



# SAFETY DATA SHEET

Revision date: 18-Jul-2014

Version: 3.0

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## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Fluconazole Powder for Oral Suspension (Greenstone LLC)

**Trade Name:** Not applicable

**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product used as antifungal agent

### Details of the Supplier of the Safety Data Sheet

Greenstone LLC  
100 Route 206 North  
Peapack, NJ 07977  
800-435-7095

**Emergency telephone number:**  
800-435-7095

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

#### GHS - Classification

Reproductive Toxicity: Category 1B  
Effects on or via lactation

#### US OSHA Specific - Classification

**Physical Hazard:** Combustible Dust

#### EU Classification:

EU Indication of danger: Toxic to reproduction, Category 2

#### EU Risk Phrases:

R61 - May cause harm to the unborn child.  
R64- May cause harm to breastfed babies.

### Label Elements

**Signal Word:** Danger

**Hazard Statements:** H360D - May damage the unborn child  
H362 - May cause harm to breast-fed children  
May form combustible dust concentrations in air

**Precautionary Statements:** P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P281 - Use personal protective equipment as required  
P260 - Do not breathe dust/fume/gas/mist/vapors/spray  
P263 - Avoid contact during pregnancy/while nursing  
P264 - Wash hands thoroughly after handling  
P270 - Do not eat, drink or smoke when using this product  
P308 + P313 - IF exposed or concerned: Get medical attention/advice  
P405 - Store locked up  
P501 - Dispose of contents/container in accordance with all local and national regulations

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**Other Hazards** No data available  
**Australian Hazard Classification (NOHSC):** Hazardous Substance. Non-Dangerous Goods.

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Hazardous**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	Not Listed	*
Colloidal silicon dioxide	7631-86-9	231-545-4	Not Listed	Not Listed	*
Fluconazole	86386-73-4	Not Listed	Xn;R22 Repr.Cat.2;R61 R64 R52/53	Acute Tox. 4(H302) Repr. 1B (H360D) Lact. (H362) Aquatic Acute 3 (H402) Aquatic Chronic 3 (H412)	6.6
Sucrose	57-50-1	200-334-9	Not Listed	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Natural orange flavor	NOT ASSIGNED	Not Listed	Not Listed	Not Listed	*
Sodium benzoate	532-32-1	208-534-8	Not Listed	Not Listed	*
Sodium citrate, dihydrate	6132-04-3	Not Listed	Not Listed	Not Listed	*
Xanthan gum	11138-66-2	234-394-2	Not Listed	Not Listed	*

**Additional Information:** \* Proprietary  
 Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.  
 In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

**For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16**

### 4. FIRST AID MEASURES

**Description of First Aid Measures**

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

### Most Important Symptoms and Effects, Both Acute and Delayed

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.  
**Medical Conditions Aggravated by Exposure:** None known

### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

### Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

### Precautions for Safe Handling

Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical drug product

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Colloidal silicon dioxide

Australia TWA	2 mg/m <sup>3</sup>
Austria OEL - MAKs	4 mg/m <sup>3</sup>
	0.3 mg/m <sup>3</sup>
Czech Republic OEL - TWA	0.1 mg/m <sup>3</sup>
	4.0 mg/m <sup>3</sup>
Estonia OEL - TWA	2 mg/m <sup>3</sup>
Finland OEL - TWA	5 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	4 mg/m <sup>3</sup>
Germany (DFG) - MAK	4 mg/m <sup>3</sup>
Ireland OEL - TWAs	6 mg/m <sup>3</sup>
	2.4 mg/m <sup>3</sup>
Latvia OEL - TWA	1 mg/m <sup>3</sup>
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
	Listed
Slovakia OEL - TWA	4.0 mg/m <sup>3</sup>

#### Fluconazole

Manufacturer OEL:	500ug/m <sup>3</sup>
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#### Sucrose

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	10 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

#### Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
ACGIH OELs - Notice of Intended Changes	Listed
Australia TWA	10 mg/m <sup>3</sup>
Austria OEL - MAKs	5 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Denmark OEL - TWA	6 mg/m <sup>3</sup>
Estonia OEL - TWA	5 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>

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Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Poland OEL - TWA	10.0 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Romania OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>

### Exposure Controls

#### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

#### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

#### Hands:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

#### Eyes:

Wear safety glasses or goggles if eye contact is possible.

#### Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

#### Respiratory protection:

If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Physical State:

Powder

#### Color:

White

#### Odor:

Oranges (natural flavoring added)

#### Odor Threshold:

No data available.

#### Molecular Formula:

Mixture

#### Molecular Weight:

Mixture

#### Solvent Solubility:

No data available

#### Water Solubility:

No data available

#### pH:

No data available.

#### Melting/Freezing Point (°C):

No data available

#### Boiling Point (°C):

No data available.

#### Partition Coefficient: (Method, pH, Endpoint, Value)

#### Sodium benzoate

No data available

#### Sucrose

No data available

#### Colloidal silicon dioxide

No data available

#### Xanthan gum

No data available

#### Sodium citrate, dihydrate

No data available

#### Natural orange flavor

No data available

#### Fluconazole

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Predicted Log P 5.0

**Citric acid, anhydrous**

No data available

**Titanium dioxide**

No data available

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** No data available

**Viscosity:** No data available

**Flammability:**

**Autoignition Temperature (Solid) (°C):** No data available

**Flammability (Solids):** No data available

**Flash Point (Liquid) (°C):** No data available

**Upper Explosive Limits (Liquid) (% by Vol.):** No data available

**Lower Explosive Limits (Liquid) (% by Vol.):** No data available

**Polymerization:** Will not occur

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available

**Chemical Stability:** Stable under normal conditions of use.

**Possibility of Hazardous Reactions**

**Oxidizing Properties:** No data available

**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

**Short Term:** Active ingredient may be harmful if swallowed. May cause eye irritation (based on components)

**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.

**Known Clinical Effects:** Adverse effects most commonly reported in clinical use include skin rash, headache, nausea, and abdominal pain. Rare cases of serious liver damage and allergic reactions have been reported. There have been reports of multiple congenital abnormalities in infants whose mothers were being treated for 3 or more months with high dose (400-800mg/day) fluconazole. Fluconazole is found in human breast milk at concentrations similar to plasma. Therefore, nursing mothers should limit exposure.

