

Safety Data Sheet

According to Regulation (EU) 2015/830

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	Temporary Cement Filling Material
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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	Repr. 1A: H360Df; Aquatic Chronic 2: H411;
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2.2 Label Elements

Hazard Pictograms	
Signal Word	Danger
Hazard Statement	Repr. 1A: H360Df – May damage the unborn child. Suspected of damaging fertility. Aquatic Chronic 2: H411 – Toxic to aquatic life with long lasting effects.
Precautionary Statement: Prevention	P273 – Avoid release to the environment P280 – Wear protective gloves/protective clothing/eye protection/face protection.
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
Barium Sulphate		7727-43-7	231-784-4	01-2119491274-35	10-20%	
Tetraethylene Glycol Dimethyl Ether		143-24-8	205-594-7	01-2119958965-16	10-20%	Repr. 1A: H360Df;
Zinc Oxide	030-013-00-7	1314-13-2	215-222-5	01-2119463881-32	10-20%	Aquatic Acute 1: H400; Aquatic Chronic 1: H410;

4. **FIRST AID MEASURES**

4.1 **Description of first aid measures**

Inhalation	Move the exposed person to fresh air.
Eye Contact	Rinse immediately with plenty of water for 15 minutes holding the eyelids open.
Skin contact	Wash off immediately with plenty of soap and water. Remove contaminated clothing.
Ingestion	Do NOT induce vomiting.

4.2 **Most important symptoms and effects, both acute and delayed**

Inhalation	May cause irritation to mucous membranes.
Eye Contact	May cause irritation to eyes.
Skin contact	May cause irritation to skin.
Ingestion	Ingestion may cause nausea and vomiting.

4.3 **Indication of any immediate medical attention and special treatment needed**

Inhalation	Seek medical attention if irritation or symptoms persist.
Eye Contact	Seek medical attention if irritation or symptoms persist.
Skin contact	Seek medical attention if irritation or symptoms persist.
Ingestion	Seek medical attention if irritation or symptoms persist.

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**

	Burning produces irritating, toxic and obnoxious fumes.
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5.3 **Advice for firefighters**

	Wear suitable respiratory equipment when necessary.
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6. **ACCIDENTAL RELEASE MEASURES**

6.1 **Personal precautions, protective equipment and emergency procedures**

	Ensure adequate ventilation of the working area. Wear suitable protective equipment.
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6.2 **Environmental precautions**

	Do not allow product to enter drains. Prevent further spillage if safe.
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6.3 **Methods and material for containment and cleaning up**

	Transfer to suitable, labelled containers for disposal. Clean spillage area thoroughly with plenty of water.
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6.4 **Reference to other sections**

	See section 13 for disposal information. See section 8 for exposure controls/personal protection.
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7. **HANDLING AND STORAGE**

7.1 Precautions for safe handling

	Avoid contact with eyes and skin. Ensure adequate ventilation of the working area. Adopt best Manual Handling considerations when handling, carrying and dispensing.
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7.2 Conditions for safe storage, including any incompatibilities

	Keep in a cool, dry, well-ventilated area. Keep containers tightly closed. Store in original container.
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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

Barium Sulphate	WEL 8-hr limit ppm:	-	WEL 8-hr limit mg/m3:	-
	WEL 15 min limit ppm:	-	WEL 15 min limit mg/m3:	-
	WEL 8-hr limit mg/m3 total inhalable dust:	10	WEL 15 min limit mg/m3 total inhalable dust:	-
	WEL 8-hr limit mg/m3 total respirable dust:	4	WEL 15 min limit mg/m3 total respirable dust:	-

8.2 Exposure controls

8.2.1 Appropriate engineering controls

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

	Wear chemical protective clothing.
Eye/face protection	Approved safety goggles.
Skin protection – Hand protection	Chemical resistant gloves.
Respiratory protection	Wear suitable respiratory equipment when necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES
9.1. Information on basic physical and chemical properties

Appearance	Paste	Vapour pressure	Not applicable.
Colour	White/Pink	Vapour density	Not applicable.
Odour	Mild	Relative density	No data available
Odour threshold	Not applicable.	Fat solubility	No data available
pH	No data available	Partition coefficient	No data available
Melting point	No data available	Autoignition temperature	No data available
Freezing point	No data available	Viscosity	No data available
Initial boiling point	No data available	Explosive properties	No data available
Flash point	No data available	Oxidising properties	No data available
Evaporation rate	No data available	Solubility	Insoluble in water
Flammability (solid, gas)	No data available		

9.2. Other information

Conductivity	No data available
Surface tension	No data available
Gas group	Not applicable.
Benzene content	No data available

Lead content	No data available
VOC (Volatile organic compounds)	No data available

10. STABILITY AND REACTIVITY

10.1 Reactivity

	No data available.
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10.2 Chemical stability

	Stable under normal conditions.
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10.3 Possibility of hazardous reactions

	No data is available on this product.
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10.4 Conditions to avoid

	Heat. Moisture.
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10.5 Incompatible materials

	Strong acids. Strong bases.
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10.6 Hazardous decomposition products

	No data available.
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11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity	No data available.
Skin corrosion/irritation	May cause irritation to skin.
Serious eye damage/irritation	May cause irritation to eyes.
Respiratory or skin sensitisation	May cause irritation to mucous membranes.
Germ cell mutagenicity	No mutagenic effects reported.
Carcinogenicity	No carcinogenic effects reported.
Reproductive toxicity	May cause harm to the unborn child. Suspected of damaging fertility.
STOT-single exposure	No data available.
STOT-repeated exposure	No data available.
Aspiration hazard	Irritating to respiratory system.
Repeated or prolonged exposure	Irritating to skin.

11.1.4 Toxicological Information

Barium sulphate	ORAL Rat LD50: >5000 mg/kg bw
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12. ECOLOGICAL INFORMATION

12.2 Persistence and degradability

	No data is available on this product.
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12.3 Bio accumulative potential

	No data is available on this product.
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Partition coefficient

	Temporary Filling Material No data available
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12.4 Mobility in soil

	No data is available on this product.
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12.5 Results of PBT and vPvB assessment

	No data is available on this product.
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12.6 Other adverse effects

	Very toxic to aquatic life with long lasting effects.
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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 06 chemicals consisting of or containing dangerous substances.
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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 canisters. Empty containers can be sent for disposal or recycling.
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14. TRANSPORT INFORMATION

Hazard pictograms


14.1 UN number

	UN3077
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14.2 UN proper shipping name

	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID N.O.S.
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14.3 Transport hazard class(es)

ADR/RID	9
Subsidiary risk	-
IMDG	9
Subsidiary risk	-
IATA	9
Subsidiary risk	-

14.4 Packing group

Packing Group	III
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14.5 Environmental hazards

Environmental hazards	Yes
Marine pollutant	Yes

ADR/RID

Hazard ID	90
Tunnel category	(E)

IMDG

EmS Code	F-A S-F
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IATA

Packing Instruction (Cargo)	956
Maximum quantity	400 kg
Packing instruction (Passenger)	956
Maximum quantity	400kg

15. REGULATORY INFORMATION
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulations	COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and
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	Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.
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15.2 Chemical Safety Assessment

	No data available.
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16. OTHER INFORMATION

Other information

Revision	This document differs from the previous version in the following areas: 2-Hazard pictograms.
Text of Hazard Statements in Section 3	Repr. 1A: H360Df – May damage the unborn child. Suspected of damaging fertility. Aquatic Acute 1: H400 – Very toxic to aquatic life. Aquatic Chronic 1: H410 – Very toxic to aquatic life with long lasting effects.

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.