View Section : 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16

SECTION 1: CHEMICAL PRODUCT and COMPANY IDENTIFICATION (N/A)

Product Name:	**Aztreonam for Injection, USP**
Manufacturer Name:	APP Pharmaceuticals
Address:	1501 East Woodfield Road Suite 300 East Schaumburg, IL 60173 Emergency Telephone: (800) 551-7176
Product Description:	Category: Anti-Infective
Business Phone:	(847) 969-2700
Revision Date:	09/07/07 Version: 1.0.0 Chemical Name: Aztreonam

To Top of page

SECTION 2 : COMPOSITION, INFORMATION ON INGREDIENTS : (N/A)

Ingredient Name	CAS#	Ingredient Percent
Aztreonam	78110-38-0	
EC Index Number:	1	
	Amount: 500 mg, 1 gm and 2 gm vials	
L-Arginine	74-79-3	
EC Index Number:	1	
	Amount: 780 mg per gram of aztreonam	

To Top of page

SECTION 3 : HAZARDS IDENTIFICATION : (N/A)

Applies to All Ingredients :

Route of Exposure:	Inhalation, eye/skin contact, or ingestion
Carcinogenicity:	Chemical Listing as Carcinogen
OSHA Designation:	No
NTP Designation:	No
IARC Designation:	No
Signs/Symptoms:	Signs & Symptoms of Exposure & Overexposure: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Possible adverse reactions include: skin rash with redness or itching; stomach cramps or pain; altered sense of taste; bad breath; headache; breast tenderness; increased sweating; flushing; trouble sleeping; mouth ulcer; nausea; vomiting; small, non-raised, round, purplish or red spots on the skin; burning or prickling feeling of skin; muscular aches; runny nose; and ringing in ears. Possible allergic reaction to material if inhaled, ingested or in contact with skin. Occupational exposure has not been fully investigated.
Aggravation of Pre-Existing Conditions:	Medical Conditions Aggravated by Accidental Exposure: Individuals with a known hypersensitivity to aztreonam or any other component in the formulation. Note: Not Applicable

To Top of page

SECTION 4 : FIRST AID MEASURES : (N/A)

Eye Contact:	Immediately flush eyes with copious quantities of water for at least 15 minutes.
Skin Contact:	Wash affected areas with copious quantities or water.
Inhalation:	Remove to fresh air immediately. Seek medical attention. When appropriate and trained in CPR, provide artificial respiration.
Ingestion:	Do not induce vomiting. Flush mouth out with water immediately. Seek medical attention.

Contact Info: For Adverse Event Information, please call (800) 551-7176 or (847) 969-2700.

To Top of page

SECTION 5 : FIRE FIGHTING MEASURES : (N/A)

Fire:	Fire Point: Not Established
Flash Point:	Closed Cup Flash Point: Not Established Open Cup Flash Point: Not Established
Flash Point Method:	Closed Cup Open Cup
Upper Flammable or Explosive Limit:	Not Established
Lower Flammable or Explosive Limit:	Not Established
Auto Ignition Temperature:	Not Established
Hazardous Combustion Byproducts:	When heated to decomposition material emits toxic fumes of NOx and SOx. Emits toxic fumes under fire conditions.
Fire Fighting Instructions:	Water spray, dry chemical, carbon dioxide, or foam as appropriate to surroundings.
Fire Fighting Equipment:	Firefighters should wear protective clothing and self-contained breathing equipment. General Hazard: Burning produces irritant fumes.

To Top of page

SECTION 6 : ACCIDENTAL RELEASE MEASURES : (N/A)

Spill Cleanup Measures:	Wear recommended personal protective equipment (Sec Section 8 - Exposure Controls/Personal Protection). Use absorbent towels or brooms to clean-up spill. Ventilate area and wash spill site after pick-up is complete.

To Top of page

SECTION 7 : HANDLING and STORAGE : (N/A)

Handling:	General Handling: When handling pharmaceutical products, avoid all contact with skin, eyes, nostrils, and mouth. Avoid inhalation of dust, fumes, mist, and/or vapors. Wash thoroughly after handling.
Storage:	Storage Conditions: Store original packages at 20 deg to 25 deg C (68 deg to 77 deg F). Avoid excessive heat.

