

SAFETY DATA SHEET (GHS)

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE/PRODUCT AND MANUFACTURER/IMPORTER**1.1 Product identifier:-**

Product name:	Amalcap Plus (Liquid)
Product number:	532281AN / 532282AN / 532283AN / 532287AN / 532288AN / 532289AN

1.2 Other means of identification:-

Not applicable.

1.3 Recommended use of the chemical and restrictions on use:-

Not applicable.

Identified uses: | Dental filling material – amalgam (Pre-dosed capsules).**1.4 Details of the manufacturer and importer:-**

Manufacturer:	Ivoclar Vivadent AG Bendererstrasse 2 FL-9494 Schaan Principality of Liechtenstein Tel: + 423 235 35 35 Fax: + 423 235 33 60
Importer:	Ivoclar Vivadent Ltd 12 Omega St, Rosedale, Auckland, New Zealand Phone +64 9 914 9999 Fax +64 9 914 9990 www.ivoclarvivadent.co.nz
Emergency phone number:	0800 764 766 (National Poison Centre) Poisons Hotline (24 hours / 7 days)

2. HAZARD(S) IDENTIFICATION**2.1 GHS Classification:-**

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 GHS Label elements, including precautionary statements:-**Hazard Pictogram:**

GHS06



GHS08



GHS09

Signal word:

Hazard-determining components of labelling:

Hazard statements:

Danger
Mercury

H330 Fatal if inhaled.
 H360D May damage the unborn child.
 H372 Causes damage to organs through prolonged or repeated exposure.
 H400 Very toxic to aquatic life.
 H410 Very toxic to aquatic life with long lasting effects.
 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.

Precautionary statements:

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.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient name	CAS No.	Classification	Concentration
Mercury	7439-97-6	Acute Tox. 2 - H330 Repr. 1B - H360D STOT RE 1 - H372 Aquatic Acute 1 - H400 Aquatic Chronic 1 - H410	
Non-hazardous ingredients	N/A	N/A	to 100%

Additional information:

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

For the full text of the H-Statements mentioned in this Section, refer to Section 16.

4. FIRST AID MEASURES

4.1 Description of necessary first aid measures:-

General advice:

Remove contaminated clothing and shoes immediately and launder thoroughly before reusing.

First aid facilities include first aid rooms and medical centres.

If a risk assessment determines that a first aid room or medical centre is not needed, a rest area within the workplace may be suitable to assist an injured or ill person.

If inhaled:

Ensure supply of fresh air.

Remove affected person from the immediate area.

Keep patient warm. Consult doctor if symptoms persist. In case of unconsciousness place patient stably in side position for transportation.

In case of skin contact:

Wash off immediately with water and soap and rinse thoroughly.

In case of eye contact:

If skin irritation continues, consult a doctor.

Remove contact lenses, irrigate copiously with clean, fresh water for at least 15 minutes holding the eyelids apart and seek medical advice.

If swallowed:

Do not induce vomiting.

Rinse mouth thoroughly with water.

Let plenty of water be drunk in small gulps.

Never give anything by mouth to an unconscious person.

Call a doctor immediately.

4.2 Symptoms caused by exposure:-

Please refer to section 2.2 and section 11.

4.3 Medical attention and special treatment :-

Antidote – DMPS

5. FIRE FIGHTING MEASURES

5.1 Suitable extinguishing equipment:-

Suitable extinguishing media:

The product is not flammable.
Use fire extinguishing methods suitable to surrounding conditions.

Unsuitable extinguishing media:

No further relevant information available.

5.2 Specific hazards arising from the substance/mixture/product:-

In case of fire very toxic mercury fumes will generate.
Fumes are heavier than air.

5.3 Special protective equipment and precautions for fire fighters:-

Special personal protective equipment:

Wear self-contained respiratory protective device.

Precautions:

Cool endangered receptacles with water spray.

Hazchem code:

8 Corrosive substances.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:-

Wear protective equipment. Keep unprotected persons away.

Use of suitable equipment (incl PPE) to prevent contamination of skin, eyes, clothing, removal of ignition sources, ventilation, emergency procedures (eg. evacuate, consult expert).

6.2 Environmental precautions:-

Do not allow to enter sewers/surface or ground water.

