

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 Powder
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1.2 Relevant identified uses of the substance or 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

Classification - EC 1272/2008	The product is not classified according to the CLP regulation
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2.2 Label Elements

Hazard Pictograms	
Signal Word	
Hazard Statement	
Precautionary Statement: Prevention	
Precautionary Statement: Response	

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.	EINECS No.	Substance within a Community workplace exposure limit
Silver		7440-22-4	231-131-3	25-50%
Copper		7440-50-8	231-159-6	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	Move the exposed person to fresh air, consult doctor in case of complaints
Eye Contact	Mechanical effects only. Rinse open eye for several minutes under running water. Then consult a doctor.
Skin contact	Rinse with water. Generally, the product does not irritate the skin.
Ingestion	Rinse out mouth and then drink plenty of water.

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

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

General information

	If you feel unwell, seek medical advice (show the label where possible).
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5. FIRE FIGHTING MEASURES
5.1 Extinguishing media

	The product is not flammable
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5.2 Special hazards arising from the substance or mixture

	No further relevant information available
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5.3 Advice for firefighters

	Wear self-contained respiratory protective device. Cool endangered receptacles with water spray.
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6. ACCIDENTAL RELEASE MEASURES
6.1 Personal precautions, protective equipment and emergency procedures

	Not required
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6.2 Environmental precautions

	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

	Pick up mechanically.
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6.4 Reference to other sections

	See section 16 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. For use in dentistry only.
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7.2 Conditions for safe storage, including any incompatibilities

	Store only in closed original receptacles. Store in a well ventilated place.
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7.3 Specific end use(S)

	See section 1.2. Relevant identified uses of the substance or mixture and uses advised against for further information.
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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Exposure Limit Values

Silver CAS: 7440-22-4	WEL Long Term Value: 0.1 mg/m ³
Copper CAS: 7440-50-8	WEL Short Term Value: 2mg/m ³ dust and mists WEL Long Term Value: 0.2mg/m ³ fumes WEL long Term Value: 1mg/m ³ dust and mists

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.
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8.2.2 Individual protection measures

Eye/face protection	Not required
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. 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Form	Powder	Vapour pressure	Not applicable.
Colour	Grey	Vapour density	Not applicable.
Odour	Odourless	Relative density	Not determined
Odour threshold	Not determined	Flammability (solid, gas)	Not determined
pH	Not applicable	Partition coefficient	No data available
Melting point	Undetermined	Autoignition temperature	Product does not present an explosion hazard
Freezing point	Undetermined	Viscosity	No data available
Initial boiling point	Undetermined	Explosion limits	Not determined
Flash point	Not applicable	Partition coefficient: n-octanol/water	Not determined
Evaporation rate	Not applicable	Solubility in/Miscibility with water	Insoluble

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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11. TOXICOLOGICAL INFORMATION
11.1 Information on toxicological effects

Acute toxicity	Based on available data, the classification criteria are not met
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	Based on available data, the classification criteria are not met
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	Based on available data, the classification criteria are not met
STOT-single exposure	Based on available data, the classification criteria are not met
STOT-repeated exposure	Based on available data, the classification criteria are not met
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.

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

	No further relevant information available
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12.5 Results of PBT and vPvB assessment

	Not applicable
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12.6 Other adverse effects

	No data is available on this product.
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General Notes: Water hazard class 1 (German Regulation) (Self-assessment): Slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewer system.

13. DISPOSAL CONSIDERATIONS
13.1 Waste treatment methods

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

	18 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care). 18 01 wastes from natal care, diagnosis, treatment or prevention of disease in humans. 18 01 10 amalgam waste from dental care.
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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
14.1 UN number

	Void
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14.2 UN proper shipping name

	Void
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14.3 Transport hazard class(es)

	Void
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14.4 Packing group

	Void
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14.5 Environmental hazards

Marine pollutant:	No
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14.6 Special precautions for user

	Not applicable
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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: product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

UN Model Regulation: Void

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 · 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
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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

<p>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.</p> <p>· 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 · * Data compared to the previous version altered.</p>
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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.

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