

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 22 June 2009
 Document Number: 11430MS
 Date Revised: 24 June 2016
 Revision Number: 4


1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	U/P Root Canal Powder
Chemical Name/Classification:	Mixture
Product Identifier (Part/Item Number):	11430(1/2 oz), 11431(2 oz), 11432(8 oz), 11427 (30 Capsules), 11428(100 Capsules), 11429 (500 Capsules), 11611 (15 Capsules), 11615
U.N. Number:	UN3077 (International) None (North America)
U.N. Dangerous Goods Classification:	9, PGIII (International) None (North America) (Zinc oxide)
Recommended Use:	Preparation of cement restorations
Restrictions on Use:	For professional use only
Manufacturer/Supplier Name:	Sultan Healthcare
Manufacturer/Supplier Address:	1301 Smile Way York, PA 17404
Manufacturer/Supplier Telephone Number:	1-201-871-1232 or 800-637-8582 (Product Information)
Emergency Contact Telephone Number:	800-535-5053 (INFOTRAC) 1-352-323-3500 (Outside the United States – Call Collect)
Email address:	customer.service@sultanhc.com

2. HAZARD(s) IDENTIFICATION

EU Classification (1999/45/EC as amended): Dangerous for the Environment (N) R50/53

EU Labeling:

 <p style="text-align: center;">Dangerous for the Environment</p>	<p>R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.</p> <p>S35 This material and its container must be disposed of in a safe way.</p> <p>S61 Avoid release to the environment. Refer to special instructions / Safety data sheets.</p>
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US Hazard Classification: Hazardous

3. COMPOSITION AND INFORMATION ON INGREDIENTS





Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification	WT %
Zinc Oxide	1314-13-2 / 215-222-5	oxozinc	N R50/53 Aquatic Acute Category 1 (H400) Aquatic Chronic Category 1 (H410)	40-50
Hydrogenated Rosin	65997-06-0 / 266-041-3		Not classified as dangerous	20-30
Bismuth Subcarbonate	5892-10-4 / 227-567-9	Bis(oxobismutha nyl) carbonate	Not classified as dangerous	10-20
Barium Sulfate	7727-43-7 / 231-784-4	barium(2+) sulfate	Not classified as dangerous	10-20

4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	Flush eyes with water, holding the eyelids apart. Get medical attention if irritation persists.
Skin	Wash with soap and water. Get medical attention if irritation develops.
Inhalation	None needed under normal use conditions. If irritation develops, remove to fresh air and get medical attention.
Ingestion	Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious or drowsy person. Get medical attention.
Most important symptoms of exposure	Dust may cause eye and skin irritation. Inhalation of fumes may cause metal fume fever with symptoms including coughing, fever, chills, headache, tightness of the chest, and nausea. Swallowing large amounts may cause gastrointestinal irritation, nausea and damage to the kidneys, liver, blood and spleen. .
Other	None known.
Note to Physicians (Treatment, Testing, and Monitoring): Treatment of overexposure should be directed at the control of symptoms and clinical conditions.	

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media:	Use media appropriate for the surrounding fire.
Fire Fighting Procedures:	Cool fire exposed containers with water.
Specific Hazards Arising from the Chemical:	Combustion may produce oxides of carbon, sulfur and barium and zinc oxide fumes.
Precautions for Fire Fighters:	Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.



Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Wear eye and skin protection.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and Materials for Containment and Clean-up: Collect with a damp towel and place in appropriate containers for disposal. Avoid generating dust.

Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

7. HANDLING AND STORAGE

Precautions for Safe Handling: Avoid contact with the eyes, skin and clothing. Use with adequate ventilation. Avoid breathing dust. Wash thoroughly after handling. Keep containers closed when not in use.

