

# 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 RootPLUS Base Paste			
I.2 <u>Relevant identified uses of the substance of mixture and uses advised against</u>			
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	1.4 <u>Emergency telephone number</u>		
Emergency telephone	0044 (0) 230 866 677		
number	(8am – 5pm Monday to Friday)		

## 2. HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance or mixture

Aquatic Chronic 1: H410;
Warning
Aquatic Chronic 1: H410 – Very Toxic to aquatic life with long lasting effects.
P273 – Avoid release to the environment.
P391 – Collect spillage.
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
Zinc Oxide	030-013-00-7	1314-13-2	215-222-5	01-2119463881-32		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 or		
Skin contact	Wash off immediately with plenty of soap and water. Remove contaminated clothing.	
Ingestion	Do NOT induce vomiting.	
4.2 Most imp	ortant 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	in contact Seek medical attention if irritation or symptoms persist.	
Ingestion	Seek medical attention if irritation or symptoms persist.	
General inform	ation	
	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	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				
	Avoid raising dust. Ensure adequate ventilation of the working area. 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 Condition	s for safe storage, including any incompatibilities

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. <u>EXPOSURE CONTROLS/PERSONAL PROTECTION</u>

### 8.1 Control parameters

### 8.1.1 Exposure Limit Values

OTT EXPOSUIC EITHE VALUES				
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	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:	

DNE: Derived no-effect level.

## **Exposure Pattern-Workers**

Zinc oxide	Long term – inhalation – Systemic effects	5 mg/m <sup>3</sup>
	Long term – dermal – Systemic effects	87mg/kg

### **Exposure Pattern-General Population**

Zinc oxide	Long term – inhalation – Systemic effects	2.5 mg/m <sup>3</sup>			
	Long term – dermal – Systemic effects	87 bw/day			
	Long term – oral – Systemic effects	0.83 bw/day			

## 8.2 Exposure controls



8.2.1 Appropriate engineering controls				
	Ensure adequate ventilation of the working area.			
8.2.2 Indiv	8.2.2 Individual protection measures			
	Wear chemical protective clothing.			
Eye/face protection		Approved safety goggles.		
Skin protection –		Chemical resistant gloves.		
Hand protection	on			
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	Orange	Vapour density	Not applicable.
Odour	Phenolic	Relative density	No data available
Odour threshold	Not applicable.	Fat solubility	No data available
рН	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		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	Reactivit	y .
		No data available.
10.2	Chemica	l stability
		Stable under normal conditions.
10.3	Possibilit	y of hazardous reactions
		No data is available on this product.
10.4	Conditio	ns to avoid
		Heat. Moisture.
10.5	Incompa	tible materials
		Strong acids. Strong bases.
10.6	Hazardo	us 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	May cause irritation to eyes.
damage/irritation	
Respiratory of skin	May cause irritation to mucous membranes.
sensitisation	
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	Irritating to respiratory system.
Repeated or prolonged	Irritating to skin.
exposure	

### 11.1.4 Toxicological Information

Titanium dioxide	ORAL Rat LD50: 5000 mg/kg bw	
Zinc oxide	Dermal Rat LD50: 2000 mg/kg	Oral Rat LD50: 5000mg/kg

## 12. ECOLOGICAL INFORMATION

## 12.1 Toxicity

Titanium dioxide	Daphnia EC50/48h: 100.0000 mg/l	Algae IC50/72h: 61.0000 mg/l
	Fish LC50/96h: 1000.0000 mg/l	
Zinc oxide	Daphnia EC50/48h: 1.0000 mg/l	Algae IC50/72h: 0.1700 mg/l
	Rainbow trout LC50/96h: 330-780 mg/l	Bluegill sunfish LC50/96h: 320 mg/l
42.2 Densistence and de su	1.1.99	

## 12.2 Persistence and degradability

No data is available on this product.

## **12.3** Bio accumulative potential



	No data is available on this product.		
artition coeff	icient		
	RootPLUS Base Paste No	o data available	Zinc Oxide No data available
	Titanium dioxide	No data available	
12.4 Mobility	y in soil		
	No data is available on this proc	duct.	
12.5 Results	of PBT and vPvB assessment		
	No data is available on this product.		
12.6 Other a	dverse effects		
	Toxic to aquatic life with long la	asting effects.	
	1	asting effects.	

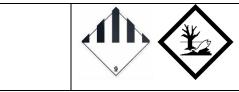
#### 13. DISPOSAL CONSIDERATIONS

### **13.1** Waste treatment methods

	Dispose of in compliance with all local and national regulations.
General	information
Disposal	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. Methods
•	Do not empty into 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

## Hazard pictograms



### 14.1 UN number

U	N3077	
14.2 UN proper s	shipping	g name
E	VVIRON	MENTALLY HAZARDOUS SUBSTANCE, SOLID N.O.S.
14.3 Transport h	azard c	lass(es)
ADR/RID	9	
Subsidiary risk	-	
IMDG	9	
Subsidiary risk	-	
IATA	9	
Subsidiary risk	-	
14.4 Packing gro	up	
Packing Group	Ш	
14.5 Environmen	ntal haz	ards
Environmental ha	zards	Yes
Marine pollutant		Yes
ADR/RID		
Hazard ID	90	
Tunnel category	(E)	
IMDG		



EmS Code	F-A S-F	
ΙΑΤΑ		
Packing Instructio	n (Cargo)	956
Maximum quantit	Σ <b>γ</b>	400 kg
Packing instructio	n (Passenger)	956
Maximum quantity		400kg

## 15. <u>REGULATORY INFORMATION</u>

### 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.

## 15.2 Chemical Safety Assessment

No data available.

### 16. OTHER INFORMATION

#### **Other information**

Text of Hazard Statements in	Aquatic Acute 1: H400 – Very toxic to aquatic life
Section 3	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.