SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, European Union CLP EC 1272/2008 and the Global Harmonization Standard

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

PRODUCT IDENTIFIER/TRADE/MATERIAL NAME: GRISEOFULVIN ORAL SUSPENSION, USP (MICRONIZED)

DESCRIPTION: Suspension of Griseofulvin Solid in Aqueous Solution
RELEVANT USE of the SUBSTANCE: Human Pharmaceutical – Antibiotic
USES ADVISED AGAINST: Non-Pharmaceutical Use
CHEMICAL NAME: For Active Ingredient: 7-chloro-2',4,6-trimethoxy-6'β-methylspiro[benzofuran - 2(3H),1'-[2]cyclohexane]-3-4'-dione
CHEMICAL FAMILY: For Active Ingredient: Benzofuran/Penicillium
FORMULA: For Active Ingredient: $C_{17}H_{17}ClO_6$
HOW SUPPLIED: Oral Solution
OTHER DESIGNATIONS: 125 mg in 5 mL: NDC:0472-0013-04: 120 mL in 1 bottle

SUPPLIER OF THE SAFETY DATA SHEET

RESPONSIBLE PARTY U.S.:	**Actavis, Inc.**
U.S. ADDRESS:	400 Interpace Parkway, Morris Corporate Center III Parsippany, NJ 07054, USA
U.S. BUSINESS PHONE/GENERAL SDS INFORMATION:	1-800-272-5525
RESPONSIBLE PARTY EUROPE:	
EUROPEAN ADDRESS:	
EUROPEAN BUSINESS PHONE:	
EMERGENCY PHONE (U.S./NORTH AMERICA):	CHEMTREC: 1-800-424-9300 (24 hours) U.S., Canada, Puerto Rico
EMERGENCY PHONE (OUTSIDE U.S.):	CHEMTREC: +1-703-527-3887 (24 hours) Outside North America
Email:	SDS@Actavis.com

NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, Canadian WHMIS [Controlled Products Regulations], EU Directives through EC 1907: 2006, and European Union CLP EC 1272/2008, required information is included in appropriate sections based on the U.S. ANSI Z400.1-2010 format. This product has been classified in accordance with the hazard criteria of the countries listed above.

DATE OF PREPARATION: May 29, 2014 **DATE OF REVISION:** New

2. HAZARDS IDENTIFICATION

EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU 67/548/EEC LABELING AND CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

EMERGENCY OVERVIEW:

Product Description: This product is white to off-white powder in and orange, aqueous suspension with an orange/vanilla odor.

Health Hazards: Accidental ingestion may be harmful. Inhalation and eye contact may cause irritation. In therapeutic use, the most common adverse reactions are of the hypersensitivity type, including skin rashes, hives, and rarely, angioneurotic edema, and erythema multiforme. Therapeutic use can cause adverse effects on the liver and skin. Allergic reactions, sometimes serious, have been reported; persons susceptible to penicillins can suffer severe reactions. As a penicillum, sensitization and allergic reaction by skin contact and inhalation may be possible. Long-term ingestion can cause severe diarrhea due to overgrowth of *clostridium difficile* bacteria. Ingestion May cause photosensitivity reactions and cause sunburn when exposed to UV radiation. May cause harm to fetus during pregnancy. May cause adverse fertility effects. Limited evidence of carcinogenic and mutagenic potential from plant, insect and mammalian studies. More information on adverse effects from therapeutic use is described in Section 11 (Toxicological Information).

Flammability Hazards: This product is not flammable. If involved in a fire, the water component may evaporate and the residual may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including aluminum, carbon, magnesium, silicon, sodium and nitrogen oxides and chlorine).

Reactivity Hazards: This product is not reactive.

Environmental Hazards: Large quantities released to the aquatic and terrestrial environment may have an adverse effect.

Other Hazards: No other hazard information currently known.

Emergency Considerations: Emergency responders should wear appropriate protection for situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	LABEL ELEMENTS EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements/Symbol
ACTIVE INGREDIENT:				
Griseofulvin 7-Chloro-2',4,6-trimethoxy-6'β-methylspiro[benzofuran-2(3H),1'-[2]cyclohexene]-3,4'-dione	126-07-8	204-767-4	Proprietary	SELF-CLASSIFICATION: EU 67/548 Classification: Reproductive Toxicity Cat. 2, Carcinogenicity Cat. 3, Mutagenicity Cat. 3, Harmful Risk Phrase Codes: R61, R62, R40, R68, R42/43 Hazard Symbols: T, Xn GHS & EU 1272/2008 Classification: Reproductive Cat. 1B, Germ Cell Mutagenicity Cat. 2, Carcinogenic Cat. 2, Acute Oral Toxicity Cat. 5, Skin Sensitization Cat. 1B, Respiratory Sensitization Cat. 1B Hazard Codes: H360Df, H341, H351, H303, H317, H334 Hazard Symbol/Pictogram: GHS08
EXCIPIENTS:				
Artificial Orange/Vanilla Flavoring	Mixture	Mixture	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Docusate Sodium	577-11-7	209-406-4	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Harmful, Irritant Risk Phrases: R22, R38, R41 Hazard Symbol: Xn/Xi EU/GHS 1272/2008 Classification: Acute Oral Toxicity Cat. 4, Skin Irritation Cat. 2, Eye Damage Cat. 1 Hazard Statement Codes: H302, H315, H318 Hazard Symbol/Pictogram: GHS05, GHS07
Ethyl Alcohol	64-17-5	200-578-5	Proprietary	EU 67/548 Classification: Highly Flammable Risk Phrases: R11 Hazard Symbol: F EU/GHS 1272/2008 Classification: Flammable Liquid Cat. 2 Hazard Statement Codes: H225 Hazard Symbol/Pictogram: GHS02
FD& C Red No. 40	4548-53-2	224-909-9	Proprietary	SELF CLASSIFICATION EU (67/548/EEC): Classification: Not Applicable EU/GHS 1272/2008: Classification: Acute Oral Toxicity Cat. 5 Hazard Statement Codes: H303 Hazard Symbols/Pictograms: None Applicable
FD&C Yellow No. 6	2783-94-0	220-491-7	Proprietary	SELF-CLASSIFICATION EU 67/548: Classification: Not Applicable GHS and EU 1272/2008 Classification: Acute Oral Toxicity Cat. 5 Hazard Codes: H303 Hazard Symbol/Pictogram: Not Applicable
Magnesium Aluminum Silicate	1327-43-1	215-478-8	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Magnesium Stearate	557-04-0	209-150-3	Proprietary	EU (67/548/EEC): No Classification Applicable EU/GHS 1272/2008: No Classification Applicable
Menthol	89-78-1	201-939-0	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Irritant Risk Phrases: R38, R41 Hazard Symbol: Xn/Xi EU/GHS 1272/2008 Classification: Acute Oral Toxicity Cat. 5, Skin Irritation Cat. 2, Eye Damage Cat. 1 Hazard Statement Codes: H303, H315, H318 Hazard Symbol/Pictogram: GHS05, GHS07
Methyl Paraben	99-76-3	202-785-7	Proprietary	SELF CLASSIFICATION EU (67/548/EEC): Classification: Not Applicable EU/GHS 1272/2008: Classification: Acute Oral Toxicity Cat. 5 Hazard Statement Codes: H303 Hazard Symbols/Pictograms: Not Applicable
Propylene Glycol	57-55-6	200-338-0	Proprietary	EU 67/548 Hazard Classification: Not Applicable GHS and EU 1272/2008 Hazard Classification: Not Applicable
Propyl Paraben	94-13-3	202-307-7	Proprietary	EU 67/548 Hazard Classification: Not Applicable GHS and EU 1272/2008 Hazard Classification: Not Applicable
Saccharin Sodium	82385-42-0	Not Listed	Proprietary	EU 67/548 Classification Not Applicable EU/GHS 1272/2008 Classification Not Applicable
Simethicone Emulsion	8050-81-5	Not Listed	Proprietary	EU 67/548 Hazard Classification: Not Applicable GHS and EU 1272/2008 Hazard Classification: Not Applicable
Sodium Alginate	9005-38-3	Not Listed	Proprietary	EU 67/548 Hazard Classification: Not Applicable GHS and EU 1272/2008 Hazard Classification: Not Applicable
Sucrose	57-50-1	200-334-9	Proprietary	EU 67/548 Hazard Classification: Not Applicable GHS and EU 1272/2008 Hazard Classification: Not Applicable

