

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

Printing date 09.03.2022

Version number 3

Revision: 09.03.2022

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

- **1.1 Product identifier**
- **Trade name:** Brealloy Lot
- **Article number:** 500 0001 0
- **1.2 Relevant identified uses of the substance or mixture and uses advised against:** -
- **Application of the substance / the mixture:** Dental alloy.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
bredent GmbH & Co.KG
Weißenhornher Straße 2
89250 Senden
Tel: +49 (0) 7309/872-0
Fax: +49 (0) 7309/872-24
- **Further information obtainable from:**
R & D
e-mail: R.D@bredent.com
- **1.4 Emergency telephone number:** (001) 352 323 3500

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Remark**
The device is a medical device pursuant to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. No safety data sheet is required for the device, so no claim is made to full compliance with the relevant statutory requirements.
- **Classification according to Regulation (EC) No 1272/2008**



health hazard

- | | | |
|---------------|-------|--|
| Resp. Sens. 1 | H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| Muta. 2 | H341 | Suspected of causing genetic defects. |
| Repr. 1B | H360F | May damage fertility. |



- | | | |
|-------------------|------|---|
| Skin Sens. 1 | H317 | May cause an allergic skin reaction. |
| 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**
Medical products and medical devices within the meaning of Directives 90/385/EEC and 93/42/EEC used in an invasive manner or in direct contact with the body as well as medical products and medical devices falling under Directive 98/79/EC are fully exempt from the provisions of the CLP Regulation and therefore do not need to be classified, packaged or labelled.
The product does not require labeling according to the CLP regulation.
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms** GHS08
- **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.
H360F May damage fertility.

(Contd. on page 2)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 3

Revision: 09.03.2022

Trade name: Brealloy Lot

(Contd. of page 1)

*H413 May cause long lasting harmful effects to aquatic life.***· Precautionary statements***P201 Obtain special instructions before use.**P261 Avoid breathing dust/fume/gas/mist/vapours/spray.**P280 Wear protective gloves/protective clothing/eye protection/face protection.**P308+P313 IF exposed or concerned: Get medical advice/attention.**P321 Specific treatment (see on this label).**P362+P364 Take off contaminated clothing and wash it before reuse.**P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.***· Additional information:***Restricted to professional users.***· 2.3 Other hazards****· Results of PBT and vPvB assessment****· PBT:** Not applicable.**· vPvB:** Not applicable.**SECTION 3: Composition/information on ingredients****· 3.2 Chemical characterisation: Mixtures****· Description:** Dental alloy.**· Dangerous components:** Void**· 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:** Supply fresh air and to be sure call for a doctor.**· After skin contact:***Immediately 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 a doctor.***· After swallowing:** Seek medical treatment.**· 4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.**· 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:** Use fire extinguishing methods suitable to surrounding conditions.**· 5.2 Special hazards arising from the substance or mixture** No further relevant information available.**· 5.3 Advice for firefighters****· Protective equipment:** No special measures required.**SECTION 6: Accidental release measures****· 6.1 Personal precautions, protective equipment and emergency procedures** Not required.**· 6.2 Environmental precautions:***Do not allow product to reach sewage system or any water course.**Inform respective authorities in case of seepage into water course or sewage system.**Do not allow to enter sewers/ surface or ground water.***· 6.3 Methods and material for containment and cleaning up:***Dispose contaminated material as waste according to item 13.*

(Contd. on page 3)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 3

Revision: 09.03.2022

Trade name: Brealloy Lot

(Contd. of page 2)

· 6.4 Reference to other sections

No dangerous substances are released.
 See Section 7 for information on safe handling.
 See Section 8 for information on personal protection equipment.
 See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.
 Prevent formation of dust.

· Information about fire - and explosion protection: No special measures required.

· 7.2 Conditions for safe storage, including any incompatibilities**· Storage:**

· Requirements to be met by storerooms and receptacles: No special requirements.

· 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

· Additional information about design of technical facilities: No further data; see item 7.

· Ingredients with limit values that require monitoring at the workplace:

7440-48-4 cobalt (50-100%)

WEL (Great Britain)	Long-term value: 0.1 mg/m ³ as Co; Carc, Sen
---------------------	--

7440-47-3 chromium (25-50%)

WEL (Great Britain)	Long-term value: 0.5 mg/m ³
---------------------	--

7439-96-5 manganese (≤1%)

WEL (Great Britain)	Long-term value: 0.2 * 0.05 ** mg/m ³ as Mn *inhalable fraction **respirable fraction
---------------------	---

· Additional information: The lists valid during the making were used as basis.

· 8.2 Exposure controls**· Personal protective equipment:****· General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.
 Do not eat, drink, smoke or sniff while working.
 Keep away from foodstuffs, beverages and feed.
 Immediately remove all soiled and contaminated clothing
 Wash hands before breaks and at the end of work.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· Protection of hands: Wear gloves for the protection against mechanical hazards according to EN 388.

· Eye protection: Safety glasses

· Body protection: Protective work clothing

GB

(Contd. on page 4)

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

Printing date 09.03.2022

Version number 3

Revision: 09.03.2022

Trade name: Brealloy Lot

(Contd. of page 3)

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Solid
Colour:	White
Odour:	Odourless
Odour threshold:	Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/freezing point:	>1200 °C
Initial boiling point and boiling range:	Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gas): Not determined.

· Decomposition temperature: Not determined.

· Auto-ignition temperature: Product is not selfigniting.

· Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

Lower:	Not determined.
Upper:	Not determined.

· Vapour pressure: Not applicable.

Density at 20 °C:	8.4 g/cm ³
Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.

· Solubility in / Miscibility with water: Insoluble.

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic:	Not applicable.
Kinematic:	Not applicable.

· Solvent content:

Organic solvents:	0.0 %
VOC (EC)	0,00 %

Solids content: 100.0 %

· 9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

· 10.2 Chemical stability

· Thermal decomposition / conditions to be avoided: No decomposition if used 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: No further relevant information available.

· 10.6 Hazardous decomposition products: No dangerous decomposition products known.

GB

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 3

Revision: 09.03.2022

Trade name: Brealloy Lot

(Contd. of page 4)

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

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

· LD/LC50 values relevant for classification:

7440-48-4 cobalt

Oral LD50 6,170 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 sensitisation

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

May cause an allergic skin reaction.

· Additional toxicological information:

· **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**

· Germ cell mutagenicity

Suspected of causing genetic defects.

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

· 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.

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.

· Additional ecological information:

· General notes:

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

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

· 12.5 Results of PBT and vPvB assessment

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· Uncleaned packaging:

· **Recommendation:** Disposal must be made according to official regulations.

GB

(Contd. on page 6)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 3

Revision: 09.03.2022

Trade name: Brealloy Lot

(Contd. of page 5)

SECTION 14: Transport information

· 14.1 UN-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
· 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 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- 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
- 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.
H360F May damage fertility.
H413 May cause long lasting harmful effects to aquatic life.
- Precautionary statements
P201 Obtain special instructions before use.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P321 Specific treatment (see on this label).
P362+P364 Take off contaminated clothing and wash it before reuse.
P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
- 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

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- Department issuing SDS: R & D

(Contd. on page 7)

GB

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

Printing date 09.03.2022

Version number 3

Revision: 09.03.2022

Trade name: Brealloy Lot

(Contd. of page 6)

· **Contact: R & D**

· **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

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)

VOC: Volatile Organic Compounds (USA, EU)

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

Repr. 1B: Reproductive toxicity – Category 1B

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

· *** Data compared to the previous version altered.**

GB