

Page 1/8

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 02.08.2018

Version number 2

Revision: 20.01.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier · Trade name: GC Miracle Mix Alloy · 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 Auxillary for dental technology \cdot 1.3 Details of the supplier of the safety data sheet · Manufacturer/Supplier: GC EUROPE N.V. Interleuvenlaan 33 B-3001 Leuven Tel. +32/(0)16/74.10.00 Fax +32/(0)16/40.26.84 msds@gc.dental · Further information obtainable from: Regulatory affairs · 1.4 Emergency telephone number: National poison center for United Kingdom of Great Britain and Northern Ireland: Belfast: +44 28 90 63 2032 Birmingham: +44 121 507 4123 Edinburgh: +44 131 242 1383 Newcastle Upon Tyne: +44 191 2606182/+44 191 2606180 Penarth: +44 292 071 55 54

SECTION 2: Hazards identification

· 2.1 Classification of the substance or mixture

• Classification according to Regulation (EC) No 1272/2008 Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.

Aquatic Acute 1 H400 Very toxic to aquatic life.

Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.

· 2.2 Label elements

• Labelling according to Regulation (EC) No 1272/2008 Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device. The product is classified and labelled according to the CLP regulation.

· Hazard pictograms



Signal word Warning
 Hazard statements
 H410 Very toxic to aquatic life with long lasting effects.

• **Precautionary statements** P273 Avoid release to the environment. P391 Collect spillage.

(Contd. on page 2)

⁻ GB

Printing date 02.08.2018

Version number 2

Revision: 20.01.2016

Trade name: GC Miracle Mix Alloy

(Contd. of page 1) P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- · 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:

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

| · Dangerous components: | | | |
|------------------------------------------------------------------------------------------|--------|------------------------------------------------|---------|
| CAS: 7440-22-4 | silver | Aquatic Acute 1, H400; Aquatic Chronic 1, H410 | 50-<75% |
| EINECS: 231-131-3 | | | |
| CAS: 7440-50-8 | copper | Aquatic Acute 1, H400; Aquatic Chronic 3, H412 | 10-<25% |
| EINECS: 231-159-6 | | | |
| Additional information: For the wording of the listed bazard phrases refer to section 16 | | | |

• 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

- · General information: If symptoms persist consult doctor.
- After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. Take affected persons into fresh air and keep quiet.

- · 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 a doctor.

• After swallowing:

Rinse out mouth and then drink plenty of water.

- 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:

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire extinguishing methods suitable to surrounding conditions.

- · For safety reasons unsuitable extinguishing agents: Water with full jet
- \cdot 5.2 Special hazards arising from the substance or mixture
- Formation of toxic gases is possible during heating or in case of fire.
- 5.3 Advice for firefighters
- · Protective equipment: Wear self-contained respiratory protective device.

(Contd. on page 3)

GB

Printing date 02.08.2018

Version number 2

Revision: 20.01.2016

(Contd. of page 2)

Trade name: GC Miracle Mix Alloy

· Additional information

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures Remove persons from danger area. Avoid formation of dust. Wear protective clothing. · 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 penetrate the ground/soil. In case of seepage into the ground inform responsible authorities. · 6.3 Methods and material for containment and cleaning up: Pick up mechanically. Prevent formation of dust. Dispose of the material collected according to regulations. · 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 Prevent formation of dust.

Any unavoidable deposit of dust must be regularly removed.

· Information about fire - and explosion protection: Dust can combine with air to form an explosive mixture.

· 7.2 Conditions for safe storage, including any incompatibilities

· Storage:

· Requirements to be met by storerooms and receptacles: Store only in unopened original receptacles.

- · Information about storage in one common storage facility: Store away from foodstuffs.
- Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

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

· 8.1 Control parameters

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

7440-22-4 silver

WEL Long-term value: 0.1 mg/m³

7440-50-8 copper

WEL Short-term value: 2** mg/m³ Long-term value: 0.2* 1** mg/m³ *fume **dusts and mists (as Cu)

(Contd. on page 4)

Printing date 02.08.2018

Version number 2

Revision: 20.01.2016

Trade name: GC Miracle Mix Alloy

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 inhale dust / smoke / mist. Wash hands before breaks and at the end of work.
Respiratory protection: Suitable respiratory protective device recommended.
Protection of hands: Protective gloves
Material of gloves The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

• *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: Safety glasses

SECTION 9: Physical and chemical properties

| General Information | | |
|------------------------------------------|-----------------------------------------------|--|
| Appearance: Form: | Powder | |
| Colour: | Grey | |
| Odour: | Characteristic | |
| Odour threshold: | Not determined. | |
| pH-value: | Not applicable. | |
| Change in condition | | |
| Melting point/freezing point: | Undetermined. | |
| Initial boiling point and boiling range: | Undetermined. | |
| Flash point: | Not applicable. | |
| Flammability (solid, gas): | Not determined. | |
| Ignition temperature: | Undetermined. | |
| 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: | Not determined. | |
| Relative density | Not determined. | |
| Vapour density | Not applicable. | |
| Evaporation rate | Not applicable. | |