See Section 15 for full classification.

3. COMPOSITION and INFORMATION ON INGREDIENTS (Continued)

CHEMICAL NAME	CAS #	EINECS #	% w/w	LABEL ELEMENTS EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements/Symbol
EXCIPIENTS (continued):				
Water	7732-18-5	231-791-2	Balance	EU 67/548 Hazard Classification: Not Applicable GHS and EU 1272/2008 Hazard Classification: Not Applicable

See Section 15 for full classification.

4 FIRST-AID MEASURES

PROTECTION OF FIRST AID RESPONDERS: First-aid responders should not attempt to treat victims of exposure to this material without adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary.

DESCRIPTION OF FIRST AID MEASURES: Upon contact of this material with skin, eyes, or mucous membranes, immediately decontaminate by flushing with water for at least 20 minutes. Remove contaminated clothing and shoes. Take a copy of this SDS to health professional with victim. Wash clothing and thoroughly clean shoes before reuse.

Inhalation: If mists or sprays from this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect occurs after removal to fresh air.

Skin Exposure: Basic hygiene should prevent any problems. If the product contaminates the skin, and adverse effect occurs, begin decontamination with running water. Minimum flushing is for 20 minutes. Do not interrupt flushing. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Seek medical attention if adverse effect occurs after flushing.

Eye Exposure: If this product enters the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 20 minutes. Do not interrupt flushing. Seek immediate medical attention after flushing if adverse effect occurs.

Ingestion Exposure: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Rinse mouth with water immediately. Victim should drink large quantities of water. If milk is available, victim should drink it after drinking water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: In therapeutic use, pre-existing porphyria, systemic lupus erythematosus (SLE), liver conditions, hepatocellular failure may be aggravated by exposure. Workplace exposure may also aggravate these conditions. Persons who may have hypersensitivity reactions to penicillins or other disorders described in Section 11 (Toxicological Information) may experience aggravation upon exposure.

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive immediate medical attention. No specific antidote is available. Treatment should be supportive for symptoms.

5. FIRE-FIGHTING MEASURES

FLASHPOINT: Not flammable.

AUTOIGNITION TEMPERATURE: Not applicable.

FLAMMABLE LIMITS & METHOD OF DETERMINATION (in air by volume, %): Not applicable.

FIRE EXTINGUISHING MEDIA: Use extinguishing media appropriate for surrounding fire.

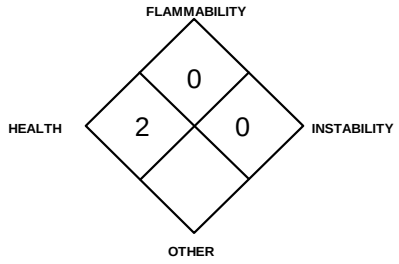
UNSUITABLE EXTINGUISHING MEDIA: None known.

SPECIFIC HAZARDS ARISING FROM THE PRODUCT: This product is not flammable. If involved in a fire, the water component may evaporate and the residual may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including aluminum, carbon, magnesium, silicon, sodium and nitrogen oxides and chlorine).

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

NFPA RATING



Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** =

SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: In the event of a spill, clear the area and protect people. The atmosphere must have levels of components lower than those listed in Section 8, (Exposure Controls and Personal Protective Equipment) if applicable, and have at least 19.5 percent oxygen before personnel can be allowed into the area without Self-Contained Breathing Apparatus (SCBA). Monitor area and confirm levels are bellow exposure limits given in Section 8 (Exposure Controls-Personal Protection), if applicable, before non-response personnel are allowed into the spill area.

6. ACCIDENTAL RELEASE MEASURES (Continued)

PROTECTIVE EQUIPMENT:

Small Spills: For incidental spills (e.g., 1 vial), wear double latex or nitrile disposable gloves and eye protection.

