RE: **Anastrozole Tablets, USP 1mg**

1mg (30s) NDC # 51991-620-33
1mg (90s) NDC # 51991-620-90
1mg (1000s) NDC # 51991-620-10

To Whom It May Concern:

The purpose of the OSHA Hazard Communication Standard (HCS) is to ensure that hazards of all chemicals produced by a manufacturer are classified and these classified hazards are communicated to employers and employees through a Safety Data Sheet (SDS).

As per 29 CFR 1910.1200(b)(6)(vii) Occupational Safety and Health Administration (OSHA), any food or drug, as defined in the Federal Food, Drug, and Cosmetic Act (FD&C Act), is exempt from the HCS and does not require a SDS if it is in its final solid dosage form and/or it is packaged by the chemical manufacturer for sale to the consumers in a retail establishment.

"Any drug as that term is defined in the Federal Food Drug and Cosmetic Act (21 U.S.C. 390 et seq.) when it is in solid, final form for direct administration to the patient (e.g., tablets or pills): drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs): and drug intended for personal consumption by employees while in the workplace (e.g., first aid supplies):"

Breckenridge Pharmaceutical Inc.'s products are regulated by the FD&C Act and are subject to the labeling requirements as governed by the Act and the FDA. Breckenridge Pharmaceutical Inc.'s products are manufactured to their final dosage forms and are packaged for sale to consumers.

Breckenridge Pharmaceutical Inc. is exempt from OSHA requirements for an SDS for the product mentioned above, However the SDS for the Active Ingredient for this product is attached as a service to our customers, to help them to comply with the regulations depending on how the product is used.

Please contact us if you have any further questions.

Quality Assurance Dept.
Breckenridge Pharmaceutical, Inc.

SECTION 1: Identification of the substance / mixture and of the company /undertaking

1.1 Product Identifier

Product form : Substance
Substance/Trade Name : **Anastrozole**
CAS No. : 120511-73-1
Formula : $C_{17}H_{19}N_5$
Synonyms : α,α,α',α'-Tetramethyl-5-(1H-1,2,4-triazol-1-ylmethyl)-1,3-benzenediacetonitrile (or) 2,2'-[5-(1H-1,2,4-triazol-1-yl-ylmethyl)-1,3-phenylene]di(2-methylpropionitrile)

1.2 Relevant identified uses of the substance or mixture and uses advised against

1.2.1 Relevant identified uses

Main use category : Active Pharmaceutical Ingredient
Use of substance /mix : For finished product Manufacturing purpose, Rx only.

1.2.2 Uses advised against

No additional information available

1.3 Name, Address and Telephone of the Responsible Party

Company Name : Natco Pharma Limited - Chemical Division
Address : Mekaguda (Village), Kothur (Mandal), Mahaboob Nagar (Dist), Telangana (State), India. Pin: 509223
Telephone : +91 8548 249493
Web site : www.natcopharma.com
E.mail : natinfo@natcopharma.co.in

1.4 Emergency Telephone number: +91 8548 249496

2. SECTION 2: Hazards Identification

2.1 Classification of substance or mixture

Physical Hazards full text of H-phrases see section 16	:	GHS-US	Not classified
		Regulation (EC) No. 1272/2008 [CLP]	Repr. 1A H360Fd
		Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]	Not classified
Health Hazards	:	Acute toxicity, oral	Category 3
		Carcinogenicity	Category 2
		Reproductive toxicity	Category 1
		Specific target organ toxicity, repeated exposure	Category 1 (endocrine system)
OSHA hazards	:	Not classified	

2.2 Label Elements

Label Elements :



GHS08

According to (EC) No: 1272/2008 (CLP)

Signal word : Danger
Hazard statement :
H 301 Toxic if swallowed
H 351 Suspected of causing cancer
H373 Danger of cumulative effects
H 360 May damage fertility or the unborn child
H 372 Causes damage to organs through prolonged or repeated exposure

Precautionary statement:

Prevention	:	P201	Obtain special instructions before use
		P202	Do not handle until all safety precautions have been read and understood.
		P264	Wash thoroughly after handling
		P280	Wear protective gloves/protective clothing/eye protection/face protection
Response	:	P312	If swallowed: Immediately call a poison center / doctor. Rinse mouth
		P308 + P313	If exposed or concerned: Get medical advice/attention.
Storage	:	P405	Store locked up
Disposal		P501	Dispose of contents/container in accordance with local/regional/ international regulations.
Other Hazard(s)	:	GHS-US: Not classified; EC No: 1272/2008 (CLP): Exposure may produce an allergic reaction.	

