



## MATERIAL SAFETY DATA SHEET

### SECTION 1 - CHEMICAL PRODUCT & COMPANY IDENTIFICATION

<b>Pfizer Inc</b>	<b>Emergency telephone</b>	1-800-228-5635
<b>Animal Health Group</b>	<b>Hours of operation</b>	24 Hours
<b>812 Springdale Drive</b>	<b>Telephone</b>	1-800-877-6250
<b>Exton, PA 19341</b>		

<b>Product name</b>	<b>Atipamezole hydrochloride sterile injectable solution</b>
<b>Synonyms</b>	ANTISEDAN® sterile injectable solution; Atipamezole hydrochloride sterile injectable solution
<b>Chemical family</b>	Imidazole
<b>Therapeutic use</b>	Antagonist to alpha-2-adrenoceptor induced sedation
<b>Description</b>	Clear aqueous solution.

### SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Hazardous Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Methylparaben	99-76-3	Trade Secret
Atipamezole hydrochloride	104075-48-1	Trade Secret
Sodium chloride	7647-14-5	Trade Secret
Water for injection, USP	7732-18-5	Trade Secret

### SECTION 3 - HAZARDS IDENTIFICATION

**CERCLA ratings (scale 0-3)** Health=1 Fire=0 Reactivity=0

**NFPA ratings (scale 0-4)** Health=1 Fire=0 Reactivity=0

**Signal word** **CAUTION!**

**Statements of hazard** MAY CAUSE EYE, SKIN AND RESPIRATORY TRACT IRRITATION.

MAY CAUSE CENTRAL NERVOUS SYSTEM EFFECTS.

#### Eye

**Short term effects** May cause eye irritation. Signs and symptoms might include redness, swelling, blurred vision or pain.

**Long term effects** None known; see short-term effects above.

#### Skin

**Short term effects** May cause skin irritation and allergic skin reactions following direct or repeated contact with this material.

**Long term effects** None known; see short term-effects above.

#### Inhalation

**Short term effects** May cause mucous membrane and respiratory tract irritation. May cause

---

### SECTION 3 - HAZARDS IDENTIFICATION continued

---

	central nervous system effects. May also cause hypersensitivity reactions in susceptible individuals.
<b>Long term effects</b>	Not known; see short-term effects above.
<b>Ingestion</b>	
<b>Short term effects</b>	Ingestion of this material may cause effects similar to those seen in animal studies including effects on nervous system and respiratory system
<b>Long term effects</b>	Not known; see short-term effects above.

---

### SECTION 4 - FIRST AID MEASURES

---

<b>Eyes</b>	Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.
<b>Skin</b>	Wash skin with soap and plenty of water. Remove contaminated clothing and shoes. Wash clothing and thoroughly clean shoes before reuse. If irritation occurs or persists, get medical attention.
<b>Inhalation</b>	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.
<b>Ingestion</b>	If swallowed, get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

---

### SECTION 5 - FIRE FIGHTING MEASURES

---

<b>General hazard</b>	Toxic or corrosive emissions may be given off in a fire. See Hazardous combustion products, below, and Hazardous decomposition products in Section 10 - STABILITY AND REACTIVITY.
<b>Fire fighting instructions</b>	Wear approved positive pressure, self contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.
<b>Extinguisher to use</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Hazardous combustion products</b>	Emits toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen, hydrogen chloride and other chlorine-containing compounds.
<b>Flash point</b>	Not known
<b>Autoignition</b>	Not known
<b>Minimum explosive concentration for dust/vapor</b>	Not known
<b>Flammability limits</b>	Not known

---

### SECTION 6 - ACCIDENTAL RELEASE MEASURES

---

<b>Occupational spill</b>	Contain the source of the spill or leak. Absorb spills with non-combustible absorbent material and transfer to labeled container for treatment and disposal. Clean spill area thoroughly with detergent and water.
<b>Clean up - large spill</b>	Review Sections 3 and 8 before proceeding with clean up. Contain the source of the spill or leak. Dike or pump spilled material into a labeled recovery container or absorb with non-combustible material. Put saturated absorbent material into a labeled container. Close container and move it to a secure holding area. Clean spill area thoroughly with detergent and water. Collect wash water with a non-combustible absorbant material and transfer to labeled

---

**SECTION 6 - ACCIDENTAL RELEASE MEASURES continued**

---

container for treatment and disposal.

