






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

- **Product identifier**
- **Trade name:** **Vivacap**
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Amalgam
- **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
msds@ivoclarvivadent.com
- **Emergency telephone number:** +423 / 235 33 13

2 Hazards identification

- **Classification of the substance or mixture**
 - **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
 -  **T+; Very toxic**
R26: Very toxic by inhalation.
 -  **T; Toxic**
R61-48/23: May cause harm to the unborn child. Toxic: danger of serious damage to health by prolonged exposure through inhalation.
 -  **N; Dangerous for the environment**
R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
 - **Information concerning particular hazards for human and environment:**
The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
 - **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
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- **Label elements**
 - **Labelling according to EU guidelines:**
The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials.
 - **Code letter and hazard designation of product:**
 - 

T+ Very toxic
N Dangerous for the environment
 - **Hazard-determining components of labelling:**
mercury
 - **Risk phrases:**
61 May cause harm to the unborn child.

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26 Also very toxic by inhalation.

48/23 Also toxic: danger of serious damage to health by prolonged exposure through inhalation.

50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

· Safety phrases:

53 Avoid exposure - obtain special instructions before use.

9 Keep container in a well-ventilated place.

28 After contact with skin, wash immediately with plenty of soap and water.

36/37/39 Wear suitable protective clothing, gloves and eyeface protection.

45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

57 Use appropriate container to avoid environmental contamination.

· Other hazards**· Results of PBT and vPvB assessment****· PBT:** Not applicable.**· vPvB:** Not applicable.**3 Composition/information on ingredients****· Chemical characterization: Mixtures****· Description:** Alloy powder and mercury in predosed capsules.**· Dangerous components:**

CAS: 7439-97-6

mercury



T+ R26;



T R61-48/23;



N R50/53

50-75%

EINECS: 231-106-7

· Additional information:

Non-Gamma-2, spherical 46 % silver alloy amalgam in self-activating capsule.

For the wording of the listed risk phrases refer to section 16.

4 First aid measures**· Description of first aid measures****· General information:** Immediately remove any clothing soiled by the product.**· After inhalation:**

Supply fresh air or oxygen; call for doctor.

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

· 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.

Call for a doctor immediately.

· Information for doctor:**· Most important symptoms and effects, both acute and delayed** No further relevant information available.**· Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

5 Firefighting measures**· Extinguishing media****· Suitable extinguishing agents:**

The product is not flammable.

Use fire extinguishing methods suitable to surrounding conditions.

· Special hazards arising from the substance or mixture

In case of a fire very toxic mercury fumes will generate.

Fumes are heavier than air.

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- **Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.
- **Additional information** Cool endangered receptacles with water spray.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **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.
- **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.
- **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.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Only adequately trained personnel should handle this product.
- **Information about fire - and explosion protection:** Keep respiratory protective device available.
- **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.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **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.

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· 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.

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

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.

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

9 Physical and chemical properties

· Information on basic physical and chemical properties**· General Information****· Appearance:**

Form:	<i>Fluid</i>
Colour:	<i>Silver grey</i>
· Odour:	<i>Odourless</i>
· Odour threshold:	<i>Not determined.</i>

· pH-value: *Not determined.*

· Change in condition

Melting point/Melting range:	<i>38°C</i>
Boiling point/Boiling range:	<i>356°C</i>

· Flash point: *Not applicable.*

· Self-igniting: *Product is not selfigniting.*

· Danger of explosion: *Product does not present an explosion hazard.*

· Explosion limits:

Lower:	<i>Not determined.</i>
Upper:	<i>Not determined.</i>

· Vapour pressure at 20°C: *0.00163 hPa*

· Density at 20°C: *13.54 g/cm³*

· Relative density *Not determined.*

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· Vapour density	<i>Not determined.</i>
· Evaporation rate	<i>Not determined.</i>
· Solubility in / Miscibility with water:	<i>Not miscible or difficult to mix.</i>
· Segregation coefficient (n-octanol/water):	<i>Not determined.</i>
· Viscosity:	
· Dynamic:	<i>Not determined.</i>
· Kinematic:	<i>Not determined.</i>
· Other information	<i>No further relevant information available.</i>

10 Stability and reactivity

- **Reactivity** *No further relevant information available.*
- **Chemical stability** *Stable under normal handling and storage conditions.*
- **Thermal decomposition / conditions to be avoided:** *No decomposition if used according to specifications.*
- **Possibility of hazardous reactions** *No dangerous reactions known.*
- **Conditions to avoid** *No further relevant information available.*
- **Incompatible materials:** *No further relevant information available.*
- **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

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** *No irritant effect.*
- **on the eye:** *No irritating effect.*
- **Sensitization:**
- Mercury may have a sensitizing effect on the skin and lungs, or act as a nephrotoxin or neurotoxin.*
- **Additional toxicological information:**
- The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:*
- Very toxic*
- 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.*

12 Ecological information

- **Toxicity**
- **Acquatic toxicity:** *No further relevant information available.*
- **Persistence and degradability** *No further relevant information available.*
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** *No further relevant information available.*
- **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) (Self-assessment): 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.*

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Also poisonous for fish and plankton in water bodies.

Very toxic for aquatic organisms

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**

· **Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **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.

14 Transport information

· **Land transport ADR/RID (cross-border)**



· **ADR/RID class:** 8 (C9) Corrosive substances.

· **Danger code (Kemler):** 80

· **UN-Number:** 2809

· **Packaging group:** III

· **Hazard label:** 8

· **Special marking:** Symbol (fish and tree)

· **UN proper shipping name:** 2809 MERCURY

· **Tunnel restriction code** E

· **Maritime transport IMDG:**



· **IMDG Class:** 8

· **UN Number:** 2809

· **Label** 8

· **Packaging group:** III

· **EMS Number:** F-A,S-B

· **Marine pollutant:** Yes

Symbol (fish and tree)

· **Segregation groups** Heavy metals and their salts (including their organometallic compounds)

· **Proper shipping name:** MERCURY

· **Air transport ICAO-TI and IATA-DGR:**



· **ICAO/IATA Class:** 8

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- **UN/ID Number:** 2809
- **Label** 8
- **Packaging group:** III
- **Proper shipping name:** MERCURY

- **Environmental hazards:** Product contains environmentally hazardous substances: mercury
- **Special precautions for user** Warning: Corrosive substances.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

15 Regulatory information

- **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 EC-directive 93/42/EEC.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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.

- **Relevant phrases**

R26 Very toxic by inhalation.

R48/23 Toxic: danger of serious damage to health by prolonged exposure through inhalation.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R61 May cause harm to the unborn child.

GB