## 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

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Address</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer Inc</td>
<td>Pfizer Pharmaceuticals Group</td>
<td>Pfizer Ltd</td>
</tr>
<tr>
<td></td>
<td>235 East 42nd Street</td>
<td>Ramsgate Road</td>
</tr>
<tr>
<td></td>
<td>New York, New York 10017</td>
<td>Sandwich, Kent</td>
</tr>
<tr>
<td></td>
<td>1-800-879-3477</td>
<td>CT13 9NJ</td>
</tr>
<tr>
<td></td>
<td></td>
<td>United Kingdom</td>
</tr>
<tr>
<td></td>
<td></td>
<td>+00 44 (0)1304 616161</td>
</tr>
</tbody>
</table>

### Emergency telephone number:
- CHEMTREC (24 hours): 1-800-424-9300
- Emergency telephone number: International CHEMTREC (24 hours): +1-703-527-3887

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

## 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

Other Hazards
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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Exemestane</td>
<td>107868-30-4</td>
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<td>Repr.Cat.2;R60-61 N; R51/53</td>
<td>Repr.1B (H360FD) Aquatic Acute 2 (H401) Aquatic Chronic 2 (H411)</td>
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<td>Silica colloidal, Ph. Eur.</td>
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<tr>
<td>Magnesium stearate</td>
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<td>209-150-3</td>
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</tr>
<tr>
<td>Microcrystalline cellulose</td>
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<td>232-674-9</td>
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<td>Not Listed</td>
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<tr>
<td>Sucrose</td>
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<td>200-334-9</td>
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<td>Titanium dioxide</td>
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<td>236-675-5</td>
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<td>Not Listed</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
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<td>Mannitol</td>
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<td>200-711-8</td>
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<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
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<td>Macrogol 6000</td>
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<tr>
<td>Polysorbate 80</td>
<td>9005-65-6</td>
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<td>Not Listed</td>
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<tr>
<td>Polyvinyl alcohol</td>
<td>9002-89-5</td>
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<td>Not Listed</td>
<td>Not Listed</td>
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<td>Sodium starch glycolate</td>
<td>9063-38-1</td>
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<td>Not Listed</td>
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<tr>
<td>Magnesium carbonate</td>
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<tr>
<td>Simethicone emulsion</td>
<td>67762-90-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
</tbody>
</table>
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
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/m³

**Silica colloidal, Ph. Eur.**
- **Austria OEL - MAKs:** 4 mg/m³

**Magnesium stearate**
- **ACGIH Threshold Limit Value (TWA):** 10 mg/m³
- **Lithuania OEL - TWA:** 5 mg/m³
- **Sweden OEL - TWAs:** 5 mg/m³

**Microcrystalline cellulose**
- **ACGIH Threshold Limit Value (TWA):** 10 mg/m³
- **Australia TWA:** 10 mg/m³
- **Belgium OEL - TWA:** 10 mg/m³
- **Estonia OEL - TWA:** 10 mg/m³
- **France OEL - TWA:** 10 mg/m³
- **Ireland OEL - TWAs:** 10 mg/m³
  - **Latvia OEL - TWA:** 4 mg/m³
  - **OSHA - Final PELS - TWAs:** 15 mg/m³
  - **Portugal OEL - TWA:** 10 mg/m³
  - **Romania OEL - TWA:** 10 mg/m³
  - **Russia OEL - TWA:** 6 mg/m³
  - **Spain OEL - TWA:** 10 mg/m³
  - **Switzerland OEL - TWAs:** 3 mg/m³
  - **Vietnam OEL - TWAs:** 10 mg/m³

**Sucrose**
- **ACGIH Threshold Limit Value (TWA):** 10 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>Exposure Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>6 mg/m³</td>
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<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
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Titanium dioxide

<table>
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<tr>
<th>Country</th>
<th>Exposure Limit</th>
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<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
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<td>ACGIH OELs - Notice of Intended Changes</td>
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<td>Australia TWA</td>
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<td>Austria OEL - MAKs</td>
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<td>Bulgaria OEL - TWA</td>
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<tr>
<td>Denmark OEL - TWA</td>
<td>6 mg/m³</td>
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<tr>
<td>Estonia OEL - TWA</td>
<td>5 mg/m³</td>
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<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
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<tr>
<td>Greece OEL - TWA</td>
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<tr>
<td>Ireland OEL - TWAAs</td>
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</tr>
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<td>Latvia OEL - TWA</td>
<td>4 mg/m³</td>
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<td>OSHA - Final PELS - TWAs:</td>
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<tr>
<td>Poland OEL - TWA</td>
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<tr>
<td>Portugal OEL - TWA</td>
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<td>Romania OEL - TWA</td>
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<td>Sweden OEL - TWAs</td>
<td>5 mg/m³</td>
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<tr>
<td>Switzerland OEL - TWAs</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>6 mg/m³</td>
</tr>
</tbody>
</table>

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


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.
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

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablets</th>
<th>Color:</th>
<th>Off-white to gray</th>
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<tbody>
<tr>
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<tr>
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<td>Boiling Point (°C):</td>
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<tr>
<td>Partition Coefficient:</td>
<td>(Method, pH, Endpoint, Value)</td>
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<td></td>
</tr>
</tbody>
</table>

Exemestane
Measured 7 Log P 2.5
Silica colloidal, Ph. Eur.
No data available
Crosopvidone
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
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: 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/m³

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
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  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)  Salmonella , E. coli  Negative
11. TOXICOLOGICAL INFORMATION

In Vitro Chromosome Aberration  Human Lymphocytes  Positive
In Vivo 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
*Pseudokirchneriella subcapitata* (Green Alga)  OECD  EC50  72 Hours  7.1 mg/L
*Oncorhynchus mykiss* (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 (CO2 Evolution)  15.21% After 28 Day(s)  Not Ready

Bio-accumulative Potential:
SAFETY DATA SHEET

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

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.

PZ00134
15. REGULATORY INFORMATION

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

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

Methylparaben
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
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: 200-334-9
- EU EINECS/ELINCS List: Not Listed

**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
15. REGULATORY INFORMATION

California Proposition 65
Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
EU EINECS/ELINCS List
carcinogen initial date 9/2/11 airborne, unbound particles of respirable size
Present
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.

Revision date: 06-Mar-2015
Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet