adverse effects: No further 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 number:

The waste code number according to the Regulation of  
the European Waste Catalogue (EWC) is dependent on  
the waste producer and can therefore be different for a  
product. The waste code number must therefore be  
determined separately by each waste producer.

**SECTION 14: Transport information**

## 14.1. UN number or ID number

ADR, IMDG, IATA:

This product is not subject to transport regulations.

## 14.2. UN proper shipping name

ADR, IMDG, IATA:

Not applicable

## 14.3. Transport hazard class(es)

ADR, IMDG, IATA:

Not applicable

## 14.4. Packing group

ADR, IMDG, IATA:

Not applicable

## 14.5. Environmental hazards

Dangerous for the environment:

No

Marine pollutant:

No

Special marking:

No supplementary information available

## 14.6. Special precautions for user:

Not applicable

## 14.7. Maritime transport in bulk according to IMO instruments:

Not applicable

**SECTION 15: Regulatory information**

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

EU-Regulations:

Contains no substance on the REACH candidate list.

Contains no substance on the REACH Annex XIV List.

National regulations:

No additional information available.

## 15.2. Chemical safety assessment:

Chemical safety assessments for substances in this  
mixture were not carried out by the supplier.

**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:

General revision, adaptation to Regulation (EU) 2020/878



### Keralloy BioStar

#### Full text of H- and EUH-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 acronyms:

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP:	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DMEL:	Derived Minimal Effect Level
DNEL:	Derived No-Effect Level
EC50:	The effective concentration of substance that causes 50% of the maximum response (Median Effective Concentration)
IATA:	International Air Transport Association
IMDG:	“International Maritime Dangerous Goods Code” for the transport of dangerous goods by sea
LC50:	Lethal Concentration to 50 % of a test population (Median Lethal Concentration)
LD50:	Lethal Dose to 50% of a test population (Median Lethal Dose)
LOAEL:	Lowest Observed Adverse Effect Level
NOAEC/L:	No Observed Adverse Effect Concentration/Level
NOEC/L:	No Observed Effect Concentration/Level
OECD:	Organisation for Economic Cooperation and Development
PBT:	Persistent, Bioaccumulative and Toxic substance
PNEC:	Predicted No-Effect Concentration
REACH:	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SDS:	Safety Data Sheet
STP:	Sewage Treatment Plant
UFI:	Unique Formula Identifier
vPvB:	Very Persistent and Very Bioaccumulative
Aquatic Chronic 4:	Hazardous to the aquatic environment — Chronic Hazard, Category 4
Carc. 1B:	Carcinogenicity, Category 1B
Muta. 2:	Germ cell mutagenicity, Category 2
Repr. 1B:	Reproductive toxicity, Category 1B
Resp. Sens. 1:	Sensitisation — Respiratory, category 1
Skin Sens. 1:	Sensitisation — Skin, category 1