SECTION 3: Composition / Information on ingredients

3.1 Substance

Name	CAS number	%
Anastrozole	120511-73-1	100

3.2 Mixtures

Not applicable

SECTION 4: First-aid measures

4.1 Description of First aid measures

Inhalation	:	P304+P340	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	:	P303+P361	Rinse skin with water/shower.
		P353	Get medical attention if irritation develops and persists.
Eye contact	:	P305+P351	Rinse with water holding the eyes wide open. Remove contact lenses.
		P338	Get medical attention if irritation develops and persists.
Ingestion	:	P330	Rinse mouth out with water

4.2 Most important symptoms/effects, acute and delayed

Reproductive system effects

4.3 Indication of Immediate medical attention and special treatment needed

In all cases of doubt, or when symptoms persist, seek medical attention.

In case of shortness of breath, give oxygen, keep victim warm. Keep victim under observation. Symptoms may be delayed. Treatment of overdose should be symptomatic and supportive and may include the following.

1. Administer activated charcoal as slurry; 2. Heamodialysis may be beneficial [Meditext 2008 and USP DI 2008]

General Information: Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

SECTION 5: Fire-fighting measures

Suitable extinguishing media	:	Water, Foam, Dry chemical or CO_2
Unsuitable extinguishing media	:	None known
Specific hazards arising from the chemical	:	No unusual fire or explosion hazards noted.
Fire-fighting instructions	:	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Fire-fighters should use self-contained breathing equipment and protective clothing.
Specific methods	:	Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accident release measures

6.1. Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

Methods for clean up : Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts (moisten if appropriate) during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid all contact and inhalation of dust, mist, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.

7.2. Conditions for safe storage including any incompatibilities

Technical measures : This material should be handled and stored as per label instructions to ensure product integrity.

Storage conditions : Store in tight light resistant container, store at 25°C excursions permitted between 15°C and 30°C.

Incompatible products : Strong oxidizing agents

SECTION 8: Exposure controls/personal protection

Biological limit values : No biological exposure limits noted for the ingredient(s).

Exposure guidelines : No exposure standards allocated.

Appropriate engineering controls : Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate material. Avoid any open handling of this material, particularly for grinding, crushing, weighing (or) enclosure, glove box, or other effective containment.

8.1 Individual protection measures, such as personal protective equipment

Eye/face protection : Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection

Hand protection	:	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and inner gloves only after removing other personal protective equipment.
Other	:	For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.
Respiratory protection	:	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Thermal hazards	:	Not available.
General hygiene considerations	:	Handle in accordance with good industrial hygiene and safety practice.

SECTION 9: Physical and Chemical properties

Appearance	:	Off-white powder.
Physical state	:	Solid.
Form	:	Powder.
Odor	:	Not available
Odor threshold	:	Not available
pH	:	Not available
Melting point	:	177.8-188.6 °F (81-87 °C)
Freezing point	:	Not available
Boiling point	:	Not available
Flash point	:	Not available
Evaporation rate	:	Not available
Flammability (solid, gas)	:	Not available
Flammability limit	:	Not available
Explosive limits	:	Not available
Vapor pressure	:	Not available
Vapor density	:	Not available
Relative density	:	Not available
Solubility in water	:	Moderately soluble (<1mg/L)
Solubility (Other)	:	Freely soluble in methanol, in acetone, in ethanol and in tetrahydrofuran; very soluble in acetonitrile.
Partition coefficient	:	1.56 (n-octanol/water)
Auto-ignition temp.	:	Minimum ignition energy (MIE): 1.2mJ (tested without conductance)
Specific powder (bulk) resistivity	:	>E+12 Ohm-m (at 24°C and 50% Humidity)
Decomposition temp.	:	Not available.
Viscosity	:	Not available.

SECTION 10: Stability and Reactivity

Reactivity	:	No reactivity hazards known
Chemical stability	:	Material is stable under normal conditions
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use
Conditions to avoid	:	None known
Incompatible materials	:	None known
Hazardous decomposition	:	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions

SECTION 11: Toxicological information

Information on likely routes of exposure:

