

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	Prophy Paste Orange
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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	Regulatory@perfectionplus.com
Competent Person	

1.4 Emergency telephone number

Emergency telephone	0044 (0) 230 866 677
number	(8am – 5pm Monday to Friday)

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.1.2 Classification – EC 1272/2008

	Aquatic Chronic 3: H412;
2.2 <u>Label Elements</u>	
Hazard Statement	Aquatic Chronic 3: H12 – Harmful to aquatic life with long lasting effects.
Precautionary Statement:	P273 – Avoid release to the environment.
Prevention	
2.3 Other hazards	
Other hazards	PBT, vPvB. Not applicable.

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
Orange Oil Sicilian		8028-48-6	232-433-8	01-2119493353-35	0.5-1%	Flam. Liq. 3: H226; Asp. Tox. 1: H304; Skin Irrit. 2: H315; Skin Sens. 1: H317; Aquatic Acute 1: H400; Aquatic Chronic 1: H410;
Sodium dodecyl Sulphate		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;

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).

5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

Use extinguishing media appropriate to the surrounding fire conditions.

5.2 Special hazards arising from the substance or mixture

Burning produces irritating, toxic and obnoxious fumes.

5.3 Advice for firefighters

Wear suitable respiratory equipment when necessary.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation of the working are. Wear suitable protective equipment.

6.2 Environmental precautions

Do not allow product to enter drains. Prevent further spillage if safe.

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.

6.4 Reference to other sections

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

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.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION



8.1 Control parameters

8.1.1 Exposure Limit Values

Calcium carbonate WEL 8-hr limit ppm: WEL 15 min limit ppm: WEL 8-hr limit mg/m3 total inhalable dust: WEL 8-hr limit mg/m3 total respirable dust: Calcium carbonate (Limestone) WEL 15 min limit mg/m3 total inhalable dust: WEL 8-hr limit ppm: WEL 8-hr limit ppm: WEL 8-hr limit ppm: WEL 8-hr limit ppm: WEL 15 min limit mg/m3 total inhalable dust: WEL 8-hr limit mg/m3 total inhalable dust: WEL 8-hr limit mg/m3 total respirable dust: WEL 8-hr limit mg/m3 total inhalable dust: WEL 8-hr limit mg/m3 total respirable dust: WEL 8-hr limit mg/m3 total respirable dust: WEL 8-hr limit ppm: WEL 15 min limit mg/m3 total respirable dust: WEL 15 min limit mg/m3 total respirable dust: WEL 8-hr limit ppm: WEL 15 min limit mg/m3: WEL 15 min limit mg/m3 total
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WEL 8-hr limit mg/m3 total 10 WEL 15 min limit mg/m3 total -
inhalable dust: inhalable dust:
WEL 8-hr limit mg/m3 total 4 WEL 15 min limit mg/m3 total -
respirable dust: respirable dust:
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 - WEL 15 min limit mg/m3 total -
inhalable dust: inhalable dust:
WEL 8-hr limit mg/m3 total - WEL 15 min limit mg/m3 total -
respirable dust: respirable dust:

8.2 Exposure controls





8.2.1 Appropriate engineering controls

Ensure adequate ventilation of the working area.

8.2.2 Individual protection measures

Wear chemical protective clothing.
Approved safety goggles.
Chemical resistant gloves.
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.
Odour	Characteristic	Vapour density	Not applicable.
Odour threshold	Not applicable.	Relative density	No data available
рН	No data available	Fat solubility	No data available
Melting point	No data available	Partition coefficient	No data available
Freezing point	No data available	Autoignition temperature	No data available
Initial boiling point	No data available	Viscosity	No data available
Flash point	No data available	Explosive properties	No data available



Evaporation rate	No data available	Oxidising properties	No data available
Flammability (solid, gas)	No data available	Solubility	Slightly soluble in
			water

9.2. Other information

Conductivity		No data available
Su	urface tension	No data available
Gas group		Not applicable.

10. STABILITY AND REACTIVITY

10.1 Reactivity

	No data available.
10.2 Chemical stability	
	Stable under normal conditions.

10.3 Possibility of hazardous reactions

No data is available on this product.

10.4 Conditions to avoid

Heat. Moisture.

10.5 Incompatible materials

No data available.

10.6 Hazardous decomposition products

No data available.

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 of 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

Calcium carbonate	Oral Rat LD50: 5000 mg/kg
Glycerine	Oral Rat LD50 : 12600 mg/kg

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Calcium carbonate	Daphnia EC50/48h: 1.0000 mg/l	Algae IC50/72h: 72.0000 mg/l
	Fish LC50/96h: 10.0000 mg/l	
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.
12.3 Bio accu	mulative potential

12.3 Bio accumulative potentia

No data is available on this product.



		Prophy Paste Orange No data available
12.4 Mobility in soil		
	No data is available on this product.	
12.5	12.5 Results of PBT and vPvB assessment	
	No data is available on this product.	
12.6	12.6 Other adverse effects	
		No data is available on this product.

13. <u>DISPOSAL CONSIDERATIONS</u>

13.1 Waste treatment methods

Dispose of in compliance with all local and national regulations.

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.

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.

Disposal of packaging

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

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.

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulations	COMMISION 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.

16. OTHER INFORMATION

Other information

Revision	This document differs from the previous version in the following areas:. 12-12.1 Toxicity.
Text of Hazard Statements in Section 3	Flam. Liq. 3: H226 - Flammable liquid and vapour. Asp. Tox. 1: H304 – may be fatal if swallowed and enters airways. Skin Irrit. 2: H315 - Causes skin irritation. Skin Sens. 1: H317 - May cause an allergic skin reaction. Aquatic Acute 1: H400 – Very toxic to aquatic life. Aquatic Chronic 1: H410 – Very toxic to aquatic life with long lasting effects. Flam. Sol. 2: H228 – Flammable solid. Acute Tox. 4: H302+H332 – Harmful if swallowed or if inhaled 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.

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.