



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

Printing date 18.01.2018

Version number 6

Revision: 16.01.2018

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

- **1.1 Product identifier**
- **Trade name: Futura Basic - Capsules Powder**
- **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 filling material
Amalgam
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
AB ARDENT
Generatorgatan 8
195 60 Arlandastad / Sweden

Tel: +46 8 59441250
Fax: +46 8 59116183
- **Further information obtainable from:**
Regulatory Affairs / Quality Assurance
regulatory@ardent.se
- **1.4 Emergency telephone number:** +46 8 59441250 (AB Ardent Sweden)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008 Void**
- **Hazard pictograms Void**
- **Signal word Void**
- **Hazard statements Void**
- **Additional information:**
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.
Safety data sheet available on request.
- **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:** Alloy powder and mercury in predosed capsules.

· **Dangerous components:**

CAS: 7440-22-4 EINECS: 231-131-3	silver	substance with a Community workplace exposure limit	25-50%
CAS: 7440-50-8 EINECS: 231-159-6	copper	substance with a Community workplace exposure limit	25-50%

- **Additional information:**
Non-Gamma-2, spherical 40 % silver alloy amalgam in self-activating capsule.

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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:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**
Rinse with water.
Generally the product does not irritate the skin.
- **After eye contact:**
Mechanical effects only.
Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:** Rinse out mouth and then drink plenty of water.
- **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:** The product is not flammable.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.
- **Additional information** Cool endangered receptacles with water spray.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **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**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **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 unopened original receptacles.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep container tightly sealed.
Store receptacle in a well ventilated area.

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· 7.3 *Specific end use(s)* No further relevant information available.

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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:*

CAS: 7440-22-4 silver

WEL Long-term value: 0.1 mg/m³

CAS: 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)

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

· 8.2 Exposure controls

· *Personal protective equipment:*

· *General protective and hygienic measures:*

Usual hygienic measures for dental practice and dental laboratories.

· *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:*



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

After use of gloves apply skin-cleaning agents and skin cosmetics.

· *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:* Not required.

SECTION 9: Physical and chemical properties

· 9.1 *Information on basic physical and chemical properties*

· *General Information*

· *Appearance:*

Form: Powder

Colour: Grey

· *Odour:* Odourless

· *Odour threshold:* Not determined.

· *pH-value:* Not applicable.

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· Change in condition Melting point/freezing point: Undetermined. Initial boiling point and boiling range: Undetermined.	
· Flash point:	Not applicable.
· Flammability (solid, gas):	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: · Relative density · Vapour density · Evaporation rate	Not determined. Not determined. Not applicable. Not applicable.
· 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** Stable under normal handling and storage conditions.
- **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:** None under normal conditions of storage and use.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **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.
- **Additional toxicological information:**
Alloy powder and mercury are predosed in closed capsules, therefore the danger of exposition to mercury vapours are low.
- **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.

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- **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
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **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.
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

- **European waste catalogue**

18 01 10*	amalgam waste from dental care
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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|--|-----------------|
| · 14.1 UN-Number | |
| · ADR/RID/ADN, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | |
| · ADR/RID/ADN, ADN, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) | |
| · ADR/RID/ADN, ADN, IMDG, IATA | |
| · Class | Void |
| · 14.4 Packing group | |
| · ADR/RID/ADN, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | |
| · Marine pollutant: | No |
| · 14.6 Special precautions for user | Not applicable. |

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· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN "Model Regulation":	Void

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to the Directive 93/42/EEC.
Product complies with ISO 13897 Dentistry - Amalgam capsules
Product complies with ISO 24234 Dentistry - Dental amalgam
- **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.

- **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
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
- *** Data compared to the previous version altered.**

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