SAFETY DATA SHEETS

This SDS packet was issued with item:

071679612

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071679554 071679562 071679570 071679588 071679596 071679604 071679620 071679646



Printing date 02/21/2014

Version number 3

Reviewed on 02/21/2014

1 Identification

- · Product identifier
- Trade name: Valiant, Valiant Snap-Set, Valiant Ph.D., Valiant Ph.D. XT, Valiant Ph.D. EXT
- Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

- · 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 MSDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

2 Hazard(s) identification

· Cl	assij	fication	ı of	the	substance	or	mixture
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· Classification according to Directive 67/548/EEC or Directive 1999/45/EC

Very toxic

Very toxic by inhalation.

Toxic

May cause harm to the unborn child. Toxic: danger of serious damage to health by prolonged exposure through inhalation.

Dangerous for the environment

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

Classification system:

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

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- · Label elements
- · Labelling according to EU guidelines:
- · Code letter and hazard designation of product:





Very toxic Dangerous for the environment

· Hazard-determining components of labeling: mercury

· Risk phrases:

May cause harm to the unborn child.

Also very toxic by inhalation.

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

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

· Safety phrases:

Avoid exposure - obtain special instructions before use.

Keep container in a well-ventilated place.

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

Wear suitable protective clothing, gloves and eye/face protection.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Use appropriate container to avoid environmental contamination.

- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 4Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



*4 *Health* = *4

Fire = 0

- · 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:

7439-97-6 mercury

40-45%

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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.

- · 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:

DMPS

5 Fire-fighting 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.

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7 Handling and storage

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.

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:

7439-97-6 mercury

PEL Long-term value: 0.1 mg/m³

as Hg; see OSHA standard interpretation memo

REL Long-term value: 0.05* mg/m³

Ceiling limit value: 0.1 mg/m³

as Hg; *Vapor; Skin

TLV Long-term value: 0.025 mg/m³

as Hg; Skin; BEI

· Ingredients with biological limit values:

7439-97-6 mercury

BEI 35 μg/g creatinine

Medium: urine Time: prior to shift

Parameter: Total inorganic mercury (background

15 μg/L Medium: blood

Time: end of shift at end of workweek

Parameter: Total inorganic mercury (background)

- · 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.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

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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

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
· Odour threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition	
Melting point/Melting range:	-38 °C (-36 °F)
Boiling point/Boiling range:	356 °C (673 °F)
· Flash point:	Not applicable.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.

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· Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapor pressure:	Not determined.	
Density at 20 °C (68 °F):	13.54 g/cm³ (112.991 lbs/gal)	
· Relative density	Not determined.	
· Vapour 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.

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 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.

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· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

7439-97-6 mercury

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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.
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Ecotoxical 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.

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

· UN-Number		
· DOT	UN2809	
· ADR, IMDG, IATA	2809	
· UN proper shipping name		
· IMDG, IATA	MERCURY	
· Transport hazard class(es)		
· DOT, IMDG, IATA		
· Class	8 Corrosive substances.	

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· Label	8
· ADR	
· Class	8 (C9) Corrosive substances
· Label	8
· Packing group	
· DOT, ADR, ÎMDG, IATA	III
Environmental hazards:	
· Marine pollutant:	Yes
· Special precautions for user	Warning: Corrosive substances
· Danger code (Kemler):	80
· EMS Number:	F-A,S-B
· Segregation groups	Heavy metals and their salts (including their organometallic compounds)
· Transport in bulk according to Annex II o	f
MARPOL73/78 and the IBC Code	Not applicable.

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):

7439-97-6 mercury

· TSCA (Toxic Substances Control Act):

7439-97-6 mercury

- · Proposition 65
- · Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

7439-97-6 mercury

Carcinogenic categories

7439-97-6 mercury

D

· TLV (Threshold Limit Value established by ACGIH)

7439-97-6 mercury

A4

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

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· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

- · Product related hazard information:
- · Hazard symbols:





Very toxic Dangerous for the environment

$\cdot \textit{Hazard-determining components of labeling:}$

mercury

· Risk phrases:

May cause harm to the unborn child.

Also very toxic by inhalation.

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

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

· Safety phrases:

Avoid exposure - obtain special instructions before use.

Keep container in a well-ventilated place.

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

Wear suitable protective clothing, gloves and eye/face protection.

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Use appropriate container to avoid environmental contamination.

· National regulations:

· Other regulations, limitations and prohibitive regulations

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 preparation / last revision 02/21/2014 / 2

USA