

Safety Data Sheet

According to Regulation 1907/2006/EC, Article 31

IMPORTANT

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

1. IDENTIFICATION

1.1 Product Identifier

Product Name	PerfectAlloy Liquid
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1.2 Relevant identified uses of the substance of mixture and uses advised against

Product Use	(SU22) professional uses: Public domain (administration, education, entertainment, services, craftsmen); (SU20) Health services;
Restricted Use	(SU21) Consumer Uses: Private households (=general public = consumers);
Description	Dental Product

1.3 Supplier of the Safety Data Sheet

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
Website	www.perfectionplus.com
Telephone	0044 (0) 2380 866677
Email	Regulatory@perfectionplus.com
Email address of Competent Person	Regulatory@perfectionplus.com

1.4 Emergency telephone number


Emergency telephone number	0044 (0) 230 866 677 (8am – 5pm Monday to Friday)
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2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.1.2. Classification - EC 1272/2008	Acute Tox.2:H330 Rep.1B:H360D STOT RE 1:H372 Aquatic Acute 1:H400 Aquatic Chronic 1:H410
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2.2 Label Elements

Hazard Pictograms	
Signal Word	Danger
Hazard Statement	H330 – Fatal if inhaled H360D – May damage the unborn child H372 – Causes damage to the organs through prolonged or repeated exposure H400 – Very toxic to aquatic life H410 – Very toxic to aquatic life with long lasting effects.
Precautionary Statement: Prevention	P201 - Obtain special instructions before use. P273 - Avoid release to the environment. P281 - Use personal protective equipment as required. P403+P233 - Store in a well-ventilated place. Keep container tightly closed.
Precautionary Statement: Response	P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P310 - Immediately call a POISON CENTER/doctor.

2.3 Other hazards

Other hazards	PBT. vPvB. Not applicable.
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Further 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	Substance within a Community workplace exposure limit
Mercury	080-001-00-0	7439-97-6	231-106-7	25-50%

Additional information

Non-Gamma-2, spherical 40%, 44.5% or 70% silver alloy amalgam in self-activating capsule.

4. FIRST AID MEASURES

4.1 Description of first aid measures

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

Inhalation	No further relevant information available
Eye Contact	No further relevant information available
Skin contact	No further relevant information available
Ingestion	No further relevant information available

4.3 Indication of any immediate medical attention and special treatment needed

Antidote	DMPS
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General information

	Immediately remove any clothing soiled by the product.
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5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

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

	Inform respective authorities in case of seepage into water course or sewage system. Do not allow product to enter sewers/surface or ground water.
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6.3 Methods and material for containment and cleaning up

	Spillages or 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.
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6.4 Reference to other sections

	See section 13 for disposal information. See section 8 for exposure controls/personal protection. See section 7 for safe handling.
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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.
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7.2 Conditions for safe storage, including any incompatibilities

	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.
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7.3 Specific end use(S)

	No further relevant information available.
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8. EXPOSURE CONTROLS/PERSONAL PROTECTION


8.1 Control parameters

8.1.1 Biological Limit Values

Mercury CAS: 7439-97-6	
BMGV	20 $\mu\text{mol/mol creatine}$ Medium: urine Sampling time: random Parameter: mercury

Additional Information: The lists valid during the making were used as a basis.

8.2 Exposure controls

	 
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8.2.1 Appropriate engineering controls

	Usual hygienic measures for a 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.
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8.2.2 Individual protection measures

Eye/face protection	Tightly sealed goggles
Skin protection – Hand protection	The glove has to be impermeable and resistant to the product/the substance/the preparation. After use of gloves apply skin-cleaning agents and skin cosmetics. Glove material: 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. Natural rubber, NR Nitrile rubber, NDR Butyl rubber, BR Fluorocarbon rubber (Viton)

	Penetration time of glove: The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.
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

9. **PHYSICAL AND CHEMICAL PROPERTIES**

9.1. Information on basic physical and chemical properties

Form	Fluid	Vapour pressure at 20°C	0.00163 hPa.
Colour	Silver grey	Density at 20°C	13.54 g/cm ³
Odour	Odourless	Relative density	Not determined
Odour threshold	Not determined	Vapour density	Not applicable
pH	Not applicable	Evaporation rate	Not determined
Initial boiling point and boiling range	-356°C	Partition coefficient	No data available
Melting point/freezing point	-38.86°C	Flammability (solid gas)	Not determined
Flash point	Not applicable	Partition coefficient: n-octanol/water	Not determined
Auto-ignition temperature	Product is not self-igniting.	Solubility in/Miscibility with water	Insoluble. Not miscible or difficult to mix.
Explosive properties	Product does not present an explosion hazard.	Viscosity: Dynamic: Kinematic:	Not determined Not applicable
Explosion limits	Not determined		

9.2. Other information

No further relevant information available.