Large Spills: For large spills (e.g., 1 liter or more), protective apparel should be used with a respirator when there is any danger of airborne mists or sprays being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. Minimum level of personal protective equipment for releases in which the level of oxygen is less than 19.5% or is unknown must be **Level B: triple-gloves (rubber gloves and nitrile gloves over latex gloves), chemical resistant suit and boots, hard hat, and Self-Contained Breathing Apparatus.**

METHODS FOR CLEANUP AND CONTAINMENT:

Small Spills: Absorb up spilled material with damp sponge, polypads or other suitable material.

Large Spills: Trained personnel following pre-planned procedures should handle non-incidental releases. Access to the spill areas should be restricted. Absorb spilled product carefully, avoiding the generation of mists or sprays onto polypads or other non-reactive absorption.

All Spills: Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Do not mix with wastes from other materials. If necessary, discard contaminated response equipment or rinse with soapy water before returning such equipment to service. Dispose of in accordance with applicable international, national, state, and local procedures (see Section 13, Disposal Considerations).

ENVIRONMENTAL PRECAUTIONS: Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

7. HANDLING and USE

PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

PRECAUTIONS FOR SAFE HANDLING: All employees who handle this product should be trained to handle it safely. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this compound, and during patient administration. As with all chemicals, avoid getting this product ON YOU or IN YOU. Wash thoroughly after handling this product or equipment and containers that contain this product. Do not eat or drink while using this product. Avoid breathing airborne mists or spray generated by this product. Ensure this product is used with adequate ventilation (refer to Section 8, Exposure Controls-Personal Protection). Remove contaminated clothing immediately. Keep container tightly closed when not in use. Open containers slowly on a stable surface in areas that have been designated for use of this product. Wipe down areas in which this product is used, so that product does not accumulate. Empty containers may contain residual material; therefore, empty containers should be handled with care.

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight, sources of intense heat or other sources of ignition or where freezing is possible. Store at 20-25°C (68-77°F) and away from moisture, humidity and light. Product should be stored in secondary containers or in a diked area, as appropriate. Store away from incompatible materials (see Section 10, Stability and Reactivity).

SPECIFIC END USE(S): This product is a human pharmaceutical. Follow all industry standards for use of this product.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or butyl rubber (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

Ventilation and Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS.

Occupational/Workplace Exposure Limits/Guidelines:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	IDLH mg/m^3	mg/m^3
Griseofulvin	126-07-8	NE	NE	NE	NE	NE	NE	NE	NE
Artificial Orange/Vanilla Flavoring Mixture		NE	NE	NE	NE	NE	NE	NE	NE
Docusate Sodium	577-11-7	NE	NE	NE	NE	NE	NE	NE	NE
Ethyl Alcohol	64-17-5	NE	1000	1000	NE	1000	NE	3300 (10% of LEL)	DFG MAKs: TWA = 500 PEAK = 2•MAK, 15 min. average value, 1-hr interval, 4 per shift DFG Germ Cell Mutagen Category: 5 DFG MAK Pregnancy Risk Classification: C Carcinogen: MAK-5, TLV-A3

NE = Not Established.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/CONTROL PARAMETERS (continued):

Occupational/Workplace Exposure Limits/Guidelines (continued):

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	IDLH mg/m^3	mg/m^3
Griseofulvin	126-07-8	NE	NE	NE	NE	NE	NE	NE	NE
FD&C Red No. 40	4548-53-2	NE	NE	NE	NE	NE	NE	NE	Carcinogen: IARC-3
FD&C Yellow No. 6	2783-94-0	NE	NE	NE	NE	NE	NE	NE	Carcinogen: IARC-3
Magnesium Aluminum Silicate	1327-43-1	NE	NE	NE	NE	NE	NE	NE	NE
Magnesium Stearate	557-04-0	10	NE	NE	NE	NE	NE	NE	Carcinogen: TLV-A4
Menthol	89-78-1	NE	NE	NE	NE	NE	NE	NE	NE
Methyl Paraben	99-76-3	NE	NE	NE	NE	NE	NE	NE	NE
Propylene Glycol	57-55-6	NE	NE	NE	NE	NE	NE	NE	AIHA WEEL: TWA = 10
Propyl Paraben	94-13-3	NE	NE	NE	NE	NE	NE	NE	NE
Saccharin Sodium Exposure limits for saccharin & its salts	82385-42-0	NE	NE	NE	NE	NE	NE	NE	Carcinogen: IARC-3
Simethicone	8050-81-5	NE	NE	NE	NE	NE	NE	NE	NE
Sodium Alginate	9005-38-3	NE	NE	NE	NE	NE	NE	NE	NE
Sucrose	57-50-1	10	NE	15 (total dust), 5 (resp. fraction)	NE	10 (total dust), 5 (respirable fraction)	NE	NE	Carcinogen: TLV-A4
Water, Purified	7732-18-5	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established. See Section 16 for Definitions of Other Terms Used.

International Occupational Exposure Limits: Currently, the following exposure limits have been established by various countries for components of this product. The exposure limits given may not be the most current; individual country authorities should be contacted to check on more current limits.

ETHANOL:
Australia: TWA = 1000 ppm (1880 mg/m^3), JUL 2008
AUSTRIA: MAK-TMW = 1000 ppm (1900 mg/m^3); KZW = 2000 ppm (3800 mg/m^3), 2007
Belgium: TWA = 1000 ppm (1907 mg/m^3), MAR 2002
Denmark: TWA = 1000 ppm (1900 mg/m^3), MAY 2011
Finland: TWA = 1000 ppm (1900 mg/m^3), STEL = 1300 ppm (2500 mg/m^3), NOV2011
France: VME = 1000 ppm (1900 mg/m^3), VLE = 5000 ppm (9500), FE B2006
Germany: MAK = 960 mg/m^3 (500 mL/m^3), 2005
Hungary: TWA = 1900 mg/m^3, STEL = 7600 mg/m^3, SEP 2000
Iceland: TWA = 1000 ppm (1900 mg/m^3), NOV 2011
Korea: TWA = 1000 ppm (1900 mg/m^3), 2006
Mexico: TWA = 1000 ppm (1900 mg/m^3), 2004
The Netherlands: MAC-TGG = 1000 mg/m^3, 2003
New Zealand: TWA = 1000 ppm (1880 mg/m^3), JAN 2002
Norway: TWA = 500 ppm (950 mg/m^3), JAN 1999
Peru: TWA = 1000 ppm (1884 mg/m^3), JUL2005
The Philippines: TWA = 1000 ppm (1900 mg/m^3), JAN 1993
Poland: MAC(TWA) = 1000 mg/m^3, MAC(STEL) = 3000 mg/m^3, JAN 1999

