

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




- **1.1 Product identifier**
- **Trade name:** *Futura Standard - Capsules Liquid*
- **CAS Number:**
7439-97-6
- **EC number:**
231-106-7
- **Index number:**
080-001-00-0
- **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**

Acute Tox. 2	H330	Fatal if inhaled.
Repr. 1B	H360D	May damage the unborn child.
STOT RE 1	H372	Causes damage to organs through prolonged or repeated exposure.
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**
The substance is classified and labelled according to the CLP regulation.
- **Hazard pictograms**

		
GHS06	GHS08	GHS09

- **Signal word** *Danger*
- **Hazard-determining components of labelling:**
mercury
- **Hazard statements**
H330 Fatal if inhaled.
H360D May damage the unborn child.

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H372 Causes damage to organs through prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

· Precautionary statements

P201 Obtain special instructions before use.

P273 Avoid release to the environment.

P281 Use personal protective equipment as required.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P310 Immediately call a POISON CENTER/doctor.

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

· 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.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· 3.1 Chemical characterisation: Substances

· CAS No. Description

7439-97-6 mercury

· Identification number(s)

· **EC number:** 231-106-7

· **Index number:** 080-001-00-0

· **Description:** Alloy powder and mercury in predosed capsules.

· **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

· **General information:** Immediately remove any clothing soiled by the product.

· After inhalation:

Supply fresh air.

In case of unconsciousness place patient stably in side position for transportation.

Seek medical treatment.

· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

· After swallowing:

Rinse out mouth and then drink plenty of water.

Do not induce vomiting; call for medical help immediately.

· **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**

Antidote:

DMPS

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SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
The product is not flammable.
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture**
In case of a fire very toxic mercury fumes will generate.
Fumes are heavier than air.
- **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**
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:**
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:**
Spillages of mercury should be removed immediately, including from places which are difficult to access. Use a plastic syringe to draw it up. Smaller quantities can be covered by sulphur powder and removed. Avoid inhalation of vapour.
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **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.
Ensure good ventilation/exhaustion at the workplace.
For use in dentistry only.
- **Information about fire - and explosion protection:** Keep respiratory protective device available.
- **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.
- **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.

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- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.

- **Ingredients with biological limit values:**

CAS: 7439-97-6 mercury

BMGV ()	20 µmol/mol creatinine
	Medium: urine
	Sampling time: random
	Parameter: mercury

- **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.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Store protective clothing separately.

Do not inhale gases / fumes / aerosols.

- **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.

- **Recommended filter device for short term use:** Special gas filter Hg-P3

- **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.

Natural rubber, NR

Nitrile rubber, NBR

Butyl rubber, BR

Fluorocarbon rubber (Viton)

- **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 goggles

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SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· Form:	Fluid
· Colour:	Silver grey
· Odour:	Odourless
· Odour threshold:	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

· Melting point/freezing point:	-38.86 °C
· Initial boiling point and boiling range:	356 °C

· **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 at 20 °C:** 0.00163 hPa

· Density at 20 °C:	13.54 g/cm ³
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not determined.

· **Solubility in / Miscibility with water:**

Insoluble.
Not miscible or difficult to mix.

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

· **Viscosity:**

· Dynamic:	Not determined.
· 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.

· **Additional information:** Avoid contact with ammoniac, amines, metals and strong acids.

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SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity**
Fatal if inhaled.
- **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**
Mercury may have a sensitizing effect on the skin and lungs, or act as a nephrotoxin or neurotoxin.
- **Additional toxicological information:**
Alloy powder and mercury are predosed in closed capsules, therefore the danger of exposition to mercury vapours are low.
Avoid exposure of mercury to pregnant person.
- **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**
May damage the unborn child.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure**
Causes damage to organs through prolonged or repeated exposure.
- **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.
- **Ecotoxicological effects:**
- **Remark:** Very toxic for fish
- **Additional ecological information:**
- **General notes:**
Water hazard class 3 (German Regulation) (Assessment by list): 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.
Also poisonous for fish and plankton in water bodies.
Very toxic for aquatic organisms
- **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, IMDG, IATA	UN3506
· 14.2 UN proper shipping name · ADR/RID/ADN · IMDG · IATA	3506 MERCURY CONTAINED IN MANUFACTURED ARTICLES, ENVIRONMENTALLY HAZARDOUS MERCURY CONTAINED IN MANUFACTURED ARTICLES, MARINE POLLUTANT MERCURY CONTAINED IN MANUFACTURED ARTICLES
· 14.3 Transport hazard class(es) · ADR/RID/ADN	
	
· Class · Label	8 (CT3) Corrosive substances. 8+6.1
· IMDG	
	
· Class · Label	8 Corrosive substances. 8/6.1
· IATA	
	
· Class · Label	8 Corrosive substances. 8 (6.1)
· 14.4 Packing group · ADR/RID/ADN, IMDG, IATA	Void
· 14.5 Environmental hazards: · Marine pollutant:	Yes Symbol (fish and tree)
· Special marking (ADR/RID/ADN):	Symbol (fish and tree)
· 14.6 Special precautions for user · EMS Number:	Warning: Corrosive substances. F-A, S-B
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.

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· **Transport/Additional information:**

· **ADR/RID/ADN**

· **Limited quantities (LQ)**

5 kg

· **Excepted quantities (EQ)**

Code: E0

Not permitted as Excepted Quantity

· **Transport category**

3

· **Tunnel restriction code**

E

· **IMDG**

· **Limited quantities (LQ)**

5 kg

· **Excepted quantities (EQ)**

Code: E0

Not permitted as Excepted Quantity

· **UN "Model Regulation":**

UN3506, MERCURY CONTAINED IN MANUFACTURED ARTICLES, ENVIRONMENTALLY HAZARDOUS, 8 (6.1)

SECTION 15: Regulatory information

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

· **REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 18a, 30**

· **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

Labelling according to ISO 24234



CAUTION: This product contains mercury

· **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

Acute Tox. 2: Acute toxicity – Category 2

Repr. 1B: Reproductive toxicity – Category 1B

STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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