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

**Material Name:** Exemestane Tablets

**Trade Name:** Aromasin

**Chemical Family:** Mixture

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

---

2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exemestane</td>
<td>107868-30-4</td>
<td>Not listed</td>
<td>25</td>
</tr>
<tr>
<td>Silica colloidal, Ph. Eur.</td>
<td>112945-52-5</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>*</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crospovidone</td>
<td>9003-39-8</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Hypromellose</td>
<td>9004-65-3</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Mannitol</td>
<td>69-65-8</td>
<td>200-711-8</td>
<td>*</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
<td>*</td>
</tr>
<tr>
<td>Macrogol 6000</td>
<td>Not assigned</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>9005-65-6</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyvinyl alcohol</td>
<td>9002-89-5</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium starch glycolate</td>
<td>9063-38-1</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium carbonate</td>
<td>39409-82-0</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Simethicone emulsion</td>
<td>67762-90-7</td>
<td>Not listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

**Appearance:** Off-white to Gray Tablets

**Signal Word:** WARNING
**Statement of Hazard:**
Suspected of damaging fertility.
Suspected of damaging the unborn child.
Toxic to aquatic life.

**Additional Hazard Information:**

**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 the reproductive system.

**Known Clinical Effects:**
Adverse effects associated with the therapeutic use include hot flashes, nausea, fatigue, increased sweating, increased appetite, asthenia, and fever.

**EU Indication of danger:**
Toxic to reproduction, Category 2
Dangerous for the Environment

**EU Hazard Symbols:**

**EU Risk Phrases:**
R51 - Toxic to aquatic organisms.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

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

---

### 4. FIRST AID MEASURES

**Eye Contact:**
Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:**
Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

**Ingestion:**
Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:**
Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

### 5. FIRE FIGHTING MEASURES

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

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

**Fire Fighting Procedures:**
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:**
Not applicable
6. ACCIDENTAL RELEASE MEASURES

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

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.

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

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

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

Storage Conditions: Store in a cool place out of sun and away from heat, sparks, and flame.

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exemestane
Pfizer OEL TWA-8 Hr: 8 ug/m³

Magnesium stearate
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

Microcrystalline cellulose
OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
ACGIH Threshold Limit Value (TWA) = 5 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Titanium dioxide
OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Sucrose
OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
ACGIH Threshold Limit Value (TWA) = 5 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

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


Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:
8. PHYSICAL AND CHEMICAL PROPERTIES:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablets</th>
<th>Color:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight: Mixture</td>
</tr>
</tbody>
</table>

9. TOXICOLOGICAL INFORMATION

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

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

Exemestane
- Rat Oral LD50 > 5000 mg/kg
- Mouse Oral LD50 > 3000 mg/kg
- Rat Intraperitoneal LD50 404-488 mg/kg
- Mouse Intraperitoneal LD50 396-419 mg/kg

Magnesium stearate
- Rat Oral LD50 > 2000 mg/kg
- Rat Inhalation LC50 > 2000 mg/m³

Mannitol
- Rat Oral LD50 13500 mg/kg
- Mouse Oral LD50 22 g/kg

Microcrystalline cellulose
- Rat Oral LD50 > 5000 mg/kg
- Rabbit Dermal LD50 > 2000 mg/kg

Methylparaben
- Mouse Oral LD50 > 8000 mg/kg
- Rat Oral LD50 2280 mg/kg

Polysorbate 80
- Rat Oral LD50 25 g/kg

Titanium dioxide
- Rat Oral LD50 > 7500 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
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

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
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.

Mobility, Persistence and Degradability: The active ingredient in this formulation is water soluble and is expected to remain primarily in water.

Bioaccumulation and Toxicity: Toxicity to wastewater treatment microorganisms may occur. See aquatic toxicity data, below.

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

Exemestane
Green Algae OECD EC-50 72 Hours 7.1 mg/L

Bacterial Inhibition: (Species, Method, End Point, Duration, Result)

Exemestane
Nostoc sp. (Freshwater Cyanobacteria) MIC 9 Days 40 mg/L

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: T ; N
EU Indication of danger: Toxic to reproduction, Category 2
Dangerous for the Environment

EU Risk Phrases:
R51 - Toxic to aquatic organisms.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.
S57 - Use appropriate containment to avoid environmental contamination.

OSHA Label:
WARNING
Suspected of damaging fertility.
Suspected of damaging the unborn child.
Toxic to aquatic life.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

Exemestane
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4

Silica colloidal, Ph. Eur.
Australia (AICS): Present

Crospovidone
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present

Hypromellose
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4

Magnesium stearate
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 209-150-3

Mannitol
Inventory - United States TSCA - Sect. 8(b) Present
16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied.
End of Safety Data Sheet