ETHANOL (continued):
Russia: TWA = 1000 mg/m^3, STEL = 2000 mg/m^3, JUN 2003
Sweden: TWA = 500 ppm (1000 mg/m^3); STEL = 1000 ppm (1900 mg/m^3), JUN 2005
Switzerland: MAK-W =500 ppm (960 mg/m^3), KZG-W = 1000 ppm (1920 mg/m^3), DEC 2006
Thailand: TWA = 1000 ppm (1900 mg/m^3), JAN 1993
Turkey: TWA = 1000 ppm (1900 mg/m^3), JAN 1993
United Kingdom: TWA = 1000 ppm (1920 mg/m^3), OCT 2007
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

MAGNESIUM ALUMINUM SILICATE:
Denmark: TWA = 1 fibers/cc, OCT 2002
France: VME = 2 mg(Al)/m^3, FEB 2006
Korea: TWA = 2 mg(Al)/m^3, 2006
New Zealand: TWA = 2 mg(Al)/m^3, JAN 2002
Sweden: TWA = 1 mg(Al)/m^3, JUN 2005

MAGNESIUM STEARATE:
New Zealand: TWA = 10 mg/m^3 (inspirable dust), JAN 2002
Sweden: TWA = 5 mg/m^3, JUN 2005
Belgium: TWA = 10 mg/m^3, MAR 2002

METHYL PARABEN:
Russia: STEL = 4 mg/m^3, JUN 2003

PROPYL PARABEN:
Russia: STEL = 10 mg/m^3, JUN 2003

PROPYLENE GLYCOL:
Australia: TWA = 10 mg/m^3 (particulates), JUL 2008
Australia: TWA = 150 ppm (474 mg/m^3) (total), JUL 2008
New Zealand: TWA = 10 mg/m^3 (particulates only), JAN 2002
New Zealand: TWA = 150 ppm (474 mg/m^3) (vapor and particulates), JAN 2002
Russia: STEL = 7 mg/m^3, JUN 2003
United Kingdom: TWA = 10 mg/m^3 (particulate), 2005
United Kingdom: TWA = 150 ppm (474 mg/m^3) (total vapor), 2005

SUCROSE:
Belgium: TWA = 10 mg/m^3, MAR 2002
France: VME = 10 mg/m^3, FEB 2006
Korea: TWA = 10 mg/m^3, 2006
Mexico: TWA = 10 mg/m^3; STEL = 20 mg/m^3, 2004
The Netherlands: MAC-TGG = 10 mg/m^3, 2003
New Zealand: TWA = 10 mg/m^3 (inspirable dust), JAN 2002
Peru: TWA = 10 mg/m^3, JUL 2005
United Kingdom: TWA = 10 mg/m^3; STEL = 20 mg/m^3, OCT 2007
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Singapore, Vietnam check ACGIH TLV

PERSONAL PROTECTIVE EQUIPMENT: Use of personal protective equipment must be in compliance with U.S. OSHA 29 CFR Subpart I (beginning at 1910.132), Canadian CSA Standards Z94.4-02 and Z94.3-02, EU EN 529:2005, CEN/TR 15419:2006, and CR 13464:1999. Please reference applicable regulations and standards for relevant details.

Respiratory Protection: A respirator is not required for routine conditions of use with adequate engineering controls. A full-face Air-Purifying Respirator with high-efficiency particulate filter or a Supplied-Air Respirator must be worn during operations where engineering controls are not sufficient, large spill cleanup, or when processing generates airborne aerosols. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

Eye Protection: During operations in which mists or sprays may be generated, splash goggles or safety glasses should be considered.

Hand Protection: During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS.

Body Protection: Use appropriate protective clothing for the task (e.g., lab coat, etc.)

9. PHYSICAL and CHEMICAL PROPERTIES

The following information is for the product.

FORM: White solid suspended in liquid.
COLOR: As described in Section 2.
ODOR: Banana.
ODOR THRESHOLD: Not available.
HOW TO DETECT THIS SUBSTANCE (identification properties): The appearance of this product is a distinguishing characteristic.

The following information is for the Griseofulvin active ingredient.

FORM: Crystalline solid.
COLOR: White to off-white.
MOLECULAR WEIGHT: 252.77
MOLECULAR FORMULA: $C_{17}H_{17}ClO_6$
ODOR: Not available.
ODOR THRESHOLD: Not available.
BOILING POINT @ 760 mmHg: 570.4±50.0°C (1058.7±122°F) [predict.]
MELTING POINT: 217-224°C (442.6-435.2°F)
VAPOR PRESSURE (air = 1) @ 25°C: 0.0±1.6 mmHg [predict.]
SPECIFIC GRAVITY (water = 1): 138 g/cm^3
EVAPORATION RATE (nBuAc = 1): Not applicable.
pH: Not available.
FLASH POINT: 228.0±29.1°C (442.4±84.4°F) [predict.]
SOLUBILITY IN WATER: Practically insoluble

OTHER SOLUBILITIES: Soluble in n,n-dimethylformamide at 25°C: 12-14 g/100 mL; slightly soluble in ethanol, chloroform, methanol, acetic acid, acetone, benzene, and ethyl acetate; practically insoluble in petroleum ether
COEFFICIENT WATER/OIL DISTRIBUTION: Log P: 3.53±0.65 [predict.]

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: This product is stable under normal conditions of storage.
HAZARDOUS DECOMPOSITION PRODUCTS: ***Combustion:*** If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., aluminum, carbon, magnesium, silicon, sodium and nitrogen oxides and chlorine). ***Hydrolysis:*** None known.
INCOMPATIBLE MATERIALS: This compound is incompatible with strong oxidizers, strong acids.
POSSIBILITY OF HAZARDOUS REACTIONS/ POLYMERIZATION: No data available.
CONDITIONS TO AVOID: Avoid heat, light, and contact with incompatible chemicals.

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to employee handling in an occupational setting. The following paragraphs describe the symptoms of exposure by route of exposure.

Inhalation: Inhalation of airborne aerosols generated by this product may irritate the nose, throat, and lungs. Some available information indicates penicillums can cause respiratory sensitization and allergic reaction.