Ingestion	:	Toxic if swallowed
Inhalation	:	Due to lack of data the classification is not possible.
Skin contact	:	Due to lack of data the classification is not possible.
Eye contact	:	Due to lack of data the classification is not possible.
Symptoms related to the physical, chemical and toxicological characteristics	:	Chest pain. Difficulty breathing. Swelling of feet or lower legs. Numbness or tingling in hands or feet. Unusual tiredness or weakness. Severe dizziness. Continuing headache. Fever or chills. Cough. Hoarseness. Body aches or pain. Sore throat. Dry mouth or throat. Bluish-discoloration of leg or foot. Change in appetite or weight. Bone pain. Constipation. Diarrhea, nausea or vomiting. Runny nose. Tender glands in neck. Trouble swallowing or voice changes. Mood or mental changes. Flushing. Sweating. Skin rash or itchy skin. Breast pain. Trouble sleeping. Vaginal dryness. Heavy vaginal bleeding. Painful or difficult urination. Hair loss.
Germ cell mutagenicity	:	Due to lack of data the classification is not possible.
Reproductive toxicity	:	Possible reproductive hazard. May damage fertility or the unborn child. There was no evidence of increased birth defects in rats or rabbits administered Anastrozole doses up to 1.0 and 0.2mg/kg/day, respectively. Oral administration of Anastrozole to female rats produced significant incidence of infertility and reduced numbers of viable pregnancies at mg/kg/day. Increased pregnancy loss occurred in rats and rabbits administered doses equal to or greater than 0.1 and 0.02 mg/kg/day (LD50 (oral-rat): Between 100 to 250 mg/kg) respectively. Evidence of fetotoxicity, including delayed fetal development (i.e, incomplete ossifications and depressed fetal body weights), was observed in rats administered doses of 1mg/kg/day. In rabbits, Anastrozole caused pregnancy failure at doses equal to or greater than 1.0mg/kg/day. Multiple-dose studies in rats and administered Anastrozole for 6months studies in female dogs administered doses equal to greater than 1mg/kg/day.
Specific target organ toxicity-single exposure	:	Due to lack of data the classification is not possible.
Specific target organ toxicity-repeated	:	Causes damage to organs through prolonged or repeated exposure.

exposure

Aspiration hazard : Not classified.

SECTION 12: Ecological information

Ecotoxicity : There are no data on the ecotoxicity of this product

Persistence and degradability : No data available on the degradability of this product.

Bioacuumulative potential : Log Pow 2.37 at 20°C.
This material has a low potential for bioaccumulation and is unlikely to be biodegradable in water.

Mobility in soil : Not available

Other adverse effects : Not available

SECTION 13: Disposal considerations

Disposal instructions : Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations : Not available

Hazardous waste code : Not available

Waste from residues/unused products : Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

SECTION 14: Transport information

	DOT	ADR	IMDG	IATA
UN Number	UN2811	UN2811	UN2811	UN2811
Un proper shipping name	Toxic solid, organic, n.o.s (Anastrozole)	Toxic solid, organic, n.o.s (Anastrozole)	Toxic solid, organic, n.o.s (Anastrozole)	Toxic solid, organic, n.o.s (Anastrozole)
Transport hazard class(es)	6.1	6.1	6.1	6.1
Subsidiary class(es)	Not available	Not available	Not available	Not available
Packing group	III	III	III	III
Transport in bulk according to Annexure-II of MARPOL 73/78 and IBC code	Not applicable	Not applicable	Not applicable	Not applicable
Dangerous for environment	No			
Marine pollutant	No			

DOT; IATA



SECTION 15: Regulatory information

US federal regulations : CERCLA/SARA Hazardous substances-Not applicable.
One or more components are not listed on TSCA.

EU-Regulations No REACH Annex XVII restrictions

Superfund amendments and reauthorization act of 1986 (SARA)

Hazard categories : Immediate hazards-Yes
Delayed hazard-Yes
Fire hazard-No
Reactivity hazard-No

SARA 302 Extremely Hazardous substance : No

SARA 311/312 Hazardous Chemical : Yes

Other federal regulations

Safe Drinking Water Act (SDWA) : Not regulated.

Food and Drug Administration (FDA) : Not regulated.

US state regulations : California safe drinking water and toxic enforcement act of 1986 (Proposition 65): This material is not known to contain any currently listed as carcinogens or reproductive toxins.

International inventories

Country(s) or region	Inventory name	On inventory (Yes/no)*
Australia	Australian inventory of chemical substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances list (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

* A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

SECTION 16: Other information

Full text of R-, H= and EUH-Phrases

Repr. 1A	:	Reproductive toxicity, Category 1A
H360Fd	:	May damage fertility, Suspected of damaging the unborn child

Reference (s) : SDS of Anastrozole from USPRS and EPCRS

Disclaimer : For manufacturing purpose only,
The above information believed to be correct but does not purport to be all-inclusive and shall be used as a guide.
NATCO shall not be held liable for any damage resulting from handling or from contact with the above product.

Revision information : This document has undergone significant changes and should be reviewed in it's entirely.