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

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

· **1.1 Product identifier**

· **Trade name: Brealloy C+B 270, Brealloy F 400**

· **Article number:** 500 CB 000, 500 CB 050, 500 CB 200, 500 CB 500, 500 ML 000, 500 ML 100, 500 ML 500
· **1.2 Relevant identified uses of the substance or mixture and uses advised against:**
No further relevant information available.
· **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
Weißenhorner 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 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.

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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.
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***

Steel products in their usual solid physical state do not constitute any physical or health hazard. However, subsequent operations such as brazing, burning, cutting, grinding, heat treating, pickling, welding, or processing in any other fashion may produce potentially hazardous dust or fume which can be inhaled, swallowed, or come in contact with the skin, eyes, or mucous membranes.Possible symptoms of exposure to dust, fumes, or gages:Acute: Irritation of eyes, nose, throat, and skin; metallic taste in mouth; nausea; metal fume fever. Chronic: Only after six to ten years of exposure to iron dust or fumes does one present any signs of pneumoconiosis. Physical examinations of those exposed to iron dust have not indicated any disability. Excess inhalation of Chromium fumes has been associated with respiratory cancer. Excessive and prolonged inhalation to manganese (generally over 2 years exposure) can cause damage to the central nervous system. Specifically, the pathology resembles Parkinson's Disease. Carcinogenicity: Chromium, Cobalt-Chromium Alloys, and Nickel have been identified by the International Agency for Research on Cancer (IARC and the National Program (NTP) as potential cancer causing agents.

POSSIBLE SYMPTONS OF EXPOSURE TO DUST, FUMES, OR GASES:
Acute: Irritation of eyes, nose, throat and skin; metallic taste in mouth; nausea, metal Fume fever.
Chronic: Only after six to ten years of exposure to iron dust or fumes does one present any signs of pneumoconiosis. Physical examinations of those exposed to iron dust have not indicated and disability. Excess inhalation of Chromium fumes has been associated with respiratory cancer.
Excessive or prolonged inhalation to manganese (generally over 2 years exposure) can cause damage to the central nervous system. Specifically, the pathology resembles Parkinson's Disease.

· ***Results of PBT and vPvB assessment***

· ***PBT:*** *Not applicable.*

· ***vPvB:*** *Not applicable.*

*

SECTION 3: Composition/information on ingredients

· ***3.2 Chemical characterisation: Mixtures***

· ***Description:*** *Mixture of substances listed below with nonhazardous additions.*

· ***Dangerous components:***

CAS: 7440-48-4 *EINECS: 231-158-0*	*cobalt* *Resp. Sens. 1, H334; Muta. 2, H341; Repr. 1B, H360F* *Skin Sens. 1, H317* *Aquatic Chronic 4, H413*	*25-50%*
CAS: 7440-47-3 *EINECS: 231-157-5*	*chromium* *substance with a Community workplace exposure limit*	*10-25%*
CAS: 7440-33-7 *EINECS: 231-143-9*	*tungsten* *substance with a Community workplace exposure limit*	*10-25%*
CAS: 7439-98-7 *EINECS: 231-107-2*	*molybdenum*	*2.5-10%*
CAS: 7440-03-1 *EINECS: 231-113-5*	*niobium*	*≤ 3%*
CAS: 7439-96-5 *EINECS: 231-105-1*	*manganese* *substance with a Community workplace exposure limit*	*≤ 3%*

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· ***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.
In case of unconsciousness place patient stably in side position for transportation.
· ***After skin contact:*** *Immediately wash with water and soap and rinse thoroughly.*
· ***After eye contact:*** *Rinse opened eye for several minutes under running water.*
· ***After swallowing:*** *If symptoms persist consult doctor.*
· ***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.
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· ***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 to penetrate the ground/soil.
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.
· ***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 disposal information.

SECTION 7: Handling and storage

· ***7.1 Precautions for safe handling***
Extractors are required on all machines used for thermal processing or splinter removal processes.
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:*** *Store only in the original receptacle.*
· ***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.*

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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 (25-50%)	
WEL (Great Britain)	Long-term value: 0.1 mg/m³ as Co; Carc, Sen
7440-47-3 chromium (10-25%)	
WEL (Great Britain)	Long-term value: 0.5 mg/m³
7440-33-7 tungsten (10-25%)	
WEL (Great Britain)	Short-term value: 10 mg/m³ Long-term value: 5 mg/m³ as W
7439-96-5 manganese (≤3%)	
WEL (Great Britain)	Long-term value: 0.2* 0.05** mg/m³ 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.
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
· **Respiratory protection:**
Not necessary if room is well-ventilated.
Use suitable respiratory protective device in case of insufficient ventilation.
Filter A/P2
· **Protection of hands:** Wear gloves for the protection against mechanical hazards according to EN 388.
· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Solid
Colour:	Silver grey
· **Odour:**	Odourless
· **Odour threshold:**	Not determined.
· **pH-value:**	Not applicable.
· **Change in condition**	
Melting point/freezing point:	> 1100 °C
Initial boiling point and boiling range:	> 2000 °C
· **Flash point:**	Not applicable.
· **Flammability (solid, gas):**	Not determined.
· **Decomposition temperature:**	Not determined.
· **Auto-ignition temperature:**	Product is not selfigniting.

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· **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:**	8.1 - 8.8 g/cm³
· **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.

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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:**
No toxic effect would be expected from exposure to the solid form of Steel products. Prolonged, repeated exposure to fumes or dust generated during subsequent operations may or may not cause adverse health effects associated with the listed constituents in excess of OSHA permissible exposure limits established in 29 CFR Part 2920.1200 (See Section 2. Generic Ingredients).

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· ***CMR effects (carcinogenity, 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 1 (German Regulation) (Self-assessment): slightly hazardous for water*
· ***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.*

SECTION 14: Transport information

· ***14.1 UN-Number***	
· ***ADR, ADN, IMDG, IATA***	*Void*
· ***14.2 UN proper shipping name***	
· ***ADR, 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:***	*Not applicable.*
· ***14.6 Special precautions for user***	*Not applicable.*
· ***Stowage Category***	*B*
· ***14.7 Transport in bulk according to Annex II of Marpol and the IBC Code***	*Not applicable.*

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· ***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.
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.

· ***Relevant 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.
H360F May damage fertility.
H413 May cause long lasting harmful effects to aquatic life.

· ***Department issuing SDS:*** *R & D*
· ***Contact:*** *R & D*
· ***Abbreviations and acronyms:***
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

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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.***