To Top of page

SECTION 8 : EXPOSURE CONTROLS, PERSONAL PROTECTION : (N/A)

Engineering Controls:	General room ventilation is usually satisfactory. Use local exhaust ventilation if necessary.
Skin Protection Description:	Protect exposed skin.
Hand Protection Description:	Disposable latex gloves recommended.
Eye/Face Protection:	Wear safely glasses with sideshields.
Respiratory Protection:	Breathing apparatus only if aerosol or dust is formed.
Exposure Limits:	Compound: Aztreonam STEL: OEL: Not Established Compound: L-Arginine STEL: OEL: Not Established

Ingredient Guidelines

Ingredient: Aztreonam	
Guideline Type:	ACGIH TLV-TWA
Guideline Information:	OEL: Not Established
Guideline Type:	OSHA PEL-TWA
Guideline Information:	OEL: Not Established
Ingredient: L-Arginine	
Guideline Type:	OSHA PEL-TWA
Guideline Information:	OEL: Not Established
Guideline Type:	ACGIH TLV-TWA
Guideline Information:	OEL: Not Established

To Top of page

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES : (N/A)

Physical State/Appearance:	Physical Form: Crystalline powder
Color:	White
Odor:	Odorless.
pH:	4.5 - 7.5
Vapor Pressure:	Not Established
Vapor Density:	Relative: Not Established
Boiling Point:	Not Established

Freezing Point:	Not Established
Melting Point:	227 deg C (decomposes)
Solubility:	Solvent: Very soluble.
Percent Volatile:	Not Established
Molecular Weight:	435.44
	Note: Not Applicable

To Top of page

SECTION 10 : STABILITY and REACTIVITY : (N/A)

Chemical Stability:	Stable
Conditions to Avoid:	Exposure to light, moisture, and heat.
Hazardous Polymerization:	Will not occur

To Top of page

SECTION 11 : TOXICOLOGICAL INFORMATION : (N/A)

Applies to all ingredients:

Other Toxicological Information:

Signs & Symptoms of Exposure & Overexposure:
This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Possible adverse reactions include: skin rash with redness or itching; stomach cramps or pain; altered sense of taste; bad breath; headache; breast tenderness; increased sweating; flushing; trouble sleeping; mouth ulcer; nausea; vomiting; small, non-raised, round, purplish or red spots on the skin; burning or prickling feeling of skin; muscular aches; runny nose; and ringing in ears. Possible allergic reaction to material if inhaled, ingested or in contact with skin.
Occupational exposure has not been fully investigated.

Medical Conditions Aggravated by Accidental Exposure: Individuals with a known hypersensitivity to aztreonam or any other component in the formulation.

Other:
Pregnancy Category B: Aztreonam crosses the placenta and enters the fetal circulation. Studies in pregnant rats and rabbits revealed no evidence of embryo - or fetotoxicity or teratogenicity. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response.

L-Arginine :

Ingestion Effects:

Acute Toxicity:
LD50 Oral Rat: > 10 gm/kg
LD50: Oral Mouse: > 10 gm/kg

To Top of page

SECTION 12 : ECOLOGICAL INFORMATION : (N/A)

To Top of page

SECTION 13 : DISPOSAL CONSIDERATIONS : (N/A)

Waste Disposal: Disposal Procedure: Treatment, storage, transportation, and disposal must be in accordance with applicable federal, state, and local regulations.

To Top of page

SECTION 14 : TRANSPORT INFORMATION : (N/A)

DOT Shipping Name:	Not Applicable
DOT UN Number:	Not Applicable
DOT Hazard Class:	Not Applicable
DOT Subpart E Labeling Requirement:	Not Applicable

To Top of page

SECTION 15 : REGULATORY INFORMATION : (N/A)

To Top of page

SECTION 16 : ADDITIONAL INFORMATION : (N/A)

MSDS Revision Date:	09/07/07 Version: 1.0.0

Disclaimer:

The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using those materials based on their purpose and intended use. Abraxis BioScience, Inc. assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of

the product.

Key to Abbreviations:

ACGIH - American Conference of Governmental Industrial Hygienists
HEPA - High Efficiency Particulate Air
IARC - International Agency for Research on Cancer
NA - Not Applicable
NE - Not Established
NG - Not Given
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OEL - Occupational Exposure Limit
OSHA - Occupational Safety and Health Administration
PEL - Permissible Exposure Limit
PPM - Parts Per Million
QS - Quantity Sufficient
RCRA - Resource Conservation and Recovery Act
STEL - Short Term Exposure Limit
TLV - Threshold Limit Value
USP - United Slates Pharmacopeia

Copyright© 1996-2009 Actio Corporation. All Rights Reserved.

To Top of page

