



# SAFETY DATA SHEET

Revision date: 06-Mar-2015

Version: 2.0

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

### Product Identifier

**Material Name:** Exemestane Tablets (Greenstone LLC)

**Trade Name:** Not applicable

**Chemical Family:** Mixture

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

**Intended Use:** Antineoplastic Pharmaceutical product used as

### 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

Acute aquatic toxicity: Category 2

Chronic aquatic toxicity: Category 2

#### EU Classification:

EU Indication of danger: Toxic to reproduction, Category 2  
N - Dangerous for the environment

#### EU Risk Phrases:

R60 - May impair fertility.

R61 - May cause harm to the unborn child.

R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

### Label Elements

**Signal Word:** Danger

**Hazard Statements:** H360FD - May damage fertility. May damage the unborn child.  
H411 - Toxic to aquatic life with long lasting effects

#### Precautionary Statements:

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

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**Other Hazards**

No data available

**Australian Hazard Classification (NOHSC):**

Hazardous Substance. Non-Hazardous Substance.

**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	%
Exemestane	107868-30-4	Not Listed	Repr.Cat.2;R60-61 N; R51/53	Repr.1B (H360FD) Aquatic Acute 2 (H401) Aquatic Chronic 2 (H411)	25
Silica colloidal, Ph. Eur.	112945-52-5	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	*
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	%
Crospovidone	9003-39-8	Not Listed	Not Listed	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	Not Listed	*
Mannitol	69-65-8	200-711-8	Not Listed	Not Listed	*
Methylparaben	99-76-3	202-785-7	Not Listed	Not Listed	*
Macrogol 6000	Not assigned	Not Listed	Not Listed	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	Not Listed	*
Polyvinyl alcohol	9002-89-5	Not Listed	Not Listed	Not Listed	*
Sodium starch glycolate	9063-38-1	Not Listed	Not Listed	Not Listed	*
Magnesium carbonate	39409-82-0	Not Listed	Not Listed	Not Listed	*
Simethicone emulsion	67762-90-7	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**

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### 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.
- 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 CO2, 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:** Not applicable

#### 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

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### 7. HANDLING AND STORAGE

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

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

**Storage Temperature:** Store at 25°C (77°F)

**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.

#### Exemestane

Manufacturer OEL: 8ug/m<sup>3</sup>

#### Silica colloidal, Ph. Eur.

Austria OEL - MAKs 4 mg/m<sup>3</sup>

#### Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup>

Lithuania OEL - TWA 5 mg/m<sup>3</sup>

Sweden OEL - TWAs 5 mg/m<sup>3</sup>

#### Microcrystalline cellulose

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>

#### 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>

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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>

<b>Analytical Method:</b>	Analytical method available for exemestane. Contact Pfizer Inc for further information.
<b>Exposure Controls</b>	
<b>Engineering Controls:</b>	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. Engineering controls should be used as the primary means to control exposures.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	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>	Tablets	<b>Color:</b>	Off-white to gray
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>pH:</b>	No data available.
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>	

#### Exemestane

Measured 7 Log P 2.5

#### Silica colloidal, Ph. Eur.

No data available

#### Crospovidone

No data available

#### Magnesium carbonate

No data available

#### Magnesium stearate

No data available

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Mannitol**

No data available

**Microcrystalline cellulose**

No data available

**Methylparaben**

No data available

**Macrogol 6000**

No data available

**Polysorbate 80**

No data available

**Polyvinyl alcohol**

No data available

**Sodium starch glycolate**

No data available

**Sucrose**

No data available

**Simethicone emulsion**

No data available

**Hydroxypropyl methylcellulose**

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

### 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:** None known

**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:** There are no data for this formulation. The remaining information describes the potential hazards of the individual ingredients.

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### 11. TOXICOLOGICAL INFORMATION

**Short Term:** May cause minimal eye irritation (based on animal data).  
**Long Term:** Animal studies have shown a potential to cause adverse effects on the fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system.  
**Known Clinical Effects:** Adverse effects associated with therapeutic use include hot flashes, nausea, fatigue, increased sweating, increased appetite, asthenia, and fever.

