

**1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING****Product Identifier****Material Name: Sirolimus Tablets (Greenstone LLC)**

**Trade Name:** Not applicable  
**Synonyms:** Sirolimus tablets  
**Chemical Family:** Macrocyclic lactone

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

**Intended Use:** Pharmaceutical product used as immunosuppressive 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:**  
**CHEMTREC (24 hours): 1-800-424-9300**

**2. HAZARDS IDENTIFICATION****Classification of the Substance or Mixture****GHS - Classification**

Reproductive Toxicity: Category 1B

**EU Classification:**

EU Indication of danger: Toxic to Reproduction: Category 2

**EU Risk Phrases:**

R60 - May impair fertility.  
R61 - May cause harm to the unborn child.

**Label Elements**

**Signal Word:** Danger  
**Hazard Statements:** H360FD - May damage fertility. May damage the unborn child.

**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  
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

**Other Hazards**

## SAFETY DATA SHEET

Material Name: Sirolimus Tablets (Greenstone LLC)  
Revision date: 22-Oct-2014

Page 2 of 15  
Version: 4.0

**Australian Hazard Classification (NOHSC):** Hazardous Substance. Non-Dangerous Goods.

**Note:** This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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	%
Calcium sulfate	7778-18-9	231-900-3	Not Listed	Not Listed	*
Ferric oxide red	1309-37-1	215-168-2	Not Listed	Not Listed	*
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	Not Listed	*
Sirolimus	53123-88-9	Not Listed	Repr.Cat.2; R60-61 N; R50/53	Repr.1B (H360FD) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	0.1-0.6
Sucrose	57-50-1	200-334-9	Not Listed	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	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	%
Black Iron Oxide	1317-61-9	215-277-5	Not Listed	Not Listed	*
Carnauba wax	8015-86-9	232-399-4	Not Listed	Not Listed	*
DL-Alpha tocopherol	10191-41-0	233-466-0	Not Listed	Not Listed	*
ETHYLENE OXIDE/PROPYLENE OXIDE COPOLYMER	9003-11-6	Not Listed	Not Listed	Not Listed	*
Ferric oxide yellow	51274-00-1	257-098-5	Not Listed	Not Listed	*
Glyceryl monooleate	25496-72-4	247-038-6	Not Listed	Not Listed	*
Pharmaceutical glaze	Not assigned	Not Listed	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	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.

## SAFETY DATA SHEET

Material Name: Sirolimus Tablets (Greenstone LLC)  
Revision date: 22-Oct-2014

Page 3 of 15  
Version: 4.0

- 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.
- 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:** Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

### Special Hazards Arising from the Substance or Mixture

- Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.
- 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

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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

## SAFETY DATA SHEET

**Material Name: Sirolimus Tablets (Greenstone LLC)**  
**Revision date: 22-Oct-2014**

**Page 4 of 15**  
**Version: 4.0**

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**Storage Conditions:** Store as directed by product packaging.  
**Specific end use(s):** Pharmaceutical drug product

## SAFETY DATA SHEET

Material Name: Sirolimus Tablets (Greenstone LLC)  
Revision date: 22-Oct-2014

Page 5 of 15  
Version: 4.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Calcium sulfate

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
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>
France OEL - TWA	10 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	6 mg/m <sup>3</sup>
Germany (DFG) - MAK	1.5 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Hungary OEL - TWA	6 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
Latvia OEL - TWA	4 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>
Slovenia OEL - TWA	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

#### Ferric oxide red

ACGIH Threshold Limit Value (TWA)	5 mg/m <sup>3</sup>
Australia TWA	5 mg/m <sup>3</sup>
	10 mg/m <sup>3</sup>
Austria OEL - MAKs	5 mg/m <sup>3</sup>
	10 mg/m <sup>3</sup>
Belgium OEL - TWA	2 ppm
	5 mg/m <sup>3</sup>
Bulgaria OEL - TWA	5.0 mg/m <sup>3</sup>
Denmark OEL - TWA	3.5 mg/m <sup>3</sup>
Estonia OEL - TWA	3.5 mg/m <sup>3</sup>
Finland OEL - TWA	5 mg/m <sup>3</sup>
France OEL - TWA	5 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
Hungary OEL - TWA	6 mg/m <sup>3</sup>
Ireland OEL - TWAs	5 mg/m <sup>3</sup>
	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Lithuania OEL - TWA	3.5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	10 mg/m <sup>3</sup>
	15 mg/m <sup>3</sup>
Poland OEL - TWA	5 mg/m <sup>3</sup>
Portugal OEL - TWA	5 mg/m <sup>3</sup>
Romania OEL - TWA	5 mg/m <sup>3</sup>
Slovakia OEL - TWA	1.5 mg/m <sup>3</sup>
Spain OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	3.5 mg/m <sup>3</sup>

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
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## SAFETY DATA SHEET

