



# MATERIAL SAFETY DATA SHEET

Revision date: 27-Jun-2005

Version: 2.0

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

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**Emergency telephone number:**  
ChemSafe (24 hours): +44 (0)208 762 8322

### Material Name: Exemestane

**Trade Name:** Not determined  
**Synonyms:** PNU-155971  
**Chemical Family:** Aromatase inactivator; Antiestrogen  
**Intended Use:** Antineoplastic

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Exemestane	107868-30-4	Not listed	100

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

## 3. HAZARDS IDENTIFICATION

**Appearance:** White crystalline powder  
**Signal Word:** WARNING

**Statement of Hazard:** May cause harm to the unborn child  
May cause reproductive system effects Dangerous for the environment

**Eye Contact:** Minimal eye irritant in experimental animals  
**Skin Contact:** Not a skin irritant (based on animal data). Not a skin sensitizer (based on animal data).  
**Inhalation:** An Occupational Exposure Limit has been established for this substance; see Section 8.  
**Ingestion:** Not acutely toxic (based on animal data).

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

**Potential Health Effects:** 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.

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

**EU Hazard Symbols:**



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

**Additional Information:  
Note:**

For a more detailed discussion of potential health hazards and toxicity see Section 11. 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:** Fine particles (such as dust and mists) may fuel fires/explosions.

### 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:** Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly. Prevent discharge to drains.

**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:** Contain the source of the spill or leak if it is safe to do so. Spills should be handled by vacuuming or wet mopping. Avoid brush sweeping and generation of airborne dust. Transfer all waste to a labeled container and move it to a secure holding area. Prevent discharge to drains.

### 7. HANDLING AND STORAGE



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### Irritation / Sensitization: (Study Type, Species, Severity)

#### Exemestane

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

### 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

### 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

**Carcinogenicity Comments** Tumors seen in the mouse are thought to be species specific and not relevant to humans.

**Carcinogen Status:** Not listed as a carcinogen by IARC, NTP or US OSHA.

## 12. ECOLOGICAL INFORMATION

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

**Mobility, Persistence and Degradability:** This substance is water soluble and is expected to remain primarily in water. Not readily biodegradable.

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

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Partition Coefficient  
(n-octanol/water - Log P): 2.5 (pH 7)

## Exemestane

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

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

### Exemestane

Nostoc MIC 9 Days 40 mg/L

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

## 14. TRANSPORT INFORMATION

This material is not regulated for transportation / carriage.

## 15. REGULATORY INFORMATION

**EU Labeling:** 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

May cause harm to the unborn child

May cause reproductive system effects Dangerous for the environment

### Canada - WHMIS: Classifications

#### WHMIS hazard class:

D2a very toxic materials

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### 16. OTHER INFORMATION

**Prepared by:** Corporate Occupational Toxicology & Hazard Assessment

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**