---

**SECTION 7 - HANDLING AND STORAGE**

---

<b>General handling</b>	Keep away from heat. Use with adequate ventilation. Do not get in eyes. Avoid prolonged or repeated contact with skin and clothing. Avoid breathing vapor or mist. When handling, use proper personal protective equipment specified in Section 8. Wash thoroughly after handling.
<b>Storage</b>	Store out of direct sunlight in a well ventilated area at ambient temperature.
<b>Temperature range</b>	15 - 30 °C

---

**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION**

---

<b>Exposure limits</b>	<b>Hazardous Ingredient</b>	<b>OEL</b>	<b>Type</b>	<b>Value</b>
	Atipamezole hydrochloride	Pfizer	TWA-8	Not established

**Exposure information** No Occupational Exposure Limit (OEL) established by Pfizer for this mixture or the active ingredient it contains.

**Ventilation** General room ventilation is adequate unless the process generates airborne mist or vapor.

**Eye protection** None required under normal and foreseeable conditions of use.

**Skin protection** None required under normal and foreseeable conditions of use.

**Hand protection** Rubber gloves are recommended if there is a potential for contact.

**Respiratory protection** Under normal conditions of use, respiratory protection is not expected to be necessary. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure.

---

**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

---

<b>Physical form</b>	Liquid
<b>Color</b>	Colorless.
<b>Clarity</b>	Clear
<b>Odor</b>	Odorless.
<b>Molecular weight</b>	Not applicable
<b>Molecular formula</b>	Not applicable
<b>pH</b>	Not known
<b>Melting point</b>	Not known
<b>Pour point</b>	Not known
<b>Vapor pressure</b>	Not known
<b>Water solubility</b>	Soluble in water
<b>Solvent solubility</b>	No data available

---

**SECTION 10 - STABILITY AND REACTIVITY**

---

<b>Reactivity</b>	Stable.
<b>Conditions to avoid</b>	Avoid excessive exposure to light.
<b>Incompatibilities</b>	None known.

---

## SECTION 10 - STABILITY AND REACTIVITY continued

<b>Hazardous decomposition products</b>	No data available. See Section 5 - under Hazardous combustion products.
<b>Hazardous polymerization</b>	Will not occur.
<b>Oxidizing properties</b>	No data available.
<b>Explosive properties</b>	None known or expected.

---

## SECTION 11 - TOXICOLOGY INFORMATION

<b>Acute toxicity</b>	<b>Type</b>	<b>Route</b>	<b>Species</b>	<b>Dosage</b>
	LD50	Oral	Rat	80 mg/kg
<b>Eye</b>	No data available. See Section 3 - HAZARD IDENTIFICATION, above.			
<b>Skin</b>	No data available. See Section 3 - HAZARD IDENTIFICATION, above.			
<b>Inhalation</b>	No data available. See Section 3 - HAZARD IDENTIFICATION, above.			
<b>Ingestion</b>	Acute oral LD50s for the active ingredient are listed above in the table. While this formulation has not been tested as a whole, it would not be expected to be toxic orally based on the amount of active ingredient in the mixture.			
<b>Mutagenicity</b>	No data available.			
<b>Subchronic effects</b>	No data available.			
<b>Chronic toxicity</b>	See Chronic effects/Carcinogenicity below.			
<b>Chronic effects/ Carcinogenicity</b>	No long-term toxicity studies have been conducted to evaluate the chronic toxicity or carcinogenic potential of this material.			
<b>OSHA carcinogen</b>	No			
<b>NTP carcinogen</b>	Not classified			
<b>IARC carcinogen</b>	Not classified			
<b>Reproductive effects</b>	No data available.			
<b>Teratogenicity</b>	No data available.			
<b>At increased risk from exposure</b>	Individuals with cardiac conditions may be more susceptible to toxicity in cases of overexposure.			

---

## SECTION 12 - ECOLOGICAL INFORMATION

<b>Environmental overview</b>	The use and/or disposal of this material, its metabolites and degradation products is not expected to cause adverse effects upon animals, plants, humans, other organisms, or the environment.
-------------------------------	--

---

## SECTION 13 - DISPOSAL INFORMATION

<b>Disposal procedure</b>	Incineration is the recommended means of disposal for this material. This material may also be disposed in landfills. Federal, State, Local environmental regulations and Site conditions may affect proper disposal options.
---------------------------	---

---

**SECTION 14 - TRANSPORTATION INFORMATION**

---

**Proper shipping name** Atipamezole hydrochloride sterile injectable solution  
**General shipping instructions** Non-regulated

---

**SECTION 15 - REGULATORY INFORMATION**

---

**TSCA status** No  
**SARA section 302** No  
**SARA section 313** No  
**California proposition 65** No

---

**SECTION 16 - OTHER**

---

**Summary** Not applicable  
**Disclaimer** **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 a warranty of any kind, expressed or implied.**