



# SAFETY DATA SHEET

Revision date: 06-Mar-2015

Version: 4.0

Page 1 of 13

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

### Product Identifier

**Material Name:** Exemestane Tablets

**Trade Name:** Aromasin; Aromasine; Exemestane Pfizer

**Chemical Family:** Mixture

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

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

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

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-800-879-3477

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

**Emergency telephone number:**

**CHEMTREC (24 hours): 1-800-424-9300**

**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Emergency telephone number:**

**International CHEMTREC (24 hours): +1-703-527-3887**

## 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

## SAFETY DATA SHEET

Material Name: Exemestane Tablets  
Revision date: 06-Mar-2015

Page 2 of 13  
Version: 4.0

**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



**Other Hazards**

**Australian Hazard Classification (NOHSC):**

No data available  
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	*

## SAFETY DATA SHEET

Material Name: Exemestane Tablets  
Revision date: 06-Mar-2015

Page 3 of 13  
Version: 4.0

**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.

**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.

## SAFETY DATA SHEET

Material Name: Exemestane Tablets  
Revision date: 06-Mar-2015

Page 4 of 13  
Version: 4.0

**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

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

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

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

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### Exemestane

Pfizer OEL TWA-8 Hr: 8 µg/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>

Russia OEL - TWA 6 mg/m<sup>3</sup>

Spain OEL - TWA 10 mg/m<sup>3</sup>

Switzerland OEL - TWAs 3 mg/m<sup>3</sup>

Vietnam OEL - TWAs 10 mg/m<sup>3</sup>

5 mg/m<sup>3</sup>

#### Sucrose

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

## SAFETY DATA SHEET

Material Name: Exemestane Tablets  
Revision date: 06-Mar-2015

Page 5 of 13  
Version: 4.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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>
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>
Russia 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>
Switzerland OEL - TWAs	3 mg/m <sup>3</sup>
Vietnam OEL - TWAs	6 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

**Analytical Method:** Analytical method available for exemestane. Contact Pfizer Inc for further information.

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

Page 6 of 13  
Version: 4.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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>	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

**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)**

**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

**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

## SAFETY DATA SHEET

Material Name: Exemestane Tablets  
Revision date: 06-Mar-2015

Page 7 of 13  
Version: 4.0

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.  
**Short Term:** May cause minimal eye irritation (based on animal data). Active ingredient is not a skin irritant . Active ingredient is not a skin sensitizer . Not acutely toxic (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

## SAFETY DATA SHEET

Material Name: Exemestane Tablets  
Revision date: 06-Mar-2015

Page 8 of 13  
Version: 4.0

### 11. TOXICOLOGICAL INFORMATION

#### 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

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 NOEL None identified

4 Week(s) Rat Oral 1000 mg/kg/day LOEL Liver, Thymus, Spleen, Reproductive system

4 Week(s) Dog Oral 30 mg/kg/day LOEL Reproductive system

13 Week(s) Mouse Oral 30 mg/kg/day LOEL Reproductive system

26 Week(s) Rat Oral 30 mg/kg/day LOEL 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 LOEL Fertility

Fertility and Embryonic Development Rat Oral 20 mg/kg/day LOEL Fetotoxicity

Fertility and Embryonic Development Rat Oral 215 mg/kg/day LOEL Fertility, Fetotoxicity

Embryo / Fetal Development Rat Oral 10 mg/kg/day LOEL Developmental toxicity

Embryo / Fetal Development Rabbit Oral 30 mg/kg/day LOEL Developmental toxicity

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

##### Exemestane

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

## SAFETY DATA SHEET

Material Name: Exemestane Tablets  
Revision date: 06-Mar-2015

Page 9 of 13  
Version: 4.0

### 11. TOXICOLOGICAL INFORMATION

<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) *Salmonella* Negative

#### 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)

### 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

*Nostoc* sp. (Freshwater Cyanobacteria) TAD MIC 40 mg/L

#### **Persistence and Degradability:**

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

##### Exemestane

OECD Activated sludge Ultimate (CO<sub>2</sub> Evolution) 15.21% After 28 Day(s) Not Ready

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

# SAFETY DATA SHEET

Material Name: Exemestane Tablets  
Revision date: 06-Mar-2015

Page 10 of 13  
Version: 4.0

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

### Exemestane

Measured 7 Log P 2.5

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



#### 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.

## SAFETY DATA SHEET

Material Name: Exemestane Tablets  
Revision date: 06-Mar-2015

Page 11 of 13  
Version: 4.0

**15. REGULATORY INFORMATION**

<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	Not Listed
<b>Crospovidone</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	Not Listed
<b>Hydroxypropyl methylcellulose</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 4
<b>EU EINECS/ELINCS List</b>	Not Listed
<b>Magnesium stearate</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	209-150-3
<b>Mannitol</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>REACH - Annex IV - Exemptions from the obligations of Register:</b>	Present
<b>EU EINECS/ELINCS List</b>	200-711-8
<b>Microcrystalline cellulose</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>REACH - Annex XVII - Restrictions on Certain Dangerous Substances:</b>	Use restricted. See item 9[f]. powder
<b>EU EINECS/ELINCS List</b>	232-674-9
<b>Methylparaben</b>	
<b>CERCLA/SARA 313 Emission reporting</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>Inventory - United States TSCA - Sect. 8(b)</b>	Present
<b>Australia (AICS):</b>	Present
<b>EU EINECS/ELINCS List</b>	202-785-7

## SAFETY DATA SHEET

Material Name: Exemestane Tablets  
Revision date: 06-Mar-2015

Page 12 of 13  
Version: 4.0

### 15. REGULATORY INFORMATION

#### Macrogol 6000

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

#### Polysorbate 80

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

#### Polyvinyl alcohol

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

#### Sodium starch glycolate

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

#### Magnesium carbonate

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

#### 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
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## SAFETY DATA SHEET

Material Name: Exemestane Tablets  
Revision date: 06-Mar-2015

Page 13 of 13  
Version: 4.0

### 15. REGULATORY INFORMATION

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:** Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.

**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.

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Product Stewardship Hazard Communication

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

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**End of Safety Data Sheet**