

Safety Data Sheet
according to HPR, Schedule 1

Printing date 06/28/2019

Version number 4

Reviewed on 06/26/2019

1 Identification



- **Product identifier**
- **Trade name:** Valiant, Valiant Snap-Set, Valiant Ph.D., Valiant Ph.D. XT, Valiant Ph.D. EXT
- **Application of the substance / the mixture** Amalgam
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285

Ivoclar Vivadent Inc.
1-6600 Dixie Road
Mississauga, Ontario
L5T 2Y2
Canada
Phone: +1 905 670 8499
Fax: +1 905 670 3102
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666

General SDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard identification

- **Classification of the substance or mixture**
Acute Toxicity (Inhalation) - Category 2 H330 Fatal if inhaled.
Reproductive Toxicity - Category 1B H360 May damage fertility or the unborn child.
Specific Target Organ Toxicity - Repeated Exposure - Category 1 H372 Causes damage to organs through prolonged or repeated exposure.

- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**
 
GHS06 GHS08
- **Signal word** Danger
- **Hazard-determining components of labeling:**
mercury
- **Hazard statements**
Fatal if inhaled.

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May damage fertility or the unborn child.

Causes damage to organs through prolonged or repeated exposure.

· **Precautionary statements**

Obtain special instructions before use.

Avoid release to the environment.

Use personal protective equipment as required.

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

Immediately call a poison center/doctor.

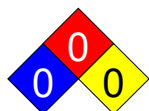
Store in a well-ventilated place. Keep container tightly closed.

· **Additional information:**

Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = *2

Fire = 0

Reactivity = 0

3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**

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

· **Dangerous components:**

CAS: 7439-97-6

mercury

40-45% w/w *

* Actual concentration ranges are withheld as a trade secret.

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.

Do not induce vomiting; immediately call for medical help.

· **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**

Antidote:

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DMPS

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5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
The product is not flammable.
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture**
In case of a fire very toxic mercury fumes will generate.
Fumes are heavier than air.
- **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:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
- **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.
Ensure adequate ventilation.
Dispose contaminated material as waste according to item 13.
- **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**
Only adequately trained personnel should handle this product.
Ensure good ventilation/exhaustion at the workplace.
For use in dentistry only.
- **Information about protection against explosions and fires:** 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 receptacle tightly sealed.
Store receptacle in a well ventilated area.
- **Specific end use(s)** No further relevant information available.

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8 Exposure controls/ Personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

CAS: 7439-97-6 mercury

EL () Long-term value: 0.025 mg/m³
Skin; R

EV () Long-term value: 0.025 mg/m³
as Hg, Skin

- **Additional information:** The lists that were valid during the creation were used as basis.

- **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.

Do not inhale gases / fumes / aerosols.

Avoid contact with the eyes and skin.

Store protective clothing separately.

- **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

- **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.

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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9 Physical and chemical properties

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

General Information *The physical and chemical properties in this section refer to the mercury.*

· **Appearance:**

Form: *Fluid*

Color: *Silver grey*

· **Odor:** *Odorless*

· **Odor threshold:** *Not determined.*

· **pH-value:** *Not determined.*

· **Change in condition**

Melting point/Melting range: *-38 °C*

Boiling point/Boiling range: *356 °C*

· **Flash point:** *Not applicable.*

· **Auto igniting:** *Product is not selfigniting.*

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

· **Explosion limits:**

Lower: *Not determined.*

Upper: *Not determined.*

· **Vapor pressure:** *Not determined.*

· **Density at 20 °C:** *13.54 g/cm³*

· **Relative density** *Not determined.*

· **Vapor density** *Not determined.*

· **Evaporation rate** *Not determined.*

· **Solubility in / Miscibility with**

Water: *Insoluble.*

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

· **Viscosity:**

Dynamic: *Not determined.*

Kinematic: *Not determined.*

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

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.*

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11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

- **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 internally approved calculation methods for preparations:

Harmful

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.

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

CAS: 7439-97-6	mercury	3
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- **NTP (National Toxicology Program)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**

- **Aquatic toxicity:** No further relevant information available.

- **Persistence and degradability** No further relevant information available.

- **Behavior 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 (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.

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 be specially treated adhering to official regulations.

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

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- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

<ul style="list-style-type: none"> · UN-Number · DOT/TDG, ADR, IMDG, IATA 	UN3506
<ul style="list-style-type: none"> · UN proper shipping name · IMDG · IATA 	<p>MERCURY CONTAINED IN MANUFACTURED ARTICLES, MARINE POLLUTANT</p> <p>MERCURY CONTAINED IN MANUFACTURED ARTICLES</p>
<ul style="list-style-type: none"> · Transport hazard class(es) · DOT/TDG (Transport dangerous goods): 	<div style="display: flex; justify-content: space-around; align-items: center;"> </div> <p>6.1 Toxic substances</p> <p>6.1, 8</p>
<ul style="list-style-type: none"> · ADR 	<div style="display: flex; justify-content: space-around; align-items: center;"> </div> <p>8 (CT3) Corrosive substances</p> <p>8+6.1</p>
<ul style="list-style-type: none"> · IMDG 	<div style="display: flex; justify-content: space-around; align-items: center;"> </div> <p>6.1 Toxic substances</p> <p>6.1/8</p>
<ul style="list-style-type: none"> · IATA 	<div style="display: flex; justify-content: space-around; align-items: center;"> </div> <p>6.1 Toxic substances</p> <p>6.1 (8)</p>
<ul style="list-style-type: none"> · Packing group · DOT/TDG, IMDG, IATA · ADR 	<p>II</p> <p>Void</p>
<ul style="list-style-type: none"> · Environmental hazards: 	<p>Product contains environmentally hazardous substances: mercury</p>

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· Marine pollutant:	Yes Symbol (fish and tree)
· Special marking (ADR):	Symbol (fish and tree)
· Special precautions for user	Warning: Corrosive substances
· Danger code (Kemler):	86
· EMS Number:	F-A,S-B
· Segregation groups	Heavy metals and their salts (including their organometallic compounds), mercury and mercury compounds
· Stowage Category	B
· Stowage Code	SW2 Clear of living quarters.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Excepted quantities (EQ)	Code: E0 Not permitted as Excepted Quantity
· IMDG	
· Limited quantities (LQ)	100 ml
· Excepted quantities (EQ)	Code: E4 Maximum net quantity per inner packaging: 1 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 3506 MERCURY CONTAINED IN MANUFACTURED ARTICLES SOLUTION, 8 (6.1), ENVIRONMENTALLY HAZARDOUS

15 Regulatory information

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

· Sara

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

CAS: 7439-97-6 | mercury

· **TSCA (Toxic Substances Control Act):**

CAS: 7439-97-6 | mercury

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS06 GHS08

· **Signal word** Danger

· **Hazard-determining components of labeling:**

mercury

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- **Hazard statements**

Fatal if inhaled.

May damage fertility or the unborn child.

Causes damage to organs through prolonged or repeated exposure.

- **Precautionary statements**

Obtain special instructions before use.

Avoid release to the environment.

Use personal protective equipment as required.

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

Immediately call a poison center/doctor.

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

- **National regulations:**

- **Other regulations, limitations and prohibitive regulations**



CAUTION: This product contains mercury

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

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

- **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.

- **Date of the latest revision of the safety data sheet** 06/28/2019 / 3

- **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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

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