

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

Printing date 15.07.2015

Version number 8

Revision: 13.07.2015

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

- **1.1 Product identifier**
- **Trade name:** **Amalcap Plus (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:**
Ivoclar Vivadent AG
Bendererstrasse 2
FL-9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35
Fax: +423 235 33 60
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclarvivadent.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

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.

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.07.2015

Version number 8

Revision: 13.07.2015

Trade name: Amalcap Plus (Liquid)

(Contd. of page 1)

H360D May damage the unborn child.

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.

P281 Use personal protective equipment as required.

P273 Avoid release to the environment.

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:**

Non-Gamma-2, spherical 70 % silver alloy amalgam in self-activating capsule.

For the wording of the listed risk 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

GB

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.07.2015

Version number 8

Revision: 13.07.2015

Trade name: Amalcap Plus (Liquid)

(Contd. of page 2)

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.

(Contd. on page 4)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.07.2015

Version number 8

Revision: 13.07.2015

Trade name: Amalcap Plus (Liquid)

(Contd. of page 3)

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

· Ingredients with biological limit values:	
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.

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

GB

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.07.2015

Version number 8

Revision: 13.07.2015

Trade name: **Amalcap Plus (Liquid)**

(Contd. of page 4)

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/Melting range: -38.86 °C

Boiling point/Boiling range: 356 °C

· Flash point: Not applicable.

· Flammability (solid, gaseous): Not determined.

· Self-igniting: Product is not selfigniting.

· Danger of explosion: 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/cm³

· Relative density: Not determined.

· Vapour density: Not applicable.

· Evaporation rate: Not determined.

· Solubility in / Miscibility with water:

Insoluble.

· 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.

GB

(Contd. on page 6)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.07.2015

Version number 8

Revision: 13.07.2015

Trade name: Amalcap Plus (Liquid)

(Contd. of page 5)

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity**
Fatal if inhaled.
- **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**
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.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.

(Contd. on page 7)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.07.2015

Version number 8

Revision: 13.07.2015

Trade name: Amalcap Plus (Liquid)

(Contd. of page 6)

- **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	2809 MERCURY, ENVIRONMENTALLY HAZARDOUS
· IMDG	MERCURY CONTAINED IN MANUFACTURED
	ARTICLES, MARINE POLLUTANT
· IATA	MERCURY CONTAINED IN MANUFACTURED
	ARTICLES
· 14.3 Transport hazard class(es)	
· ADR/RID/ADN	
	
	
	
· Class	8 (CT3) Corrosive substances.
· Label	8+6.1
· IMDG	
	
	
	
· Class	8 Corrosive substances.
· Label	8/6.1
· IATA	
	
	
· Class	8 Corrosive substances.
· Label	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	Warning: Corrosive substances.
· EMS Number:	F-A,S-B
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.

(Contd. on page 8)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.07.2015

Version number 8

Revision: 13.07.2015

Trade name: Amalcap Plus (Liquid)

(Contd. of page 7)

· 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":
UN2809, MERCURY, ENVIRONMENTALLY
HAZARDOUS, 8 (6.1), III

SECTION 15: Regulatory information

· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
· Directive 2012/18/EU
· Named dangerous substances - ANNEX I Substance is not listed.

· 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, Hazard Category 2

Repr. 1B: Reproductive toxicity, Hazard Category 1B

STOT RE 1: Specific target organ toxicity - Repeated exposure, Hazard Category 1

Aquatic Acute 1: Hazardous to the aquatic environment - Acute Hazard, Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1

· * Data compared to the previous version altered.

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.07.2015

Version number 8

Revision: 13.07.2015

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

- **1.1 Product identifier**
- **Trade name:** **Amalcap Plus (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:**
Ivoclar Vivadent AG
Bendererstrasse 2
FL-9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35
Fax: +423 235 33 60
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclarvivadent.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

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:**
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	50-100%
CAS: 7440-50-8 EINECS: 231-159-6	copper	substance with a Community workplace exposure limit	10-<25%

- **Additional information:**
Non-Gamma-2, spherical 70 % silver alloy amalgam in self-activating capsule.

(Contd. on page 2)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.07.2015

Version number 8

Revision: 13.07.2015

Trade name: Amalcap Plus (Powder)

(Contd. of page 1)

For the wording of the listed risk 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.

(Contd. on page 3)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.07.2015

Version number 8

Revision: 13.07.2015

Trade name: Amalcap Plus (Powder)

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

(Contd. of page 2)

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)

 · **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.

 · **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.

 · **Change in condition**

Melting point/Melting range: Undetermined.

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.07.2015

Version number 8

Revision: 13.07.2015

Trade name: Amalcap Plus (Powder)

(Contd. of page 3)

Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not determined.
· Self-igniting:	Product is not selfigniting.
· Danger of explosion:	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.
· 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**
- **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.
- **Additional toxicological information:**
Alloy powder and mercury are predosed in closed capsules, therefore the danger of exposition to mercury vapours are low.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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.

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.07.2015

Version number 8

Revision: 13.07.2015

Trade name: Amalcap Plus (Powder)

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

(Contd. of page 4)

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 |
|-----------|--------------------------------|
- **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. |
| · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |

(Contd. on page 6)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 15.07.2015

Version number 8

Revision: 13.07.2015

Trade name: Amalcap Plus (Powder)

(Contd. of page 5)

· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN "Model Regulation":	-

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **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.**

GB