Version number 2

Revision: 20.01.2016

Trade name: GC Miracle Mix Alloy

Printing date 02.08.2018

| | | (Contd. of page |
|-------------------------------------------|--------------------------------------------|-----------------|
| · Solubility in / Miscibility with | | |
| water: | Insoluble. | |
| · Partition coefficient: n-octanol/water: | Not determined. | |
| · Viscosity: | | |
| Dynamic: | Not applicable. | |
| Kinematic: | Not applicable. | |
| • 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.
- \cdot 10.3 Possibility of hazardous reactions No dangerous reactions known.

 \cdot 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.

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: No further relevant information available.
- · 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 Based on available data, the classification criteria are not met.
- · Repeated dose toxicity No further relevant information available.
- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction) No further relevant information available.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- Reproductive toxicity Based on available data, the classification criteria are not met.
- 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.

(Contd. on page 6)

Printing date 02.08.2018

Version number 2

Revision: 20.01.2016

(Contd. of page 5)

Trade name: GC Miracle Mix Alloy

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.

· 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 |

· Uncleaned packaging:

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

| 14.1 UN-Number | UN3077 |
|---------------------------------|-----------------------------------------------------------------------------------------|
| ADR, IMDG, IATA | 0193077 |
| 14.2 UN proper shipping name | |
| ADR | 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE |
| | SOLID, N.O.S. (silver, copper) |
| IMDG | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLIE |
| ΙΑΤΑ | N.O.S. (silver, copper), MARINE POLLUTANT ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLIE |
| | N.O.S. (silver, copper) |
| 14.3 Transport hazard class(es) | |
| - | |
| ADR | |
| | |
| Class | 9 (M7) Miscellaneous dangerous substances and articles. |
| Label | 9 |
| IMDG, IATA | |
| | |
| Class | 9 Miscellaneous dangerous substances and articles. |
| | 9 |

Printing date 02.08.2018

Version number 2

Revision: 20.01.2016

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| | (Contd. of page |
|-----------------------------------------|------------------------------------------------------------------|
| 14.4 Packing group ADR, IMDG, IATA | III |
| 14.5 Environmental hazards: | Product contains environmentally hazardous substances: zin oxide |
| Marine pollutant: | Yes Symbol (fish and tree) |
| Special marking (ADR): | Symbol (fish and tree) |
| Special marking (IATA): | Symbol (fish and tree) |
| 14.6 Special precautions for user | Warning: Miscellaneous dangerous substances and articles. |
| Danger code (Kemler): | 90 |
| EMS Number: | F-A,S-F |
| 14.7 Transport in bulk according to Ann | |
| Marpol and the IBC Code | Not applicable. |
| Transport/Additional information: | |
| ADR | |
| Limited quantities (LQ) | 5 kg |
| Excepted quantities (EQ) | Code: E1 |
| | Maximum net quantity per inner packaging: 30 g |
| | Maximum net quantity per outer packaging: 1000 g |
| Transport category | 3 |
| Tunnel restriction code | E |
| IMDG | |
| Limited quantities (LQ) | 5L |
| Excepted quantities (EQ) | Code: El |
| | Maximum net quantity per inner packaging: 30 g |
| | Maximum net quantity per outer packaging: 1000 g |
| UN "Model Regulation": | UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE |
| | SOLID, N.O.S. (SILVER, COPPER), 9, III |

SECTION 15: Regulatory information

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

- · Directive 2012/18/EU
- \cdot Qualifying quantity (tonnes) for the application of lower-tier requirements 100 t
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

· Relevant phrases

H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects. H412 Harmful to aquatic life with long lasting effects.

- · Classification according to Regulation (EC) No 1272/2008 Calculation method
- · Department issuing SDS: Regulatory affairs

(Contd. on page 8)

[—] GB -

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| Contact: msds@gc.dental Abbreviations and acronyms: ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the Internation Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Maritime Code for Dangerous Substances ELINCS: European List of Notified Chemical Substances IDSO: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Aquatic Chronic 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3 Sources • ECHA (http://echa.europa.eu/) • EnviChem (www.echemportal.org) * Data compared to the previous version altered. This version replaces all previous versions. Disclaimer: The in | | of page 7) |
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| or suggestions are made without any guarantee, representation or warranty, express or implied, on our pai | or suggestions are made without any guarantee, representation or warranty, express or implied, on o | |
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| complete, and we accordingly exclude all liability in connection with the use of this information or the produc | | |
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| limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation. | limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation | <i>on</i> . |