10. **STABILITY AND REACTIVITY**

10.1 Reactivity

	No further relevant information available.
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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
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10.4 Conditions to avoid

	No further relevant information available.
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10.5 Incompatible materials

	No further relevant information available.
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10.6 Hazardous decomposition products

	None under normal conditions of storage and use
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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.
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 of organs through prolonged or repeated exposure.
Aspiration hazard	Based on available data, the classification criteria are not met
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 a pregnant person.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic Toxicity

	No further relevant information available
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12.2 Persistence and degradability

	No further relevant information available
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12.3 Bio accumulative potential

	No further relevant information available
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12.4 Mobility in soil

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Ecotoxicological effects:

Remark: Very toxic for fish

12.5 Results of PBT and vPvB assessment

	Not applicable
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12.6 Other adverse effects

	No further relevant information available
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General Notes: Water hazard class 1 (German Regulation) (Assessment by list): extremely hazardous for water. Do not allow product to reach ground water, water course or sewer 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 to aquatic organisms.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

	Dispose of in compliance with all local and national regulations.
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General information

	<p>Recommendation: Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Taken to an approved landfill or a waste incineration plant, under conditions approved by the local authority. European Waste Catalogue - 18 01 10 Amalgam care from dental.</p> <p>Uncleaned packaging: Recommendation: Disposal must be made according to official regulations.</p>
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Disposal Methods

	Do not empty in to drains. For disposal within the EC, the appropriate code according to the European Waste Catalogue (EWC) should be used.
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Disposal of packaging

	Do NOT reuse empty containers. Empty containers can be sent for disposal or recycling.
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14. TRANSPORT INFORMATION

Hazard pictograms



14.1 UN number

ADR/RID/AND, IMDG, IATA	UN3506
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14.2 UN proper shipping name

	Void
ADR/RID/ADN	3506 MERCURY CONTAINED IN MANUFACTURED ARTICLES, ENVIRONMENTALLY HAZARDOUS
IMG	MERCURY CONTAINED IN MANUFACTURED ARTICLES, MARINE POLLUTANT
IATA	MERCURY CONTAINED IN MANUFACTURED ARTICLES

14.3 Transport hazard class(es)

	Class	Label
ADR/RID/AND	8 (CT3) Class substances	8 + 6.1
IMG	8 Class substances	8/6.1
IATA	8 Class substances	8 (6.1)

14.4 Packing group

ADR/RID/AND, IMDG, IATA	Void
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14.5 Environmental hazards

Marine pollutant:	Yes
Special marking (ADR/RID/ADN):	Symbol (fish and tree)

14.6 Special precautions for user

EMS Number	Warning: Corrosive substances. F-A, S-B
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14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code


	Not applicable
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Transport additional information:

ADR/RID/AND	
Limited quantities (LQ)	5kg
Excepted quantities (EQ)	Code: E0 Not permitted as Excepted Quantity
Transport category	3
Tunnel restriction code	E
IMDG	
Limited quantities (LQ)	5kg
Excepted quantities (EQ)	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

Regulations	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
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	<p>CAUTION: This product contains mercury</p> 
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15.2 Chemical Safety Assessment

	A Chemical Safety Assessment has not been carried out.
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16. OTHER INFORMATION

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.

• **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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 2: Acute toxicity – Category 2

Repr. 1B: Reproductive toxicity – Category 1B

STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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

Further information

This product is manufactured by AB Ardent, Generatorgatan 8, 195 60 Arlandastad, Sweden and the contained SDS information is supplied by them.

The information used in this SDS is believed to be correct however, the information is provided without any warranty, neither expressed nor implied, regarding its correctness.

The conditions or methods for handling, storage, lone use and/or in combination with other products and disposal are beyond our control.

For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product.

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