Skin Contact: Contact with the skin may cause irritation. Prolonged or repeated skin contact may cause dermatitis (dry, red skin). Skin contact may lead to sensitization and allergic reactions as a penicillum.

Eye Contact: Contact with the eyes of aerosols generated by this product may cause irritation, redness, and tearing.

Skin Absorption: No specific data is available on potential absorption of this material through intact skin. Some information indicates skin contact can cause sensitizations and allergic reactions to the active ingredient, which indicates skin absorption.

Ingestion: Ingestion is not a significant route of occupational exposure. Symptoms of acute ingestion may include those described under 'Other Health Effects'. Serious allergic reactions can occur in persons susceptible to penicillins.

Injection: Though not anticipated to be a significant route of exposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection. Symptoms may also include those described under 'Other Health Effects'.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2*
FLAMMABILITY HAZARD	(RED)	0
PHYSICAL HAZARD	(YELLOW)	0

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe * = Chronic hazard

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: In therapeutic use, the most common adverse reactions are of the hypersensitivity type, including skin rashes, hives, and rarely, angioneurotic edema, and erythema multiforme. Therapeutic use can cause adverse effects on the liver and skin. Allergic reactions, sometimes serious, have been reported; persons susceptible to penicillins can suffer severe reactions. As a penicillum, sensitization and allergic reaction by skin contact and inhalation may be possible. Long-term ingestion can cause severe diarrhea due to overgrowth of *clostridium difficile* bacteria. Ingestion May cause photosensitivity reactions and cause sunburn when exposed to UV radiation. May cause harm to fetus during pregnancy. Limited evidence of carcinogenic and mutagenic potential from plant, insect and mammalian studies. Peripheral neuropathy and paresthesias of the hands and feet have been reported and may be related to treatment duration. Other side effects reported occasionally are oral thrush, nausea, vomiting, epigastric distress, diarrhea, headache, fatigue, dizziness, insomnia, mental confusion and impairment of performance of routine activities. Proteinuria, nephrosis (sometimes associated with existing systemic lupus erythematosus), leukopenia, coagulopathy, hepatitis, elevated liver enzymes, granulocytopenia, hyperbilirubinemia, and GI bleeding have been reported rarely.

11. TOXICOLOGICAL INFORMATION (Continued)

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Exposure to this product may cause the following health effects:

Acute: This product may cause irritation via inhalation or inhalation, skin or eye contact.

Chronic: Potential fetal harm. Limited evidence of carcinogenic and mutagenic effect. Repeated skin contact may cause dermatitis (dry, red skin). Chronic exposure may cause adverse symptoms as described under 'Other Health Effects'.

TARGET ORGANS:

Acute: *Industrial Exposure*: Skin, eyes, respiratory system. *Therapeutic Doses*: Gastrointestinal system.

Chronic: *Industrial Exposure*: Skin. *Therapeutic Doses*: Gastrointestinal and central nervous systems, and other systems given under "Other Potential Health Effects'.

IRRITANCY OF PRODUCT: This product may irritate contaminated tissue.

SENSITIZATION TO THE PRODUCT: In therapeutic use, hypersensitivity reactions, including skin rashes, hives and rarely, swelling under the surface of the skin has been reported. Paresthesias of the hands and feet have been reported rarely after extended therapy. Since Griseofulvin is derived from species of penicillin, the possibility of cross sensitivity with penicillin exists; however, known penicillin-sensitive patients have been treated without difficulty.

TOXICITY DATA: Currently the following toxicity data are available for the active ingredient. Additional data are available, for excipients, but are not presented in this SDS. Contact Actavis for more information.

GRISEOFULVIN:

TDLo (Oral-Child) 215.38 mg/kg/3 weeks-intermittent: Skin and Appendages: dermatitis, allergic (after systemic exposure) Nutritional and Gross Metabolic: body temperature increase

TDLo (Unreported-Child) 210 mg/kg/3 weeks-intermittent: Skin and Appendages: dermatitis, allergic (after systemic exposure); Immunological Including Allergic: hypersensitivity delayed

LD_{50} (Oral-Rat) > 10 gm/kg

LD_{50} (Oral-Mouse) > 50 gm/kg

LD_{50} (Intraperitoneal-Rat) > 5 gm/kg

LD_{50} (Intraperitoneal-Mouse) 200 mg/kg

LD_{50} (Intravenous-Rat) 400 mg/kg: Blood: changes in cell count (unspecified), changes in bone marrow (not otherwise specified)

LD_{50} (Intravenous-Mouse) 280 mg/kg

LD_{50} (Subcutaneous-Mouse) > 12 gm/kg

TDLo (Oral-Rat) 73,500 mg/kg/14 weeks-continuous: Cardiac: cardiomyopathy including infarction; Liver: hepatitis (hepatocellular necrosis), diffuse' Kidney/Ureter/Bladder: changes primarily in glomeruli

TDLo (Oral-Rat) 36, 750 mg/kg/7 weeks-continuous: Blood: other changes, changes in erythrocyte (RBC) count

TDLo (Oral-Rat) 462 gm/kg/2 years-intermittent: Tumorigenic: neoplastic by RTECS criteria; Blood: lymphoma, including Hodgkin's disease

TDLo (Oral-Rat) 168 gm/kg/12 weeks-intermittent: Tumorigenic: equivocal tumorigenic agent by RTECS criteria; Liver: tumors; Tumorigenic: facilitates action of known carcinogen

TDLo (Oral-Rat) 1250 mg/kg: female 6-15 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus); Effects on Newborn: viability index (e.g., # alive at day 4 per # born alive)

TDLo (Oral-Rat) 2 gm/kg: female 11-14 day(s) after conception: Reproductive: Specific Developmental Abnormalities: Central Nervous System, urogenital system

TDLo (Oral-Rat) 12,500 mg/kg: female 6-15 day(s) after conception: Reproductive: Fertility: post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants); Specific Developmental Abnormalities: musculoskeletal system

TDLo (Oral-Rat) 500 mg/kg: female 9 day(s) after conception: 500 mg/kg: female 9 day(s) after conception: Reproductive: Effects on Embryo or Fetus: fetal death; Specific Developmental Abnormalities: eye/ear