Material Name: Sirolimus Tablets (Greenstone LLC)  
Revision date: 22-Oct-2014

Page 6 of 15  
Version: 4.0

Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>
<b>Microcrystalline cellulose</b>	
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>
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>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	2 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 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>
<b>Polyethylene glycol</b>	
Austria OEL - MAKs	1000 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	1000 mg/m <sup>3</sup>
Germany (DFG) - MAK	1000 mg/m <sup>3</sup> average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m <sup>3</sup>
Slovenia OEL - TWA	1000 mg/m <sup>3</sup>
<b>Sirolimus</b>	
Manufacturer OEL:	0.2ug/m <sup>3</sup>
<b>Sucrose</b>	
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>
<b>Talc (non-asbestiform)</b>	
ACGIH Threshold Limit Value (TWA)	2 mg/m <sup>3</sup>
Australia TWA	2.5 mg/m <sup>3</sup>
Austria OEL - MAKs	2 mg/m <sup>3</sup>
Belgium OEL - TWA	2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	1.0 fiber/cm <sup>3</sup>
	6.0 mg/m <sup>3</sup>
	3.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	2.0 mg/m <sup>3</sup>
Denmark OEL - TWA	0.3 fiber/cm <sup>3</sup>
Finland OEL - TWA	0.5 fiber/cm <sup>3</sup>

## SAFETY DATA SHEET

Material Name: Sirolimus Tablets (Greenstone LLC)  
Revision date: 22-Oct-2014

Page 7 of 15  
Version: 4.0

Greece OEL - TWA	10 mg/m <sup>3</sup>
	2 mg/m <sup>3</sup>
Hungary OEL - TWA	2 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	0.8 mg/m <sup>3</sup>
Lithuania OEL - TWA	2 mg/m <sup>3</sup>
	1 mg/m <sup>3</sup>
Netherlands OEL - TWA	0.25 mg/m <sup>3</sup>
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
Poland OEL - TWA	4.0 mg/m <sup>3</sup>
	1.0 mg/m <sup>3</sup>
Portugal OEL - TWA	2 mg/m <sup>3</sup>
Romania OEL - TWA	2 mg/m <sup>3</sup>
Slovakia OEL - TWA	2 mg/m <sup>3</sup>
	10 mg/m <sup>3</sup>
Slovenia OEL - TWA	2 mg/m <sup>3</sup>
Spain OEL - TWA	2 mg/m <sup>3</sup>
Sweden OEL - TWAs	2 mg/m <sup>3</sup>
	1 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>
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.

## SAFETY DATA SHEET

Material Name: Sirolimus Tablets (Greenstone LLC)  
Revision date: 22-Oct-2014

Page 8 of 15  
Version: 4.0

**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

<b>Physical State:</b>	Tablet	<b>Color:</b>	Tan, White, Yellow to Beige
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	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)**

**DL-Alpha tocopherol**

No data available

**Lactose NF, monohydrate**

No data available

**Carnauba wax**

No data available

**ETHYLENE OXIDE/PROPYLENE OXIDE COPOLYMER**

No data available

**Glyceryl monooleate**

No data available

**Microcrystalline cellulose**

No data available

**Pharmaceutical glaze**

No data available

**Povidone**

No data available

**Talc (non-asbestiform)**

No data available

**Titanium dioxide**

No data available

**Black Iron Oxide**

No data available

**Ferric oxide yellow**

No data available

**Magnesium stearate**

No data available

**Calcium sulfate**

No data available

**Sucrose**

No data available

**Polyethylene glycol**

No data available

**Ferric oxide red**

No data available

**Sirolimus**

Measured Log P >4.63



## SAFETY DATA SHEET

Material Name: Sirolimus Tablets (Greenstone LLC)  
Revision date: 22-Oct-2014

Page 9 of 15  
Version: 4.0

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**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:**

<b>Autoignition Temperature (Solid) (°C):</b>	No data available
<b>Flammability (Solids):</b>	No data available
<b>Flash Point (Liquid) (°C):</b>	No data available
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available

### 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.  
**Known Clinical Effects:** Adverse effects associated with therapeutic use include hypersensitivity reactions, nausea, weakness, skin rash, weight loss, inflammation of the mouth (stomatitis), itching sensation (pruritus), decreased red blood cell count (anemia), decreased white blood cells (leukopenia).

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

**Microcrystalline cellulose**

Rat Oral LD50 > 5000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

**Povidone**

Rat Oral LD50 100 g/kg

**Talc (non-asbestiform)**

Rat Oral LD50 > 1600 mg/kg

**Titanium dioxide**

Rat Oral LD50 > 7500 mg/kg  
Rat Subcutaneous LD50 50 mg/kg

**Black Iron Oxide**

Rat Oral LD50 >1000 mg/kg

## SAFETY DATA SHEET

Material Name: Sirolimus Tablets (Greenstone LLC)  
Revision date: 22-Oct-2014

Page 10 of 15  
Version: 4.0

### 11. TOXICOLOGICAL INFORMATION

#### Magnesium stearate

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

#### Sucrose

Rat Oral LD50 29.7 g/kg

#### Sirolimus

Mouse Oral LD50 > 2500 mg/kg  
Rat Oral LD50 > 800mg/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)

##### Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating

##### Polyethylene glycol

Eye Irritation Rabbit Mild  
Skin Irritation Rabbit Mild

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

**Sirolimus** Monkey No route specified 0.05 mg/kg/day NOAEL Lymphoid tissue, Spleen, Thymus, Gastrointestinal System

#### Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Sirolimus

Reproductive & Fertility Rat No route specified 0.1 mg/kg/day NOAEL Embryotoxicity, Fetotoxicity

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

##### Sucrose

Bacterial Mutagenicity (Ames) *Salmonella* Negative

##### Sirolimus

*In Vitro* Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative  
*In Vitro* Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative  
*In Vitro* Forward Mutation Assay Mouse Lymphoma Negative  
*In Vivo* Micronucleus Mouse Negative

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

##### Sirolimus

86 Week(s) Mouse No route specified 6 mg/kg/day LOAEL Tumors, Lymphatic system  
104 Week(s) Rat No route specified 0.2 mg/kg/day LOAEL Male reproductive system, Tumors

**Carcinogen Status:** See below

## SAFETY DATA SHEET

Material Name: Sirolimus Tablets (Greenstone LLC)  
Revision date: 22-Oct-2014

Page 11 of 15  
Version: 4.0

### 11. TOXICOLOGICAL INFORMATION

#### Povidone

IARC: Group 3 (Not Classifiable)

#### Talc (non-asbestiform)

IARC: Group 3 (Not Classifiable)

#### Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)

#### Ferric oxide red

IARC: Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The following information is available for the individual ingredients. For information on the formulated product, see "Data for the Drug Product", below.

#### Toxicity:

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

##### Sirolimus

*Pseudokirchneriella subcapitata* (Green Alga) OECD EC50 72 Hours 0.063 mg/L

**Persistence and Degradability:** No data available

#### Bio-accumulative Potential:

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

##### Sirolimus

Measured Log P >4.63

**Mobility in Soil:** No data available

#### Data for the Drug Product

#### Aquatic Toxicity

Species	Method	End Point	Duration	Result (mg/l)
<i>Oncorhynchus mykiss</i> (Rainbow Trout)	OECD	LC50	96 Hours	>100 mg/L
<i>Daphnia Magna</i> (Water Flea)	ISO	EC50	48 Hours	>100 mg/L
<i>Pseudokirchneriella subcapitata</i> (Green Alga)	ISO	IC50	72 Hours	33.6 mg/L

**Aquatic Toxicity Comments:** A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

## SAFETY DATA SHEET

Material Name: Sirolimus Tablets (Greenstone LLC)  
Revision date: 22-Oct-2014

Page 12 of 15  
Version: 4.0

### 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



#### Black Iron Oxide

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	215-277-5

#### Calcium sulfate

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	231-900-3

#### Carnauba wax

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

## SAFETY DATA SHEET

Material Name: Sirolimus Tablets (Greenstone LLC)  
Revision date: 22-Oct-2014

Page 13 of 15  
Version: 4.0

### 15. REGULATORY INFORMATION

Australia (AICS):	Present
EU EINECS/ELINCS List	232-399-4
<b>DL-Alpha tocopherol</b>	
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	233-466-0
<b>ETHYLENE OXIDE/PROPYLENE OXIDE COPOLYMER</b>	
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	Not Listed
<b>Ferric oxide red</b>	
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	215-168-2
<b>Ferric oxide yellow</b>	
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	257-098-5
<b>Glyceryl monooleate</b>	
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	247-038-6
<b>Lactose NF, monohydrate</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	Not Listed
<b>Magnesium stearate</b>	
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	209-150-3

## SAFETY DATA SHEET

Material Name: Sirolimus Tablets (Greenstone LLC)  
Revision date: 22-Oct-2014

Page 14 of 15  
Version: 4.0

### 15. REGULATORY INFORMATION

#### Microcrystalline cellulose

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 XVII - Restrictions on Certain Dangerous Substances:	Use restricted. See item 9[f]. powder
EU EINECS/ELINCS List	232-674-9

#### Pharmaceutical glaze

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

#### Polyethylene glycol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3
EU EINECS/ELINCS List	Not Listed

#### Povidone

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	Not Listed

#### Sirolimus

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

#### Talc (non-asbestiform)

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	238-877-9

## SAFETY DATA SHEET

Material Name: Sirolimus Tablets (Greenstone LLC)  
Revision date: 22-Oct-2014

Page 15 of 15  
Version: 4.0

### 15. REGULATORY INFORMATION

#### Titanium dioxide

CERCLA/SARA 313 Emission reporting  
California Proposition 65

Not Listed  
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

### 16. OTHER INFORMATION

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

Reproductive toxicity-Cat.1B; H360FD - May damage fertility. May damage the unborn child.  
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

Toxic to Reproduction: Category 2  
N - Dangerous for the environment

R60 - May impair fertility.

R61 - May cause harm to the unborn child.

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

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients.

**Revision date:** 22-Oct-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**