Conditions for Safe Storage: Store in a cool dry well ventilated place. Keep out of direct sunlight.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

Zinc Oxide	United States	5 mg/m ³ TWA OSHA PEL (respirable) 2 mg/m ² TWA ACGIH TLV (respirable), 10 mg/m ³ STEL (respirable)
	Germany	0.1 mg/m ³ TWA DFG MAK (respirable) 2 mg/m ³ TWA (inhalable)
	United Kingdom	None Established
	France	5 mg/m ³ TWA INRS VME
	Spain	10 mg/m ³ TWA VLA-ED (dust)
	Italy	None Established
	European Union	None Established
Hydrogenated Rosin	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Bismuth Subcarbonate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Barium Sulfate	United States	5 mg/m ³ TWA OSHA PEL (respirable fraction); 15 mg/m ³ TWA OSHA PEL (total dust) 10 mg/m ³ TWA ACGIH TLV
	Germany	1.5 mg/m ³ TWA DFG MAK (respirable) 4 mg/m ³ TWA DFG MAK (inhalable)
	United Kingdom	4 mg/m ³ TWA (respirable); 10 mg/m ³ TWA (inhalable)
	France	None Established
	Spain	10 mg/m ³ TWA (inhalable)
	Italy	None Established
	European Union	None Established

Biological Exposure Limits: None Established

Appropriate Engineering Controls: No special controls required.

Individual Protection Measures (PPE)



Specific Eye/face Protection: Chemical safety goggles recommended if eye contact is possible.

Specific Skin Protection: Wear impervious gloves such as rubber to avoid prolonged contact. Recommended glove: Rubber Consult glove supplier for thickness and breakthrough times.

Specific Respiratory Protection: None required under normal use conditions.

Specific Thermal Hazards: Not applicable

Recommended Personal Protective Equipment:

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

Environmental Exposure Controls: None required for normal use.

General Hygiene Considerations and Work Practices: Avoid contact with the eyes, skin and clothing. Wash thoroughly with soap and water after handling.

Protective Measures During Repair and Maintenance of Contaminated Equipment: Not applicable for product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	White powder	Explosive limits:	Not applicable
Odor:	Odorless	Vapor pressure:	Negligible
Odor threshold:	Not applicable	Vapor density:	Not applicable
pH (1:1 in Water)	8.05	Specific Gravity: (H₂O = 1)	0.86 @ 25°C
Melting/freezing point:	>500°F (260°C)	Solubility:	Insoluble
Initial boiling point and range:	Not available	Partition coefficient: n-octanol/water:	Not available
Flash point:	Not applicable	Auto-ignition temperature:	Not available
Evaporation rate:	Not applicable	Decomposition temperature:	Not available
Flammability:	Not determined	Viscosity:	Not available

Explosive Properties:	Not applicable	Oxidizing Properties:	None
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10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal use conditions.
Chemical Stability: Stable.
Possibility of Hazardous Reactions: Not expected to cause hazardous reactions.
Conditions to Avoid: Avoid exposure to moisture.
Incompatible materials: Avoid inorganic acids.
Hazardous Decomposition Products: Thermal decomposition may produce oxides of carbon, sulfur and barium and zinc oxide fumes

11. TOXICOLOGICAL INFORMATION

<p><u>Potential Health Effects:</u></p> <p><u>Eyes:</u> Dust may cause eye irritation.</p> <p><u>Skin:</u> Dust may cause skin irritation.</p> <p><u>Ingestion:</u> Swallowing large amounts may cause gastrointestinal irritation, nausea and damage to the kidneys, liver, blood and spleen.</p> <p><u>Inhalation:</u> Inhalation of dust may cause irritation of mucous membranes and upper respiratory tract, coughing, chest pains, rales and decreased lung capacity. Inhalation of fumes may cause metal fume fever.</p> <p><u>Chronic Health Effects:</u> None expected</p> <p><u>Carcinogenicity:</u> None of the components in this product are listed as carcinogens by IARC, NTP, ACGIH, OSHA or the EU Substances directive.</p> <p><u>Mutagenicity:</u> Zinc Oxide: Negative in the AMES test but positive in an in vitro mammalian chromosome aberration test.</p> <p><u>Medical Conditions Aggravated by Exposure:</u> Employees with pre-existing respiratory disorders may be at increased risk from exposure.</p> <p><u>Acute Toxicity Data:</u> Zinc Oxide: Oral rat LD50 >5 g/kg; Inhalation mouse LD50 >5.7 mg/L/4 hr</p> <p><u>Reproductive Toxicity Data:</u> In a two generational reproductive study, rats were orally administered 7.5, 15 and 30 mg/kg/day of zinc oxide. Reduction of weights in organs such as the brain, liver, kidney and spleen were noted. Effects to the reproductive organs to males and females were also observed. Gross lesions were observed in gastro-intestinal tract, lymphoreticular/ hematopoietic and reproductive tract. NOAL 7.5 mg/kg/day.</p>
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Specific Target Organ Toxicity (STOT):

Single Exposure: Zinc oxide is irritating to rabbit eyes and rabbit skin.

Repeated Exposure: Zinc Oxide: In an oral study, rats were given 5.0 mg/kg of zinc oxide for 6 months. Histology examination showed mild damage to the kidneys and moderate effects to the spleen. The LOAEL was determined to be 5.0 mg/kg.

12. ECOLOGICAL INFORMATION

Toxicity:

Zinc Oxide: 96 hr LC50 Oncorhynchus mykiss (Rainbow trout) 1.1 ppm

Persistence and Degradability: Biodegradation is not applicable to inorganic substances.

Bio-accumulative Potential: Zinc Oxide: Based on monitoring data, zinc is expected to adsorb to suspended solids and sediment in water and has been detected in the majority of aquatic organisms studied.

Mobility in Soil: Zinc compounds are expected to have low mobility in soils and are absorbed by plants and vegetables.

Other Adverse Effects: Zinc oxide is classified as very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Results of PBT/vPvB Assessment: Not required.

13. DISPOSAL CONSIDERATIONS

Regulations: Dispose in accordance with local and national environmental regulations.

Properties (Physical/Chemical) Affecting Disposal: None known.

Waste Treatment Recommendations: None needed for normal anticipated use.

14. TRANSPORT INFORMATION

UN Number:	ADR/RID: UN3077	IMDG: UN3077	IATA: UN3077	DOT: None
UN proper shipping name:	ADR/RID: Environmentally Hazardous Substance, solid n.o.s. (zinc oxide) IMDG: Environmentally Hazardous Substance, solid n.o.s. (zinc oxide) IATA: Environmentally Hazardous Substance, solid n.o.s. (zinc oxide) DOT: Not Regulated			
Transport hazard class(es):	ADR/RID: 9	IMDG: 9	IATA: 9	DOT: None
Packaging group:	ADR/RID: PG III	IMDG: PG III	IATA: PG III	DOT: None
Environmental hazards:	ADR/RID: Yes	IMDG Marine pollutant: Yes	IATA: Yes	DOT: No
Special precautions for user: Not applicable				

15. REGULATORY INFORMATION

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): The RQ for the product, based on the RQ for Zinc oxide (as Zinc) 50% of 1,000 lbs, is 2,000 lbs. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): All of the ingredients in this product are listed on the EPA TSCA Inventory.

OSHA Hazard Classification: Exposure Limit

Clean Water Act (CWA): Not Listed

Clean Air Act (CAA): Not Listed

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	No	Pressure Hazard:	No
Delayed Hazard:	No	Reactivity Hazard:	No
Fire Hazard:	No		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
Zinc Oxide (Zinc Compounds)	1314-13-2	40-50

State Regulations

California: This product contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm:

Components	C.A.S. #	WT %
None		

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Not a controlled product.

EU REACH: The substances in this product comply with the EU REACH regulation as applicable.

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3:

N Dangerous for the Environment

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.