

Material Safety Data Sheet

according to 1907/2006/EC, Article 31

MSDS No: PER262

Issue No: 6

IMPORTANT

Read this MSDS before handling and disposing of this product and pass this information on to employees, customers and users of this product.


1. IDENTIFICATION

Product Name	PerfectAlloy Capsules 40% Silver Dental mercury and metal powder for dental restoration
Company Name	Perfection Plus Ltd
Company Address	6 Westwood Court, Brunel Road, Totton, Hants. SO40 3WX. UK
Company Phone No.	+44 (0) 2380 866 677

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture	
2.1.1 Classification 1999/45/EC	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

Hazard pictograms	
Signal Word	Danger
Hazard determining components of labelling	
Hazard Statement	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.
Precautionary Statement:	P201 Obtain special instructions before use.

Prevention	<p>P273 Avoid release to the environment.</p> <p>P281 Use personal protective equipment as required.</p> <p>P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P310 Immediately call a POISON CENTER/doctor.</p> <p>P403+P233 Store in a well-ventilated place. Keep container tightly closed.</p>
Additional information	<p>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.</p>

2.3 Other hazards

Results of PBT and vPvB assessment	
PBT	Not applicable.
vPvB	Not applicable.

3 COMPOSITION/DATA ON COMPONENTS

3.1 Substances

Components Name	Cas No.	EC No	Content	Index number
Mercury	7439-97-6	231-106-7		080-001-00-0

Dangerous components: Void

Additional information:

Non-Gamma-2, spherical 40 % silver alloy amalgam in self-activating capsule.
For the wording of the listed hazard phrases refer to section 16.

4 FIRST AID MEASURES

General information: Immediately remove any clothing soiled by the product.

4.1 Description of first aid measures

Inhalation	Supply fresh air. In case of unconsciousness place patient stably in side position for transportation. Seek medical treatment.
Skin Contact	Immediately wash with water and soap and rinse thoroughly.
Eye Contact	Rinse opened eye for several minutes under running water. Then consult a doctor.
Ingestion	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

5 FIRE FIGHTING MEASURES

5.1 Extinguishing media

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.

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.

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.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Additional information about design of technical facilities: No further data; see item 7.

Ingredients with limit values that require monitoring at the workplace:	
CAS	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. Personal protection

Respiratory Protection: Good ventilation of the room. Protective measures: e.g. a mask could be needed.

8.2 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.

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



9 PHYSICAL AND CHEMICAL PROPERTIES

Mercury

Physical State	Fluid
Colour	Silver grey
Odour	Odourless
Odour Threshold	No data available
pH	No data available
Melting Point	-38.86 °C
Initial boiling Point	356 °C
Flash Point (°C)	No data available
Auto ignition temperature	Product is not selfigniting.
Flammability (solid, gas)	No data available
Explosive properties	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/cm ³
Vapour density	No data available
Relative density	No data available
Evaporation rate	Not determined.
Fat Solubility	No data available
Partition coefficient	No data available
Autoignition temperature	No data available

Viscosity	No data available
Dynamic:	Not determined
Kinematic:	Not applicable
Solubility in / Miscibility with water:	Insoluble. Not miscible or difficult to mix.

The alloy and mercury are separately packaged in an original tight capsule.

9.2 Other information

No further relevant information available.

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

Fatal if inhaled.

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.

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.

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	Not applicable
12.6 Other adverse effects	No further relevant information available.

13 DISPOSAL CONSIDERATIONS

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.

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

14 TRANSPORTATION INFORMATION

14.1 UN-Number ADR/RID/ADN, IMDG, IATA	UN3506
14.2 UN proper shipping name ADR/RID/AND	3506 MERCURY CONTAINED IN MANUFACTURED ARTICLES, 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	   <p>Class: 8 (CT3) Corrosive substances. Label: 8+6.1</p>
IMDG	   <p>Class: 8 Corrosive substances. Label: 8/6.1</p>
IATA	  <p>Class: 8 Corrosive substances. Label: 8 (6.1)</p>
14.4 Packing group ADR/RID/ADN, IMDG, IATA	Void
14.5 Environmental hazards: Marine pollutant: Special marking (ADR/RID/ADN):	Yes Symbol (fish and tree) Symbol (fish and tree)
14.6 Special precautions for user: EMS Number:	Warning: Corrosive substances. F-A,S-B
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code Transport/Additional information:	Not applicable.
ADR/RID/ADN Limited quantities (LQ) Excepted quantities (EQ) Transport category	5 kg Code: E0 Not permitted as Excepted Quantity 3

Tunnel restriction code	E
IMDG Limited quantities (LQ) Excepted quantities (EQ)	5 kg Code: E0 Not permitted as Excepted Quantity
UN "Model Regulation"	UN3506, MERCURY CONTAINED IN MANUFACTURED ARTICLES, ENVIRONMENTALLY HAZARDOUS, 8 (6.1)

15 REGULATORY INFORMATION

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3, 18a, 30

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.

16 OTHER INFORMATION

Revision	<p>This document differs from the previous version in the following areas:.</p> <ul style="list-style-type: none"> 2 - 2.1. Classification of the substance or mixture. 2 - 2.1.2. Classification - EC 1272/2008. 2 - Hazard pictograms. 2 - Signal Word. 2 - Precautionary Statement: Prevention. 2 - Further information. 3 - Composition/information on ingredients. 4 - Inhalation. 4 - Eye contact. 4 - Skin contact. 4 - Ingestion. 5 - Firefighting measures 6 - 6.1. Personal precautions, protective equipment and emergency procedures. 7 - 7.1. Precautions for safe handling. 8 - Respiratory protection. 8 - Skin protection - Handprotection. 9 - 9.1. Information on basic physical and chemical properties (Initial boiling point). 9 - 9.1. Information on basic physical and chemical properties
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	<p>(Melting point).</p> <p>9 - 9.1. Information on basic physical and chemical properties (Flash point).</p> <p>9 - 9.1. Information on basic physical and chemical properties (Flammability (solid, gas)).</p> <p>9 - 9.1. Information on basic physical and chemical properties (Autoignition temperature).</p> <p>9 - 9.1. Information on basic physical and chemical properties (Explosive properties).</p> <p>9 - 9.1. Information on basic physical and chemical properties (Vapour pressure).</p> <p>9 - 9.1. Information on basic physical and chemical properties (Relative density).</p> <p>9 - 9.1. Information on basic physical and chemical properties (Viscosity).</p> <p>9 - 9.1. Information on basic physical and chemical properties (Vapour density).</p> <p>9 - 9.1. Information on basic physical and chemical properties (Evaporation rate).</p> <p>9 - 9.1. Information on basic physical and chemical properties (Freezing Point).</p> <p>9 - 9.1. Information on basic physical and chemical properties (Fat Solubility).</p> <p>9 - 9.1. Information on basic physical and chemical properties (Solubility).</p> <p>10 - 10.4. Conditions to avoid.</p> <p>10 - 10.3. Possibility of hazardous reactions.</p> <p>10 - 10.6. Hazardous decomposition products.</p> <p>10 - 10.1. Reactivity.</p> <p>10 - 10.5. Incompatible materials.</p> <p>11 - Toxicological information.</p> <p>12 - 12.1. Toxicity.</p> <p>12 - 12.4. Mobility in soil.</p> <p>12 - 12.2. Persistence and degradability.</p> <p>12 - 12.5. Results of PBT and vPvB assessment.</p> <p>15 - Labelling.</p> <p>15 - Symbols.</p> <p>15 - Risk phrases.</p> <p>15 - Safety phrases.</p> <p>15 - 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.</p>

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**SUPERSEDES
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