Inform respective authorities in case of seepage into water course or sewage system.

6.3 Methods and materials for containment and cleaning up:-

Spillages of mercury should be removed immediately, including from places which are difficult to access.
Use plastic syringe to draw it up.

Smaller quantities can be covered by sulphur powder and removed.

Avoid inhalation of vapour.

Dispose contaminated material as waster according to item 13.

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling:-

No special measures necessary if stored and handled as prescribed.

Only adequately trained personnel should handle this product – for use in dentistry only.

Ensure good ventilation/exhaustion at the workplace.

Keep ignition sources away – do not smoke.

Wash hands before breaks and after work.

Do not eat, drink or smoke during work time.

Remove soiled or soaked clothing immediately.

Keep away from foodstuffs and beverages.

7.2 Conditions for safe storage, including any incompatibilities:-

Keep only in the original container.

Containers which are opened must be carefully closed and kept upright to prevent leakage.

Keep container tightly sealed.

Store in cool, dry conditions in well-sealed receptacles.

Store receptacle in a well ventilated area.

Recommended storage temperature for storage rooms and vessels is 20 - 30°C.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure control measures:-

Occupational exposure limits:

Ingredients with biological values:

Component	CAS No.	Value	Parameters	Basis
Mercury	7439-97-6	20 µmol/mol creatinine Medium: urine Sampling time: random Parameter: mercury		The lists valid during the making were used as basis.

Exposure should be kept to as low as practicable and below the AOES.

8.2 Biological monitoring:-

Assess in accordance with exposure limits – please refer to section 8.1.

Exposure controls / Personal protective equipment / General protective and hygienic measures:

Usual hygienic measures for dental practice.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Avoid contact with the eyes and skin.

Store protective clothes separately.

Do not inhale gases / fumes / aerosols.

8.3 Control banding:-

Use good industrial hygiene practice and general ventilation.

8.4 Engineering controls:-

In case of intensive contact, wear protective gloves (EN 374).

Before use, the protective gloves should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties).

Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves.

Protective gloves shall be replaced immediately when physically damaged or worn.

8.5 Individual protection measures include PPE:-

Eye/face protection:



Safety glasses

Use tightly fitting safety glasses as per Australian Standard AS 1336 and AS/NZS 1337.

Skin protection:



Protective gloves

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

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

Material of gloves

Butyl rubber, BR.

Fluorocarbon rubber (Viton).

PVA 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 cannot 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.

Provide for good ventilation of working area (local exhaust ventilation, if necessary).

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.

Respiratory protection:

9. PHYSICAL/CHEMICAL PROPERTIES

9.1 Information on physical/chemical properties:-

a)	Appearance/Form:	Fluid.
b)	Colour:	Silver grey.
c)	Odour:	Odourless.
d)	Odour threshold:	Not determined.
e)	pH value:	Not applicable.
f)	Melting point/melting range:	-38.86°C.
g)	Boiling point/boiling range:	356°C.
h)	Flash point:	Not applicable.
i)	Ignition temperature:	Not determined.
j)	Self-igniting:	Product is not self-igniting.
k)	Danger of explosion:	Product does not present an explosion hazard.
l)	Upper/lower flammability or explosive limits:	Lower Not determined. Upper Not determined.
m)	Vapour pressure at 20°C:	0.00163 hPa
n)	Density at 20°C:	13.54 g/cm ³ .
o)	Relative density:	Not determined.
p)	Vapour density:	Not applicable.
q)	Evaporation rate:	Not determined.
r)	Solubility in/miscibility with water:	Insoluble.
s)	Partition coefficient: n- octanol/water:	Not determined.
t)	Viscosity:	Dynamic Not determined. Kinematic Not applicable.

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.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:-

Acute toxicity / Values relevant for classification:

Fatal if inhaled.

Skin corrosion/irritation:

Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation:

Based on available data, the classification criteria are not met.

Respiratory or skin sensitization:

Mercury may have a sensitising effect on the skin and lungs, or act as a nephrotoxic or neurotoxin.

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 unborn child.

Specific target organ toxicity - single exposure:

Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure:

Causes damage to organs though prolonged or repeated exposure.

Aspiration hazard:

Based on available data, the classification criteria are not met.

