

## 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	Zinc Oxide Eugenol Filling Material Powder
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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	Eye Irrit. 2: H319; Aquatic Chronic 1: H410;
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##### **2.2 Label Elements**

Hazard Pictograms	
Signal Word	Warning
Hazard Statement	Eye Irrit. 2: H319 – Causes serious eye irritation. Aquatic Chronic 1: H410 – Very toxic to aquatic life with long lasting effects.
Precautionary Statement: Prevention	P273- Avoid release to the environment.
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
Zinc Oxide	030-013-00-7	1314-13-2	215-222-5	01-2119463881-32		Aquatic Acute 1: H400; Aquatic Chronic 1: H410;
Polymethyl methacrylate		9011-14-7				Eye Irrit. 2: H319;
Zinc Acetate		5970-45-6	209-170-2			Acute Tox. 4: H302; Eye Dam. 1: H318; 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 eyes.
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

	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**

**DNEL: 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	87 mg/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.
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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	Powder	Vapour pressure	Not applicable.
Colour	White/Off white	Vapour density	Not applicable.
Odour	Odourless	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	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 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 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	Irritating to respiratory system.
Repeated or prolonged exposure	Irritating to skin.

#### 11.1.4 Toxicological Information

Zinc Acetate	<b>ORAL Rat LD50: 794 mg/kg</b>	
Zinc oxide	<b>Dermal Rat LD50: 2000 mg/kg</b>	<b>Oral Rabbit LD50: 5000mg/kg</b>

## 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity

Zinc Acetate	<b>Algae IC50/72h: 1.700 mg/l</b>	<b>Fish LC50/96h: 0.5500 mg/l</b>
Zinc oxide	<b>Daphnia EC50/48h: 1.0000 mg/l</b> <b>Rainbow trout LC50/96h: 330-780 mg/l</b>	<b>Algae IC50/72h: 0.1700 mg/l</b> <b>Bluegill sunfish LC50/96h: 320 mg/l</b>

### 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

	<b>Zinc Oxide Cement Powder</b> No data available	<b>Zinc oxide</b> 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**

	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**

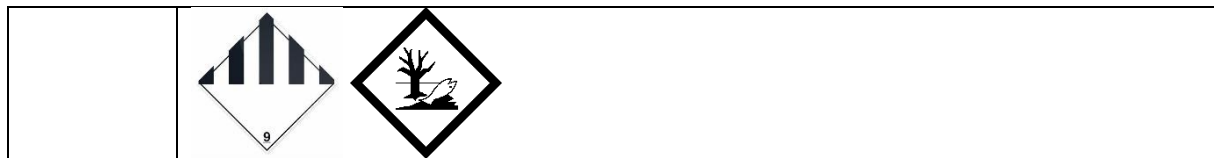
	Do not empty in to drains. For disposal within the EC, the appropriate code according to the European Waste Catalogue (EWC) should be used.
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**Disposal of packaging**

	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	400 kg
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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

Revision	This document differs from the previous version in the following areas: 2 – 2.1.2. Classification – EC 1272/2008. 2 - Hazard pictograms.
Text of Hazard Statements in Section 3	Aquatic Acute 1: H400 – Very toxic to aquatic life. Aquatic Chronic 1: H410 – Very toxic to aquatic life with long lasting effects. Eye Irrit. 2: H319 – Causes serious eye irritation. Acute Tox. 4: H302 – Harmful if swallowed. Eye Dam. 1: H318 – Causes serious eye damage.

### 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.