MATERIAL SAFETY DATA SHEET

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

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ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Exemestane Tablets

Trade Name: Aromasin
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: Off-white to Gray Tablets
Signal Word: WARNING

Statement of Hazard: Suspected of damaging fertility.
Suspected of damaging the unborn child.

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 reproductive system.

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

EU Classification
EU Indication of danger: Toxic to reproduction, Category 2

EU Hazard Symbols:

T

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

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

2. HAZARDS IDENTIFICATION

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Exemestane	107868-30-4	Not Listed	Repr.Cat.2;R60-61	25
Silica colloidal, Ph. Eur.	112945-52-5	Not Listed	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Sucrose	57-50-1	200-334-9	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Crospovidone	9003-39-8	Not Listed	Not Listed	*
Hydroxypropyl methylcelluslose	9004-65-3	Not Listed	Not Listed	*
Mannitol	69-65-8	200-711-8	Not Listed	*
Methylparaben	99-76-3	202-785-7	Not Listed	*
Macrogol 6000	Not assigned	Not Listed	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	*
Polyvinyl alcohol	9002-89-5	Not Listed	Not Listed	*
Sodium starch glycolate	9063-38-1	Not Listed	Not Listed	*
Magnesium carbonate	39409-82-0	Not Listed	Not Listed	*
Simethicone emulsion	67762-90-7	Not Listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.

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.

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: 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.

Storage Conditions: Store as directed by product packaging.

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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Exemestane

Pfizer OEL TWA-8 Hr:	8 µg/m^3

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m^3 TWA
Australia TWA	10 mg/m^3
Belgium OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sweden OEL - TWAs	Listed

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m^3 TWA
Australia TWA	10 mg/m^3
Belgium OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
OSHA - Final PELS - TWAs:	15 mg/m^3 total 5 mg/m^3
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed

Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m^3 TWA
Australia TWA	10 mg/m^3
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELS - TWAs:	15 mg/m^3 total
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

Sucrose

ACGIH Threshold Limit Value (TWA)	10 mg/m^3 TWA
Australia TWA	10 mg/m^3
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELS - TWAs:	15 mg/m^3 total 5 mg/m^3
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed

Magnesium carbonate

Estonia OEL - TWA	Listed

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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.
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.
Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.
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.
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

Physical State:	Tablets	**Color:**	Off-white to gray
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

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

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m^3

Mannitol

11. TOXICOLOGICAL INFORMATION

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

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
Rat Subcutaneous LD 50 50 mg/kg

Sucrose
Rat Oral LD50 29.7 g/kg

Hydroxypropyl methylcelluslose
Rat Oral LD50 > 10,000 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

11. TOXICOLOGICAL INFORMATION

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

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

Crospovidone
IARC: Group 3

Polyvinyl alcohol
IARC: Group 3

Titanium dioxide
IARC: Group 3 (Not Classifiable)

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: (Inoculum, Method, End Point, Result)

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

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

EU Symbol: T ;
EU Indication of danger: Toxic to reproduction, Category 2

EU Risk Phrases:

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.

Canada - WHMIS: Classifications

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

Exemestane

15. REGULATORY INFORMATION

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

Silica colloidal, Ph. Eur.

Australia (AICS):	Listed

Crospovidone

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

Hydroxypropyl methylcelluslose

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

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	209-150-3

Mannitol

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-711-8

Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	232-674-9

Methylparaben

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	202-785-7

Polysorbate 80

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

Polyvinyl alcohol

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	236-675-5

Sodium starch glycolate

Inventory - United States TSCA - Sect. 8(b)	Listed

15. REGULATORY INFORMATION

Australia (AICS):	Listed

Sucrose

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9

Magnesium carbonate

Australia (AICS):	Listed

Simethicone emulsion

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

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

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 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 15 - Regulatory Information.

Prepared by: Product Stewardship Hazard Communications
Pfizer Global Environment, Health, and Safety Operations

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. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet