

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
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 Revision Number: 4

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled):	Zinc Oxide, USP
Part/Item Number:	11803, 11804, 11807

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use:	Preparation of cement restorations
Restrictions on Use:	For professional use only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:	Sultan Healthcare
Manufacturer/Supplier Address:	1301 Smile Way York, PA, USA
Manufacturer/Supplier Telephone Number:	1-201-871-1232 or 800-637-8582 (Product Information)-
Email address:	customer.service@sultanhc.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number:	800-535-5053 (INFOTRAC) 1-352-323-3500 (Outside the United States – Call Collect)
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2. HAZARD(S) IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS SDS Classification:

Health	Environmental	Physical
None	Aquatic Acute Toxicity Category 1 Aquatic Chronic Toxicity Category 1	None

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

EU Risk (R) Phrases: R50/53

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

2.2 Labeling Elements:



Signal Word: Warning

Hazard Statements	Precautionary Statements
H410 Very toxic to aquatic life with long lasting effects.	P273 Avoid release to the environment P391 Collect spillage P501 Dispose of container / contents to approved disposal site in accordance with all local and national regulations.

2.3 Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.1 Substance

Hazardous Components	C.A.S. # EC#	IUPAC Name	CLP/GHS / EU Classification (1272/2008) (1999/45/EC)	WT %
Zinc Oxide	1314-13-2 / 215-222-5	oxozinc	Aquatic Acute 1 H400 Aquatic Chronic 1 H410	100

Refer to Section 16 for the full text of the GHS and H phrases and EU Classifications and R Phrases.

4. FIRST-AID MEASURES

4.1 Description of 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 exposed area with soap and water. Get medical attention if irritation persists. Remove contaminated clothing and launder before reuse.
Inhalation	Remove to fresh air. If breathing has stopped, administer artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Ingestion	Rinse mouth with water. Only induce vomiting if directed by medical personnel. Never give anything by mouth to an unconscious or drowsy person. Get medical attention.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

Dust may cause eye and skin irritation. Inhalation of dust or fumes may cause metal fume fever with symptoms including coughing, fever, chills, headache, tightness of the chest, and nausea. Ingestion may cause lumbar pain, oliguria, uremia, convulsions, coma, cardiac failure, and pulmonary edema.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

None required under normal conditions of use.

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

5.1 Extinguishing Media

Use media appropriate for surrounding fire.

5.2 Special Hazards Arising from the Substance or Mixture:

Combustion may produce irritating and toxic gases.

5.3 Advice for Fire-Fighters:





Fire Fighting Procedures:

Cool fire exposed containers and structures with water.

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

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

For large spills, wear protective clothing, eye protection and gloves. For small spills, wear eye protection and gloves.

Recommended Personal Protective Equipment for Containment and Clean-up:

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6.2 Environmental Precautions:

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

6.3 Methods and Material for Containment and Cleaning up:

Collect material and place in appropriate containers for disposal. Avoid generating dust.

6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 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.

Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, dry, well ventilated place.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Zinc Oxide	United States	2 mg/m ² TWA ACGIH TLV (Respirable), 10 mg/m ³ STEL (Respirable) 5 mg/m ³ TWA OSHA PEL (Respirable), 15 mg/m ³ TWA OSHA PEL (total dust)
	Germany	0.1 mg/m ³ TWA DFG MAK (Respirable) 2 mg/m ³ TWA (Inhalable)
	United Kingdom	5 mg/m ³ TWA UK OEL (Respirable) 2 mg/m ³ STEL (Respirable)
	France	5 mg/m ³ TWA INRS VME (France)
	Spain	5 mg/m ³ TWA VLA-ED (Spain) (dust)
	Italy	None established
	European Union	None established

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate general or local exhaust ventilation to maintain exposure levels below the occupational exposure limits.



Individual Protection Measures (PPE)

Specific Eye/face Protection: Chemical safety goggles recommended.

