

Safety Data Sheet

According to Regulation (EU) 2015/830

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	RestorePLUS FLOW
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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);
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	Skin Sens. 1: H317; Skin Irrit. 2: H315; Eye Irrit. 2: H319; Repr. 1B: H360FD; Aquatic Chronic 3: H412
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2.2 Label Elements

Hazard Pictograms	
Signal Word	Danger
Hazard Statement	Skins Irrit. 2: H315 – Causes skin irritation. Skin Sens. 1: H317 – May cause an allergic reaction Eye Irrit. 2: H319 – Causes serious eye irritation Repr. 1B: H360FD – May damage fertility. May damage the unborn child. Aquatic Chronic 3: H412 – Harmful to aquatic life with long lasting effects
Precautionary Statement: Prevention	P273 – Avoid release to the environment
Precautionary Statement: Response	P302+P352 – IF ON SKIN (or hair): Wash with plenty of water/. P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P333+P313 – If skin irritation or rash occurs; Get medical advice/attention. P337+P313 – If eye irritation persists: Get medical advice/attention.

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
Glass Powder		65997-18-4	266-047-6		40-50%	
Bisphenol A glycerolate dimethacrylate		1565-94-2	216-367-7		20-30%	Skin Irrit. 2: H315; Skin Sens. 1: H317; Eye Irrit. 2: H319;
Aluminium Oxide (aluminium oxides)		1334-28-1	215-691-6		1-10%	
Polyethyleneglycol Dimethacrylate		25852-47-5			1-10%	Skin Irrit. 2: H315; Eye Irrit. 2: H319; STOT SE 3: H335
Triethylene Glycol Dimethacrylate		106-16-0	203-652-6	01-2119969287-21	1-10%	Skin Sens. 1: H317;
3-Methacryloxypropyltrimethoxysilane		2530-85-0			1-10%	
Dibutyltin dilaurate		77-58-7			0.5-1%	Skin Corr. 1B: H314; Eye Dam. 1: H318; Muta.2: H341; Repr. 1B: H360FD; STOT RE 1: H372; 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	Causes serious eye irritation.
Skin contact	Causes skin irritation. May cause allergic reactions in susceptible people.
Ingestion	May cause irritation to mucous membranes.

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

	Sweep 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

Aluminium oxide (Aluminium oxides)	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

	
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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	No data available
Colour		Vapour density	No data available
Odour	Slight	Relative density	No data available
Odour threshold	No data available	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	No data available
Flammability (solid, gas)	No data available		

9.2. 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

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. Direct sunlight.
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10.5 Incompatible materials

	Reducing agents. Strong acids. Strong bases. Strong oxidising agents.
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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. May cause allergic reactions in susceptible people.
Serious eye damage/irritation	Causes severe eye irritation.
Respiratory or skin sensitisation	May cause irritation to mucous membranes.
Germ cell mutagenicity	No mutagenic effects reported.
Carcinogenicity	No carcinogenic effects reported.
Reproductive toxicity	No teratogenic effects reported.
STOS-single exposure	No data available.
STOT-repeated exposure	No data available.
Aspiration hazard	May cause irritation to mucous membranes.
Repeated or prolonged exposure	No data available.

11.1.4 Toxicological Information

Aluminium Oxide	ORAL Rat LD50: >10000 mg/kg	Inhalation Rat LC50/4 h: >2.6 mg/l
Dibutyltin dilaurate	ORAL Rat LD50: 2071 mg/kg	Dermal Rabbit LD50: 2000 mg/kg

Triethylene Glycol Dimethacrylate	ORAL Rat LD50: 10837 mg/kg	
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12. ECOLOGICAL INFORMATION

12.1 Toxicity

Dibutyltin dilaurate	Daphnia EC50/48h: 1.7000 mg/l	Algae IC50/72h: 1.0000 mg/l
Triethylene Glycol Dimethacrylate	Fish LC50/96h: 16.4000 mg/l	

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

	RestorePLUS FLOW 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

	No data is available on this product.
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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

14.1 UN number

	This product is not classified as dangerous for carriage.
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14.2 UN proper shipping name

	This product is not classified as dangerous for carriage.
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14.3 Transport hazard class(es)

	This product is not classified as dangerous for carriage.
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14.4 Packing group

	This product is not classified as dangerous for carriage.
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14.5 Environmental hazards

	This product is not classified as dangerous for carriage.
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14.6 Special precautions for user

	This product is not classified as dangerous for carriage.
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14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

	This product is not classified as dangerous for carriage.
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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 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

Text of Hazard Statements in Section 3	Skin Irrit. 2: H315- Causes skin irritation. Skin Sens. 1: H317 – May cause an allergic reaction. Eye Irrit. 2: H319 – Causes serious eye irritation. STOT SE 3: H335 – May cause respiratory irritation. Skin Corr. 1B: H314 – Causes severe skin burns and eye damage. Eye Dam. 1: H318 – Causes serious eye damage. Muta. 2: H341 – Suspected of causing genetic defects. Repr. 1B: H360FD – May damage fertility. 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.
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Further information

This product is manufactured by Advanced Healthcare Limited, Units 2-4 Leavers Estate, Chiddingstone causeway, Tonbridge, Kent, UK, TN11 8JU 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.

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.