

SAFETY DATA SHEET

according to Regulation (EU) 2015/830

Prophy Paste

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name	Prophy Paste (0331/ 0402)
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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;
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Restricted use	[SU21] Consumer uses: Private households (= general public = consumers);
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Description	Dental product.
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1.3. Details of the supplier of the safety data sheet

Company Address	Manufacturer: Premium Plus International Ltd. 1001, Yuen Long Trading Centre No.33, Wang Yip Street West Yuen Long, N.T. Hong Kong	Authorized Representative: Premium Plus UK Ltd. 2, Knighton Heath Industrial Estate 847 Ringwood Road, Bournemouth Dorset BH11 8NE U.K.
	Web Telephone Email	www.premiumplushk.com 852-2761-3211 mailbox@premiumplusuk.com

1.4. Emergency telephone number

Emergency telephone number	44-1202-611-011 (8:30 am - 5:00 pm Mon - Fri)
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SECTION 2: Hazards identification

2.2. Label elements

Hazard Statement	No Significant Hazard
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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.
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SECTION 3: Composition/information on ingredients

3.2. Mixtures

Prophy Paste

Revision 2

Revision date 2018-12-17

3.2. Mixtures

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification
Glycerine (Glycerol, mist)		56-81-5	200-289-5		10 - 20%	
Titanium Dioxide		13463-67-7	236-675-5	01-2119489379-17	1 - 10%	
Sodium Lauryl Sulfate		151-21-3	205-788-1	01-2119489461-32	0 - 0.5%	Flam. Sol. 2: H228; Acute Tox. 4: H302+H332; Skin Irrit. 2: H315; Eye Dam. 1: H318; STOT SE 3: H335; Aquatic Chronic 3: H412;

SECTION 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	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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SECTION 5: Firefighting 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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SECTION 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

Prophy Paste

Revision 2

Revision date 2018-12-17

6.4. Reference to other sections

See Section 13 for disposal information. See Section 8 for exposure controls/personal protection.

SECTION 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.

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.

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.



SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. Exposure Limit Values

Glycerine (Glycerol, mist)	WEL 8-hr limit ppm: -	WEL 8-hr limit mg/m3: 10
	WEL 15 min limit ppm: -	WEL 15 min limit mg/m3: -
	WEL 8-hr limit mg/m3 total inhalable dust: -	WEL 15 min limit mg/m3 total inhalable dust: -
	WEL 8-hr limit mg/m3 total respirable dust: -	WEL 15 min limit mg/m3 total respirable dust: -
Titanium Dioxide	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 8.2.2. Individual protection measures Eye / face protection Skin protection - Handprotection Respiratory protection	 
	Ensure adequate ventilation of the working area.
	Wear chemical protective clothing.
	Approved safety goggles.
	Chemical resistant gloves.
Wear suitable respiratory equipment when necessary.	

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Prophy Paste

Revision 2

Revision date 2018-12-17

9.1. Information on basic physical and chemical properties

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

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

SECTION 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

	No data available.
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10.6. Hazardous decomposition products

	No data available.
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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	No data available.
Skin corrosion/irritation	May cause irritation to skin.

Prophy Paste

Revision 2

Revision date 2018-12-17

11.1. Information on toxicological effects

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	No teratogenic effects reported.
STOT-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

Glycerine	Oral Rat LD50: 12600 mg/kg
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SECTION 12: Ecological information

12.1. Toxicity

Glycerine	Daphnia EC50/48h: 10000.0000 mg/l	Algae IC50/72h: 2900.0000 mg/l
	Fish LC50/96h: 5000.0000 mg/l	

12.2. Persistence and degradability

	No data is available on this product.
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12.3. Bioaccumulative potential

	No data is available on this product.
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Partition coefficient

	Prophy Paste 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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SECTION 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 into 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

Prophy Paste

Revision 2

Revision date 2018-12-17

Disposal of packaging

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

SECTION 14: Transport information

14.1. UN number

The product is not classified as dangerous for carriage.

14.2. UN proper shipping name

The product is not classified as dangerous for carriage.

14.3. Transport hazard class(es)

The product is not classified as dangerous for carriage.

14.4. Packing group

The product is not classified as dangerous for carriage.

14.5. Environmental hazards

The product is not classified as dangerous for carriage.

14.6. Special precautions for user

The product is not classified as dangerous for carriage.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

The product is not classified as dangerous for carriage.

SECTION 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.

15.2. Chemical safety assessment

No data available.

SECTION 16: Other information

Other information

Revision

This document differs from the previous version in the following areas:.

- 1 - Description.
- 1 - Product Use.
- 1 - Restricted use.
- 2 - Other hazards.
- 2 - Precautionary Statement: Disposal.
- 6 - 6.4. Reference to other sections.
- 7 - 7.3. Specific end use(s).
- 9 - 9.1. Information on basic physical and chemical properties (Colour).
- 9 - 9.1. Information on basic physical and chemical properties (Vapour pressure).
- 9 - 9.1. Information on basic physical and chemical properties (Vapour density).
- 9 - 9.1. Information on basic physical and chemical properties (Odour threshold).

Prophy Paste

Revision 2

Revision date 2018-12-17

Other information

Text of Hazard Statements in Section 3	9 - 9.2. Other information (Gas group). 11 - Repeated or prolonged exposure. 11 - Germ cell mutagenicity. 11 - Carcinogenicity. 11 - Reproductive toxicity. 11 - STOT-single exposure. 11 - STOT-repeated exposure. 11 - Aspiration hazard. 12 - 12.1. Toxicity. Flam. Sol. 2: H228 - Flammable solid. Acute Tox. 4: H302+H332 - Harmful if swallowed or if inhaled Skin Irrit. 2: H315 - Causes skin irritation. Eye Dam. 1: H318 - Causes serious eye damage. STOT SE 3: H335 - May cause respiratory irritation. Aquatic Chronic 3: H412 - Harmful to aquatic life with long lasting effects.
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Further information

	The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication however no guarantee is made to its accuracy. This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process.
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