Additional information:

Ally powder and mercury are pre-dosed in closed capsules, therefore the danger of exposition to mercury vapours are low.

Avoid exposure of mercury to pregnant person.

11.2 Information on possible routes of exposure:-

Short Term (Acute) Exposure:

No further relevant information available.

Swallowed:

No further relevant information available.

Eyes:

No further relevant information available.

Skin:

No further relevant information available.

Inhaled:

No further relevant information available.

Long Term (Chronic) Exposure:

Causes damage to organs though prolonged or repeated exposure.

Swallowed:

No further relevant information available.

Eyes:

No further relevant information available.

Skin:

No further relevant information available.

Inhaled:

No further relevant information available.

11.3 Early onset symptoms related to exposure:-

No further relevant information available.

11.4 Delayed health effects from exposure:-

No further relevant information available.

11.5 Exposure levels and health effects:-

No further relevant information available.

11.6 Interactive effects:-

No further relevant information available.

11.7 Other:-

No further relevant information available.

12. ECOLOGICAL INFORMATION

12.1 Ecotoxicity:-

Very toxic for fish.

12.2 Persistence/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.

12.5 Other adverse effects:-

No further relevant information available.

Additional ecological information / General notes:

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.

12.6 Other adverse effects:-

No further relevant information available.

13. DISPOSAL CONSIDERATIONS

13.1 Disposal methods:-

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.

Disposal must be made according to official regulations.

14. TRANSPORT INFORMATION

UN number ADR / IMDG / IATA:-

UN3506

UN proper shipping name or technical name:-

ADR:

2809 MERCURY, ENVIRONMENTALLY HAZARDOUS
MERCURY CONTAINED IN MANUFACTURED
ARTICLES, MARINE POLLUTANT
MERCURY CONTAINED IN MANUFACTURED
ARTICLES, MARINE POLLUTANT

IMDG, IATA:

Transport hazard class(es):



Label:

Packaging group:

Environmental hazards:

8 (CT3) Corrosive substances.

8+6.1

Void

Yes.

Symbol (fish & tree)

Warning: Corrosive substances.

80

F-A, S-B.

Not applicable.

Special precautions for user:

Danger code:

EMS Number:

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:

Additional information – ADR:-

Limited quantities:

Excepted quantities:

5kg

Code: E0

Not permitted as excepted quantity.

3

E

Transport category:

Tunnel restriction code:

Additional information – IMDG:-

Limited quantities:

Excepted quantities:

5kg

Code: E0

Not permitted as excepted quantity.

Hazchem or emergency action code:

8 (CT3) Corrosive substances.

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture/product:-

Classified as Hazardous according to the criteria of the National Occupational Health and Safety Commission (NOHSC) approved criteria for the classifying hazardous substances [NOHSC: 1008] 3rd edition.

Standard for the Uniform Scheduling of Medicines and Poisons.

Carcinogen classification under WHS Regulation 2011, Schedule 10.

Notification status in accordance with section 3 and current national legislation.

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.

HSNO Approval: HSR003014

EPA NZ Classes of hazardous properties: Class 8

16. OTHER INFORMATION

Key to abbreviations/acronyms used in SDS:-

H330 Fatal if inhaled.

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.

Key literature references/data sources used to compile SDS:-

Standard EN420:2003 General requirements for protective gloves: disposable gloves, e.g. nitrile rubber, material thickness 0.1 mm (Australian Standard 2161).

Long-term exposure (Level 6: < 480 min): protective gloves, e.g. nitrile rubber, material thickness 0.7 mm (Australian Standard 2161).

Personal eye protection - Eye and face protectors for occupational applications: safety glasses (Australian Standard AS 1336 and AS/NZS 1337.1:2010).

Copyright statement:-

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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).

LC50: Lethal concentration, 50 percent.

LD50: Lethal dose, 50 percent.

Flam. Liq. 2: Flammable liquids, Hazard Category 2.

Flam. Liq. 3: Flammable liquids, Hazard Category 3.

Acute Tox. 4: Acute toxicity, Hazard Category 4.

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2.

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2.

Repr. 2: Reproductive toxicity, Hazard Category 2.

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3.

STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2.

Asp. Tox. 1: Aspiration hazard, Hazard Category 1.

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