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

##### **Exemestane**

Rat Oral LD 50 > 5000 mg/kg  
Mouse Oral LD 50 > 3000mg/kg  
Rat Intraperitoneal LD 50 404-488mg/kg  
Mouse Intraperitoneal LD 50 396-419mg/kg

##### **Magnesium stearate**

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

##### **Mannitol**

Rat Oral LD 50 13500 mg/kg  
Mouse Oral LD 50 22 g/kg

##### **Microcrystalline cellulose**

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

##### **Polysorbate 80**

Rat Oral LD50 25 g/kg

##### **Sucrose**

Rat Oral LD50 29.7 g/kg

##### **Hydroxypropyl methylcellulose**

Rat Oral LD50 > 10,000 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)

##### **Exemestane**

Eye Irritation Rabbit Minimal  
Skin Irritation Rabbit Non-irritating  
Skin Sensitization - M & K Guinea Pig Negative

##### **Microcrystalline cellulose**

Skin Irritation Rabbit Non-irritating



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### 11. TOXICOLOGICAL INFORMATION

Eye Irritation Rabbit Non-irritating

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

##### Exemestane

4 Week(s)	Rat	Oral	150 mg/kg/day	NOAEL	None identified
4 Week(s)	Rat	Oral	1000 mg/kg/day	LOAEL	Liver, Thymus, Spleen, Reproductive system
4 Week(s)	Dog	Oral	30 mg/kg/day	LOAEL	Reproductive system
13 Week(s)	Mouse	Oral	30 mg/kg/day	LOAEL	Reproductive system
26 Week(s)	Rat	Oral	30 mg/kg/day	LOAEL	Female reproductive system

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

##### Exemestane

Reproductive & Fertility-Males	Rat	Oral	500 mg/kg/day	LOAEL	Fertility
Fertility and Embryonic Development	Rat	Oral	20 mg/kg/day	LOAEL	Fetotoxicity
Fertility and Embryonic Development	Rat	Oral	215 mg/kg/day	LOAEL	Fertility, Fetotoxicity
Embryo / Fetal Development	Rat	Oral	10 mg/kg/day	LOAEL	Developmental toxicity
Embryo / Fetal Development	Rabbit	Oral	30 mg/kg/day	LOAEL	Developmental toxicity

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

##### Exemestane

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Positive
<i>In Vivo</i> Chromosome Aberration	Mouse Bone Marrow	Negative
Unscheduled DNA Synthesis	Rat Hepatocyte	Negative
Mammalian Cell Mutagenicity	Hamster	Negative

##### Sucrose

Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
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#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Exemestane

2 Year(s)	Rat	Oral	315 mg/kg/day	NOAEL	Not carcinogenic
2 Year(s)	Mouse	Oral	150 mg/kg/day	LOAEL	Tumors, Liver, Kidneys

Carcinogen Status: See below

##### Silica colloidal, Ph. Eur.

IARC: Group 3 (Not Classifiable)

##### Crospovidone

IARC: Group 3 (Not Classifiable)

##### Polyvinyl alcohol

IARC: Group 3 (Not Classifiable)

##### Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)

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### 11. TOXICOLOGICAL INFORMATION

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater. Harmful effects to aquatic organisms could occur.

**Toxicity:**

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

**Exemestane**

<i>Pseudokirchneriella subcapitata</i> (Green Alga)	OECD	EC50	72 Hours	7.1 mg/L
<i>Oncorhynchus mykiss</i> (Rainbow Trout)	OECD	LC50	96 Hours	2.8 mg/L

**Bacterial Inhibition: (Inoculum, Method, End Point, Result)**

**Exemestane**

<i>Nostoc</i> sp. (Freshwater Cyanobacteria)	TAD	MIC	40 mg/L
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**Persistence and Degradability:**

**Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)**

**Exemestane**

OECD	Activated sludge	Ultimate (CO2 Evolution)	15.21% After	28 Day(s)	Not Ready
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**Bio-accumulative Potential:**

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

**Exemestane**

Measured	7	Log P	2.5
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**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.

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### 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



##### **Exemestane**

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

##### **Silica colloidal, Ph. Eur.**

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

##### **Crospovidone**

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

##### **Hydroxypropyl methylcellulose**

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 4
EU EINECS/ELINCS List	Not Listed

##### **Magnesium stearate**

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

##### **Mannitol**

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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	200-711-8
<b>Microcrystalline cellulose</b>	
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
<b>Methylparaben</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	202-785-7
<b>Macrogol 6000</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed
<b>Polysorbate 80</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>Polyvinyl alcohol</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>Sodium starch glycolate</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>Magnesium carbonate</b>	
CERCLA/SARA 313 Emission reporting	Not Listed

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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

#### Simethicone emulsion

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

#### 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

### 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.2; H401 - Toxic to aquatic life  
Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - 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.  
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 15 - Regulatory Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information. Updated Section 8 - Exposure Controls / Personal Protection.

## SAFETY DATA SHEET

**Material Name:** Exemestane Tablets (Greenstone LLC)  
**Revision date:** 06-Mar-2015

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**Version: 2.0**

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**Revision date:** 06-Mar-2015  
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**