Specific Skin Protection: Wear impervious gloves are recommended for prolonged skin contact.

Specific Respiratory Protection: None required under normal use conditions.

Specific Thermal Hazards: Not applicable

Recommended Personal Protective Equipment			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:			
Appearance:	White powder	Explosive limits:	Not applicable
Odor:	Odorless	Vapor pressure:	Not applicable
Odor threshold:	Not applicable	Vapor density:	Not applicable
pH:	6.95 – 7.37	Relative density:	5.61
Melting/freezing point:	3587°F (1974.8°C)	Solubility:	Insoluble
Initial boiling point and range:	Not available	Partition coefficient: n-octanol/water:	Not available
Flash point:	Not flammable	Auto-ignition temperature:	Not available
Evaporation rate:	Not applicable	Decomposition temperature:	Not available
Flammability:	Not flammable	Viscosity:	Not available
Explosive Properties:	Not applicable	Oxidizing Properties:	None

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: No unusual reactivity.

10.2 Chemical Stability: Stable

10.3 Possibility of Hazardous Reactions: Hazardous reactions are unlikely.

10.4 Conditions to Avoid: Avoid exposure to moisture.

10.5 Incompatible materials: Avoid strong oxidizing agents and magnesium.

10.6 Hazardous Decomposition Products: Thermal decomposition may produce zinc oxide fumes.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Dust may cause eye irritation.

Skin: Dust may cause skin irritation.

Ingestion: Swallowing may cause lumbar pain, oliguria, uremia, convulsions, coma, cardiac failure, and pulmonary edema.

Inhalation: Inhalation of dust may cause irritation of mucous membranes and upper respiratory tract. Excessive inhalation of fumes may cause metal fume fever with symptoms of coughing, fever, chills, headache, tightness of the chest, and nausea.

Chronic Health Effects: None expected

Carcinogenicity: Not classifiable as to human carcinogenicity. Based on inadequate evidence in humans and animals.

Mutagenicity: No data available.

Medical Conditions Aggravated by Exposure: Employees with pre-existing respiratory disorders may be at increased risk from exposure.

Acute Toxicity Data:

Zinc Oxide: Oral rat LD50 >8.4 g/kg

Reproductive Toxicity Data: No data available.

Specific Target Organ Toxicity (STOT):

Single Exposure: Zinc oxide is irritating to rabbit eyes.

Repeated Exposure: 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

12.1 Toxicity:

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

12.2 Persistence and Degradability: Zinc is found in almost all minerals in the earth's crust with an average concentration of about 70 mg/kg. It is an essential trace element for life that is found in all living organisms. Zinc compounds are expected to exist in the particulate phase in the ambient atmosphere.

12.3 Bio-accumulative Potential: 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.

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

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

12.6 Results of PBT/vPvB Assessment: Not required

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

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

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	None	Not regulated	None	None	No
ADR/RID	UN3077	Environmentally Hazardous Substance, solid n.o.s. (zinc oxide)	9	PG III	Yes
IMDG	UN3077	Environmentally Hazardous Substance, solid n.o.s. (zinc oxide)	9	PG III	Marine Pollutant-Yes
IATA/ICAO	UN3077	Environmentally Hazardous Substance, solid n.o.s. (zinc oxide)	9	PG III	Yes

14.6 Special precautions for user: Not applicable

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable – product is transported only in packaged form.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

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) 100% of 1,000 lbs, is 1,000 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.

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:	Yes	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	100

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 Environmental Protection Act: All the components of this product are listed on the Canadian DSL.

Canadian Workplace Hazardous Materials Information System (WHMIS): Class D-2-B

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.

S57 Use appropriate container to avoid environmental contamination.

Acute Aquatic 1 Acute Aquatic Toxicity Category 1

Chronic Aquatic 1 Chronic Aquatic Toxicity 1

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long lasting effects

Supersedes: February 13, 2012

Revision Summary: Comprehensive review, new format.

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