**Acute Toxicity: (Species, Route, End Point, Dose)**

**Sodium benzoate**

Rat Oral LD50 4,070 mg/kg

Mouse Oral LD50 1600mg/kg

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### 11. TOXICOLOGICAL INFORMATION

#### Sucrose

Rat Oral LD50 29.7 g/kg

#### Xanthan gum

Rat Oral LD50 > 5000 mg/kg

#### Fluconazole

Rat (F) Oral LD50 1575 mg/kg

Rat (M) Oral LD50 1325mg/kg

Mouse Oral LD50 1410mg/kg

Mouse (M) Oral LD50 1520mg/kg

Dog Intravenous LD50 > 100mg/kg

#### Citric acid, anhydrous

Rat Oral LD50 3000 mg/kg

#### Titanium dioxide

Rat Oral LD50 > 7500 mg/kg

Rat Subcutaneous LD50 50 mg/kg

#### Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### Citric acid, anhydrous

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

No data available

##### Skin Irritation / Sensitization

No data available

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Sodium benzoate

10 Day(s) Rat Oral 27370 mg/kg LOAEL Liver, Blood

10 Day(s) Mouse Oral 45 g/kg LOAEL Liver, Kidney, Blood, Ureter, Bladder

##### Fluconazole

3 Month(s) Rat Oral 5 mg/kg/day NOAEL Liver

6 Month(s) Dog Oral 7.5 mg/kg/day NOAEL Liver

12 Month(s) Rat Oral 10 mg/kg/day LOAEL Liver

12 Month(s) Dog Oral 2.5 mg/kg/day NOAEL Liver

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### Sodium benzoate

Embryo / Fetal Development Rat Oral 44 g/kg LOEL Developmental toxicity

##### Fluconazole

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### 11. TOXICOLOGICAL INFORMATION

Reproductive & Fertility	Rat	Oral 20 mg/kg/day	NOAEL	Negative
Embryo / Fetal Development	Rabbit	Oral 20 mg/kg/day	NOAEL	Maternal Toxicity, Not Teratogenic
Embryo / Fetal Development	Rat	Oral 5 mg/kg/day	NOAEL	Fetotoxicity, Maternal Toxicity
Embryo / Fetal Development	Rat	Oral 80 mg/kg/day	LOAEL	Maternal Toxicity, Developmental toxicity

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Sucrose

Bacterial Mutagenicity (Ames) *Salmonella* Negative

##### Fluconazole

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

*In Vivo* Cytogenetics Mouse Bone Marrow Negative

*In Vitro* Cytogenetics Human Lymphocytes Negative

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Fluconazole

24 Month(s) Rat Female Oral 10 mg/kg/day NOAEL Not carcinogenic

24 Month(s) Rat Female Oral 5 mg/kg/day LOEL Benign tumors, Liver

24 Month(s) Mouse Oral 10 mg/kg/day NOEL Not carcinogenic

Carcinogen Status: See below

##### Colloidal silicon dioxide

IARC: Group 3 (Not Classifiable)

##### Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this mixture have not been fully evaluated. Harmful effects to aquatic organisms could occur. See Aquatic toxicity data of the active ingredient, below:

#### Toxicity:

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### Fluconazole

*Daphnia magna* (Water Flea) LC50 48 Hours 35 mg/L

*Pimephales promelas* (Fathead Minnow) LC50 > 50 mg/L

*Cyprinodon variegatus* (Sheepshead Minnow) LC50 > 50 mg/L

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

**Persistence and Degradability:** No data available

#### **Bio-accumulative Potential:**



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## Partition Coefficient: (Method, pH, Endpoint, Value)

### Fluconazole

Predicted Log P 5.0

Mobility in Soil: No data available

## 13. DISPOSAL CONSIDERATIONS

### Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## 15. REGULATORY INFORMATION

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

#### Canada - WHMIS: Classifications

##### WHMIS hazard class:

Class D, Division 2, Subdivision A



#### Citric acid, anhydrous

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1

#### Colloidal silicon dioxide

CERCLA/SARA 313 Emission reporting	Not Listed
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California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-545-4

#### Fluconazole

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3 Schedule 4
EU EINECS/ELINCS List	Not Listed

#### Natural orange flavor

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

#### Sodium benzoate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	208-534-8

#### Sodium citrate, dihydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### Sucrose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9

#### Titanium dioxide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen initial date 9/2/11 airborne, unbound particles of respirable size
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5

#### Xanthan gum

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

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### 15. REGULATORY INFORMATION

EU EINECS/ELINCS List

234-394-2

### 16. OTHER INFORMATION

#### Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child  
Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children  
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects

Xn - Harmful  
Toxic to Reproduction: Category 2

R22 - Harmful if swallowed.  
R61 - May cause harm to the unborn child.  
R64 - May cause harm to breastfed babies.  
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology Information. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

**Revision date:** 18-Jul-2014  
Product Stewardship Hazard Communication

**Prepared by:** Global Environment, Health, and Safety Operations

It is believed that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time

**End of Safety Data Sheet**