TDLo (Oral-Mouse) 357 gm/kg/17 weeks-intermittent: Liver: other changes

TDLo (Oral-Mouse) 33.6 gm/kg/2 weeks-continuous: Nutritional and Gross Metabolic: weight loss or decreased weight gain

TDLo (Oral-Mouse) 134.4 gm/kg/8 weeks-continuous: Liver: changes in liver weight; Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation

TDLo (Oral-Mouse) 7.2 gm/kg/3 days-continuous: Liver: other changes; Biochemical: Metabolism (Intermediary): porphyrin including bile pigments

TDLo (Oral-Mouse) 1.8 gm/kg/3 days-continuous: Liver: other changes

TDLo (Oral-Mouse) 21 gm/kg/5 weeks-continuous: Liver: jaundice, cholestatic; Liver: changes in liver weight; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: phosphatases

TDLo (Oral-Mouse) 16.8 gm/kg/1 week-continuous: Liver: changes in liver weight; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: hepatic microsomal mixed oxidase (dealkylation, hydroxylation, etc.), Enzyme inhibition, induction, or change in blood or tissue levels: transaminases

TDLo (Oral-Mouse) 50.4 gm/kg/3 weeks-continuous: Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: phosphatases; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases, Enzyme inhibition, induction, or change in blood or tissue levels: peptidases

TDLo (Oral-Mouse) 84 gm/kg/5 weeks-continuous: Behavioral: alteration of classical conditioning; Liver: changes in liver weight

TDLo (Oral-Mouse) 42 gm/kg/10 weeks-continuous: Behavioral: alteration of classical conditioning; Liver: changes in liver weight

GRISEOFULVIN (continued):

TDLo (Oral-Mouse) 204 gm/kg/85 days-continuous: Liver: hepatitis, fibrous (cirrhosis, post-necrotic scarring)

TDLo (Oral-Mouse) 440 gm/kg/52 weeks-continuous: Tumorigenic: neoplastic by RTECS criteria; Liver: tumors

TDLo (Oral-Mouse) 10 gm/kg: female 8-9 day(s) after conception: Reproductive: Specific Developmental Abnormalities: musculoskeletal system

TDLo (Oral-Guinea Pig) 109 gm/kg/52 weeks-continuous: Nutritional and Gross Metabolic: weight loss or decreased weight gain

TDLo (Oral-Mammal-Domestic) 1 gm/kg: female 48-52 day(s) after conception: Reproductive: Specific Developmental Abnormalities: musculoskeletal system

TDLo (Intraperitoneal-Rat) 35 mg/kg/5 days-intermittent: Liver: changes in liver weight; Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol); Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: other Enzymes

TDLo (Subcutaneous-Mouse) 120 mg/kg/49 weeks-intermittent: Tumorigenic: neoplastic by RTECS criteria; Liver: tumors

TDLo (Unreported-Mouse) 28.35 mg/kg/3 weeks-intermittent: Reproductive: Paternal Effects: spermatogenesis (incl. genetic material, sperm morphology, motility, and count)

TCLo (Inhalation-Rat) 40 mg/m^3/60 days-continuous: Immunological Including Allergic: decrease in humoral immune response; Biochemical: Metabolism (Intermediary): Plasma proteins not involving coagulation

TD (Oral-Mouse) 730 gm/kg/52 weeks-continuous: Tumorigenic: neoplastic by RTECS criteria; Liver: tumors

Micronucleus Test (Human Lymphocyte) 5 mg/L

Micronucleus Test (Human Lymphocyte) 25 mg/L/23 hours

DNA Inhibition (Human Fibroblast) 20 mg/L/3 days-continuous

DNA inhibition (Human Lymphocyte) 20 mg/L/3 days-continuous

Cytogenetic Analysis (Human Lymphocyte) 40 mg/L/3 days

Cytogenetic Analysis (Human Lymphocyte) 7.5 mg/L/24 hours

Sex Chromosome Loss and Non-Disjunction (Human Lymphocyte) 5 mg/L

DNA Damage (Human Lymphocyte) 11.0 mg/L/48 hours

Micronucleus Test (Human Fibroblast) 10 mg/L

Mutation Test Systems-Not Otherwise Specified (Microorganism-Not Otherwise Specified) 10 mg/L

Specific Locus Test (Oral-*Drosophila melanogaster*) 2 gm/L

DNA Repair (Oral-*Drosophila melanogaster*) 3 gm/L

Mutation in Microorganisms (Mold-*Aspergillus nidulans*) 17 µmol/L

Cytogenetic Analysis (Mold-*Aspergillus nidulans*) 400 mg/L

Cytogenetic Analysis (Oral-grasshopper) 5 mg

Cytogenetic Analysis (Intravenous-Rat) 200 mg/kg

Cytogenetic Analysis (Mouse Embryo) 50 mg/L

Cytogenetic Analysis (Hamster Embryo) 50 mg/L

Cytogenetic Analysis (Hamster Fibroblast) 10 mg/L

Cytogenetic Analysis (chicken Fibroblast) 50 mg/L

Cytogenetic Analysis (Oral-Mouse) 200 mg/kg

Micronucleus Test (Mouse-Cells-Not Otherwise Specified) 10 mg/L

Micronucleus Test (Oral-Mouse) 1 gm/kg

Micronucleus Test (Mouse Mammary Gland) 5.6 mg/L/24 hours

Micronucleus Test (Hamster Embryo) 20 mg/L/4 hours

Micronucleus Test (Hamster Fibroblast) 25 mg/L/3 hours

Micronucleus Test (Hamster Fibroblast) 6.3 mg/L/24 hours

Micronucleus Test (Hamster Mouse Cells-Not Otherwise Specified) 100 mg/L/3 hours

Micronucleus Test (Mouse Cells-Not Otherwise Specified) 4.9 mg/L/24 hours

Micronucleus Test (Hamster Ovary) 70.8 µmol/L/24 hours

Micronucleus Test (Mouse Cells-Not Otherwise Specified) 35.43 µmol/L

Micronucleus Test (Mouse Cells-Not Otherwise Specified) 200 mg/L/24 hours

Sex Chromosome Loss and Non-Disjunction (Mold-*Aspergillus nidulans*) 6 mg/L

Sex Chromosome Loss and Non-Disjunction (Oral-Mouse) 500 mg/kg

Sister Chromatid Exchange (Intraperitoneal-Mouse) 100 mg/kg

Sperm Morphology (Intraperitoneal-Mouse) 29,750 mg/kg/5 days-intermittent

Morphological Transformation (Hamster Embryo) 8 mg/L

CARCINOGENIC POTENTIAL: In sub-acute toxicity studies, orally administered Griseofulvin produced hepatocellular necrosis in mice, but this has not been seen in other species. Chronic feeding of Griseofulvin, at levels ranging from 0.5 to 2.5% of the diet, resulted in the development of liver tumors in several strains of mice, particularly in males. Smaller particle sizes resulted in an enhanced effect. Lower oral-dosage levels have not been tested.

11. TOXICOLOGICAL INFORMATION (Continued)

CARCINOGENIC POTENTIAL (continued): Subcutaneous administration of relatively small doses of Griseofulvin once a week during the first three weeks of life has also been reported to induce hepatomata in mice. Thyroid tumors, mostly adenomas but some carcinomas, have been reported in male rats receiving Griseofulvin at levels of 2.0%, 1.0% and 0.2% of the diet, and in female rats receiving the two higher dose levels. Studies in other animal species were inadequate assessments of tumorigenicity. Disturbances in porphyrin metabolism have been reported in Griseofulvin-treated laboratory animals. Griseofulvin has been reported to have a colchicine-like effect on mitosis and was co-carcinogenic with methylcholanthrene in cutaneous tumor induction in laboratory animals.

Griseofulvin is listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

IARC-2B (Possibly Carcinogenic to Humans)

Excipient component are listed as follows:

ETHANOL: ACGIH TLV-A3 (Confirmed Animal Carcinogen with Unknown Relevance to Humans); MAK-5 (Substances with Carcinogenic and Genotoxic Effects, the potency of which is considered to be so low that, provided the MAK and BAT values are observed, no significant contribution to human cancer risk is to be expected.)

FD&C RED NO. 40, FD&C YELLOW NO. 6, POVIDONE, SODIUM SACCHARIN: IARC-3 (Unclassifiable as to Carcinogenicity in Humans)

MAGNESIUM STEARATE (as a stearate compound), SUCROSE: ACGIH TLV-A4 (Not Classifiable as Human Carcinogen)

The remaining components are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

REPRODUCTIVE TOXICITY INFORMATION: There are no adequate and well-controlled studies of Griseofulvin in pregnant women; however, Griseofulvin can cause fetal harm when administered to a pregnant woman, especially in the first trimester. In the workplace, the risk to the fetus should be communicated and the appropriate action should be taken to prevent exposure in accordance with company policy and regulatory requirements. In formulated products, Griseofulvin is rated by the FDA for therapeutic risk as Pregnancy Risk Category X (Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits) in the first trimester of pregnancy and Pregnancy Risk Category C (Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks) for second and third trimesters.

Mutagenicity: Griseofulvin, a carcinogenic spindle poison, was tested in two types of somatic-cell assays of Drosophila melanogaster, one of which detects the induction of DNA damage and the other mutation/mitotic recombination. In both assays, Griseofulvin was fed to tester larvae and genetic endpoints examined after emergence. In the wing spot test, trans-heterozygous flies carrying mwh and flr3 wing-hair mutations produced both significant and dose-dependent increases in the frequency of mwh single spots over the control level but no increase of twin spots. In the DNA repair test, double-mutant larvae carrying both mei-9(a) (excision repair-defective) and mei-41(D5) (post-replication repair-defective) mutations showed hypersensitivity to killing by Griseofulvin compared with their DNA repair-proficient counterparts, suggesting that GF caused potentially lethal DNA damages which were efficiently repaired by the DNA repair-proficient but not -defective larvae. These lines of evidence clearly demonstrate that Griseofulvin is genotoxic in somatic cells of Drosophila. It is noted that Griseofulvin-fed larvae showed a developmental delay and surviving adult flies had morphological abnormalities in their eyes and wings. Griseofulvin interferes with chromosomal distribution during cell division, causing aneuploidy in plant and mammalian cells. These effects have been demonstrated *in vitro* at concentrations that may be achieved in the serum with the recommended therapeutic dosage.

Embryotoxicity/Teratogenicity:

Human Information: Griseofulvin crosses the placenta. Conjoined twins have been reported rarely in patients taking Griseofulvin during the first trimester of pregnancy.

Animal Information: Griseofulvin has been shown to be embryotoxic and teratogenic in pregnant rats when given at a daily oral dose of 250 mg/kg/day [4X the Maximum Recommended Human Dose (MRHD) based on a Body Surface Area (BSA)]. Griseofulvin also has been shown to be embryotoxic and teratogenic in pregnant cats treated weekly with Griseofulvin at doses of 500 to 1000 mg/week. There are reports of teratogenicity in a Golden Retriever when doses of 750 mg/day [1.2X the MRHD based on BSA] were administered for four weeks prior to and throughout the pregnancy, and in a study in which beagles were administered 35 mg/kg/day [1.9X the MRHD based on BSA] for intervals from one week up to the entire gestation period. Teratogenicity was also seen in mice when Griseofulvin was administered in doses equivalent to 5g/kg/day [40X the MRHD based on BSA] for 2 consecutive days at various stages of the pregnancy.

Reproductive Toxicity: Griseofulvin induces abnormalities in murine sperm. Suppression of spermatogenesis has been reported to occur in rats and sperm abnormalities have been observed in Griseofulvin treated mice, but these were not detected in man. It is not known if Griseofulvin is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for tumorigenicity shown for Griseofulvin in animal studies and because there is potential for adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, ACGIH Biological Exposure Indices (BEIs) have not been determined for the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY IN SOIL: This product has not been tested for mobility in soil.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability.

BIO-ACCUMULATIVE POTENTIAL: No information available.

12. ECOLOGICAL INFORMATION (Continued)

ECOTOXICITY: No data is available for this product. All releases to terrestrial, atmospheric and aquatic environments should be avoided.

RESULTS OF PBT AND vPvB ASSESSMENT: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

OTHER ADVERSE EFFECTS: This material has no known ozone depletion potential.

ENVIRONMENTAL EXPOSURE CONTROLS: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT/DISPOSAL METHODS: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. Waste containers should be handled with uncontaminated gloves. Reusable equipment should be decontaminated using 0.05M Boric acid solution adjusted to pH 9 with 10 N sodium hydroxide followed by a detergent wash and then clean water rinse or by using a bleach solution (triple wash) and a detergent solution followed by clean water rinse.

PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING: Wear proper protective equipment when handling waste materials.

U.S. EPA WASTE NUMBER: Not applicable.

EUROPEAN WASTE CODES: Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION: This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA: This product is NOT classified as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product is not classified as Dangerous Goods, by rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO): This product is NOT classified as Dangerous Goods, per rules of IMO.

UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE (UNECE): This product is NOT classified by the United Nations Economic Commission for Europe to be dangerous goods.

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: Not applicable.

ENVIRONMENTAL HAZARDS: This product is neither environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) nor a marine pollutant according to the IMDG Code and is not listed in Annex III under MARPOL 73/78.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity (TPQ): There are no specific Threshold Planning Quantities for any component of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA Reportable Quantities (RQ): Not applicable.

U.S. TSCA inventory status: Component of this product are on the TSCA Inventory.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): The Griseofulvin component of this product is on the California Proposition 65 lists. WARNING! This product contains a compound known to the State of California to cause cancer.

Other U.S. Federal Regulations: Regulations of the FDA under the Federal Food, Drug and Cosmetic Act are applicable to pharmaceutical preparations.

ADDITIONAL CANADIAN REGULATIONS:

Canadian DSL/NDSL Inventory Status: Components of this product are on the DSL Inventory.

Other Canadian Regulations: Requirements under the Canadian Heath Canada, Laboratory Biosafety Guidelines may be applicable.

Canadian WHMIS Classification and Symbol: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

ADDITIONAL EUROPEAN UNION REGULATIONS:

Safety, Health, and Environmental Regulations/Legislation Specific for the Product: When formulated in a finished medicinal compound for human use, this material is subject to Directive 2001/83/EC and subsequent amendments to the directive.

Chemical Safety Assessment: No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

16. OTHER INFORMATION

U.S. ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): WARNING! MAY BE HARMFUL IF ACCIDENTALLY INGESTED. INGESTION MAY CAUSE ALLERGIC REACTIONS. MAY ALSO CAUSE SENSITIZATION VIA SKIN CONTACT AND INHALATION. REPEATED INGESTION MAY CAUSE SYSTEMIC EFFECTS. MAY CAUSE HARM TO FETUS. LIMITED EVIDENCE OF CARCINOGENIC AND MUTAGENIC POTENTIAL. Do not taste or swallow. Avoid contact with skin, eyes, and clothing. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. FIRST-AID: In case of contact, flush skin or eyes with plenty of water. If adverse respiratory reaction occurs from allergic reaction, give oxygen and seek immediate medical attention. If ingested, DO NOT induce vomiting. Seek immediate medical attention. IN CASE OF FIRE: Use water fog, dry chemical, CO_2, or "alcohol" foam. IN CASE OF SPILL: Absorb spilled product with appropriate materials/absorbent. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Safety Data Sheet for additional information.

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU 67/548/EEC LABELING AND CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

CLASSIFICATION OF COMPONENTS:

CLP Regulation (EC) 1272/2008

Griseofulvin: This is a self-classification.
- Classification: Reproductive Toxicity Category 1B, Carcinogenicity Category 2, Germ Cell Mutagenicity Category 2, Acute Oral Toxicity Category 5, Skin Sensitization Category 1B, Respiratory Sensitization Category 1B
- Hazard Statements: H361Df: May damage the unborn child. Suspected of damaging fertility. H351: Suspected of causing cancer. H341: Suspected of causing genetic effects. H303: May be harmful if swallowed. H317: May cause an allergic skin reaction. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Docustate Sodium: This is a self-classification.
- Classification: Acute Oral Toxicity Category 4, Skin Irritation Category 2, Eye Damage Category 1
- Hazard Statement Codes: H302: Harmful if ingested. H315: Causes skin irritation. H318: Causes serious eye damage.

Ethyl Alcohol: This is a published classification.
- Classification: Flammable Liquid Category 2
- Hazard Statements: H225: Highly flammable liquid and vapour. H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness.

FD&C Red No. 40, FD&C Yellow No. 6, Methyl Paraben: This is a self-classification.
- Classification: Acute Oral Toxicity Category 5
- Hazard Statement Codes: H303: May be harmful if ingested.

Menthol: This is a self-classification.
- Classification: Acute Oral Toxicity Category 5, Skin Irritation Category 2, Eye Damage Category 1
- Hazard Statement Codes: H303: May be harmful if ingested. H315: Causes skin irritation. H318: Causes serious eye damage.

All Other Components: An official classification for these substances has not been published nor is applicable.

67/548/EEC:

Griseofulvin: This is a self-classification.
- Classification: Reproductive Toxicity Category 2, Carcinogenic Category 3, Germ Cell Mutagenicity Category 3, Harmful
- Risk Phrases: R61: May cause harm to the unborn child. R62: Possible risk of impaired fertility. R40: Limited evidence of a carcinogenic effect. R68: Possible risk of irreversible effects. R42/43: May cause sensitisation by inhalation and skin contact.

Docustate Sodium: This is a self-classification.
- Hazard Classification: Harmful, Irritant
- Risk Phrases: R22: Harmful if swallowed. R38: Irritating to skin. R41: Risk of serious damage to eyes.

Ethyl Alcohol: This is a published classification.
- Hazard Classification: Highly Flammable
- Risk Phrases: R11: Highly flammable. R36: Irritating to eyes. R67: Vapours may cause drowsiness and dizziness.

Menthol: This is a self-classification.
- Hazard Classification: Irritant
- Risk Phrases: R38: Irritating to skin. R41: Risk of serious damage to eyes.

All Other Components: An official classification for these substances has not been published nor is applicable.

REFERENCES AND DATA SOURCES: Contact the supplier for information.

METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

REVISION DETAILS: September 2013: Up-date to include additional active ingredient percentage. Up-date throughout to current classification and format.

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc. • PO Box 1961, Hilo, HI 96721 • 800/441-3365 • 808/969-4846

DATE OF PRINTING: May 30, 2014