

Safety Data Sheet

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

1.1 Product Identifier

Product Name	Gutta Percha Points
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1.2 Relevant identified uses of the substance of mixture and uses advised against

Product Use	(SU22) professional uses: (SU20) Health services;
Restricted Use	(SU21) Consumer Uses: Private households (=general public = consumers);
Description	Dental Product for professional use only

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 Aquatic Toxicity 1 Chronic Aquatic Toxicity 1
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2.2 Label Elements

Hazard Pictograms	
Signal Word	
Hazard Statement	Acute aquatic toxicity (Category 1) Chronic aquatic toxicity (Category 1) H400 - Very toxic to aquatic life H410 - Very Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
Precautionary Statement: Prevention	P273 – Avoid release to the environment
Precautionary Statement: Response	P391 – Collect spillage

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

3.2 Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	CONC. (%w/w)	Classification
Gutta Percha (Trabns-1.4,-polyisoprene)		9003-31-0			30	
Zinc Oxide		1314-13-2	215-222-5		40	H410 N, R50/53
Barium Sulphate		7727-43-7	231-784-4		28	
Calcium Carbonate		471-34-1	217-439-9		2	

4. FIRST AID MEASURES

4.1 Most important symptoms and effects, both acute and delayed

Inhalation	None expected for this product
Eye Contact	None expected for this product
Skin contact	None expected for this product
Ingestion	Ingestion of this material can cause mouth, throat, oesophageal and gastrointestinal tract irritation

4.2 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

	Use extinguishing media appropriate to the surrounding fire conditions.
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5.2 Special hazards arising from the substance or mixture

	Hazardous combustion products: Carbon Monoxide, carbon Dioxide, Hydrocarbons, and Zinc fumes.
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5.3 Advice for firefighters

	Evacuate all personnel, use protective equipment for firefighting. Use self-contained breathing apparatus when product is involved in fire.
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6. HANDLING AND STORAGE

6.1 Precautions for safe handling

	Handle and store with care. Give special attention to chemical materials that must be avoided. Follow all prevention measures in the SDS/Labels.
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6.2 Conditions for safe storage, including any incompatibilities

	Keep in a cool place. Keep containers tightly closed. Keep out of reach of children.
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6.3 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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7. EXPOSURE CONTROLS/PERSONAL PROTECTION

7.1 Exposure controls


7.1.1 Appropriate engineering controls

	Ensure adequate ventilation of the working area.
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7.1.2 Individual protection measures

Eye/face protection	Approved safety goggles.
Skin protection – Hand protection	Gloves.

8. PHYSICAL AND CHEMICAL PROPERTIES
8.1 Information on basic physical and chemical properties

Appearance	Solid tapered shaped points	Vapour pressure	N/a
Colour	White	Vapour density	N/a
Odour	Slight rubber smell	Relative density	2.5~2.65 g/cm ³
Odour threshold	Not applicable.	Flammability (solid, gas)	N/a
pH	N/a	Partition coefficient	N/a
Melting point	70°C	Autoignition temperature	N/a
Freezing point	N/a	Viscosity	N/a
Initial boiling point	N/a	Explosive properties	N/a
Flash point	N/a	Oxidising properties	N/a
Evaporation rate	N/a		

8.2 Other information

Conductivity	No data available
Surface tension	No data available
Gas group	No data available
Benzene content	No data available
Lead content	No data available
VOC (Volatile organic compounds)	No data available

9. STABILITY AND REACTIVITY
9.1 Reactivity

	Stable
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9.2 Chemical stability

	Stable when stored and handled under recommended conditions.
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9.3 Possibility of hazardous reactions

	None
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9.4 Conditions to avoid

	Direct sunlight
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9.5 Incompatible materials

	None
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9.6 Hazardous decomposition products

	Carbon Monoxide, Carbon Dioxide, Hydrocarbons and Zinc fumes.
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10. TOXICOLOGICAL INFORMATION
10.1 Information on toxicological effects

Acute toxicity	Device is biocompatible when used as directed by dental professionals per ISO 10993-1.
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11. ECOLOGICAL INFORMATION
11.1 Toxicity

Toxicity	Not determined
Aquatic toxicity (acute)	Not determined

11.2 Persistence and degradability

	Not determined
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11.3 Bio accumulative potential

	Not determined
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11.4 Mobility in soil

	Not determined
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11.5 Results of PBT and vPvB assessment

	Not determined
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11.6 Other adverse effects

	None known
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12. DISPOSAL CONSIDERATIONS
12.1 Waste treatment methods

	Dispose of in compliance with all local and national regulations.
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13. TRANSPORT INFORMATION
13.1 UN number

	Classification information on transportation of hazardous materials not available
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13.2 UN proper shipping name

	N/a
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13.3 Transport hazard class(es)

	N/a
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13.4 Packing group

	N/a
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13.5 Environmental hazards

Environmental hazards	No
Marine pollutant	N/a

13.6 Special precautions for user
ADR/RID

	N/a
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IMDG

	N/a
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IATA

	N/a
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13.7 Transportation in bulk according to Annex II of MARPOL 73/78 and the IBC Code

	N/a
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14. OTHER INFORMATION
Other information

Text of Hazard Statements in Section 3	H400 - Very toxic to aquatic life H410 - Very toxic to aquatic life with long lasting effects
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Further information

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.

This SDS is relevant for large quantities of product, the instructions for safe use of quantities typically used during a normal procedure is as referenced in the Instructions for Use.

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.

This SDS was prepared and is to be used only for this product. If the product is used as a component in or in combination with another product, this SDS information may not be applicable.