A Division of Fresenius Kabi USA

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Product Name:	**Anastrozole Tablets**
Product Use/Restriction:	Aromatase Inhibitor Contains pharmacologically active material with anti-cancer properties.
Manufacturer Name:	Distributed / Manufactured by Fresenius Kabi USA, LLC
Address:	1501 East Woodfield Road Suite 300 East Schaumburg, IL 60173-5837
General Phone Number:	(847) 706-2084
Customer Service Phone Number:	(888) 386-1300
Emergency Phone Number:	(800) 424-9300
CHEMTREC:	For emergencies in the US, call CHEMTREC: 800-424-9300
MSDS Creation Date:	June 28, 2010
MSDS Revision Date:	January 08, 2012

HMIS

Health Hazard	1*
Fire Hazard	1
Reactivity	0
Personal Protection	X

* Chronic Health Effects

SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Anastrozole	120511-73-1	1 mg per tablet	

SECTION 3 - HAZARDS IDENTIFICATION

Emergency Overview:	This product is intended for therapeutic use only when prescribed by a physician. For oral administration only. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Exposure to dust from crushed tablets may cause adverse health effects.
Route of Exposure:	Inhalation Ingestion
Potential Health Effects:	
Eye:	Dust may cause slight irritation.
Skin:	Skin contact with powder or dust may cause irritation
Inhalation:	Inhalation of powder or dust may cause irritation
Ingestion:	Ingestion of this product may result in central nervous system effects including headache, abdominal pain, nausea, fatigue, and may lead hot flushes
Chronic Health Effects:	Possible risk of harm to the unborn child. May impair fertility. Limited evidence of a carcinogenic effect.

SECTION 4 - FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176 or (847) 706-2084.

SECTION 5 - FIRE FIGHTING MEASURES

Flammable Properties:	Dust may be flammable
Flash Point:	Not established.
Flash Point Method:	Not established.

Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personnel Precautions:	For large spills:Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	This material will settle out of the air.
Methods for cleanup:	Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

SECTION 7 - HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at controlled room temperature 20 to 25°C (68 to 77°F) [See USP Controlled Room Temperature].
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling dust, vapor or mist.

SECTION 8 - EXPOSURE CONTROLS, PERSONAL PROTECTION - EXPOSURE GUIDELINES

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended oral administration purpose. Otherwise (such as in manufacturing), use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended oral administration purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions (such as in manufacturing). A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 - PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Tablets
Color:	White
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Not established.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	Not established.
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 - STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Incompatible Materials:	Avoid acids and bases. Avoid contact with oxidizing agents.

SECTION 11 - TOXICOLOGICAL INFORMATION

Anastrozole :

Ingestion:	Oral - Rat TDLo: 580 mg/kg/29D (Continuous) [Endocrine - Change in gonadotropins Related to Chronic Data - Changes in ovarian weight Related to Chronic Data - Changes in uterine weight] Oral - Rat TDLo: 1960 mg/kg/7W (Continuous) [Related to Chronic Data - Changes in prostate weight Related to Chronic Data - Changes in testicular weight] Oral - Rat TDLo: 350 mg/kg/14D (Intermittent) [Liver - Changes in liver weight Related to Chronic Data - Changes in prostate weight] Oral - Mouse TDLo: 2.1 mg/kg/21D (Intermittent) [Tumorigenic - Active as anti-cancer agent]
Other Toxicological Information:	Intraperitoneal. - Rat TDLo: 22500 ug/kg/15D (intermittent) [Endocrine - Other changes Blood - Changes in serum composition (e.g., TP, bilirubin, cholesterol)]

SECTION 12 - ECOLOGICAL INFORMATION

Bioaccumulation:	Low potential for bioaccumulation.
Biodegradation:	Not biodegradable in water
Mobility In Environmental Media:	The mobility depends on soil type; low for acidic soil and moderated for soil with pH 7.7

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 - TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.

SECTION 15 - REGULATORY INFORMATION

Anastrozole :

TSCA Inventory Status:	Exempt
Canada DSL:	Exempt

SECTION 16 - ADDITIONAL INFORMATION

HMIS Health Hazard:	1*

HMIS Fire Hazard:	1
HMIS Reactivity:	0
HMIS Personal Protection:	X
MSDS Creation Date:	June 28, 2010
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