



MATERIAL SAFETY DATA SHEET

SECTION 1 - CHEMICAL PRODUCT & COMPANY IDENTIFICATION

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

Product name	Atipamezole hydrochloride sterile injectable solution
Synonyms	ANTISEDAN® sterile injectable solution; Atipamezole hydrochloride sterile injectable solution
Chemical family	Imidazole
Therapeutic use	Antagonist to alpha-2-adrenoceptor induced sedation
Description	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.
Long term effects	Not known; see short-term effects above.
Ingestion	
Short term effects	Ingestion of this material may cause effects similar to those seen in animal studies including effects on nervous system and respiratory system
Long term effects	Not known; see short-term effects above.

SECTION 4 - FIRST AID MEASURES

Eyes	Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.
Skin	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.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.
Ingestion	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

General hazard	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.
Fire fighting instructions	Wear approved positive pressure, self contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.
Extinguisher to use	Use carbon dioxide, dry chemical, or water spray.
Hazardous combustion products	Emits toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen, hydrogen chloride and other chlorine-containing compounds.
Flash point	Not known
Autoignition	Not known
Minimum explosive concentration for dust/vapor	Not known
Flammability limits	Not known

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Occupational spill	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.
Clean up - large spill	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

General handling	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.
Storage	Store out of direct sunlight in a well ventilated area at ambient temperature.
Temperature range	15 - 30 °C

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits	Hazardous Ingredient	OEL	Type	Value
	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

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

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	Stable.
Conditions to avoid	Avoid excessive exposure to light.
Incompatibilities	None known.

SECTION 10 - STABILITY AND REACTIVITY continued

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

SECTION 11 - TOXICOLOGY INFORMATION

Acute toxicity	Type	Route	Species	Dosage
	LD50	Oral	Rat	80 mg/kg
Eye	No data available. See Section 3 - HAZARD IDENTIFICATION, above.			
Skin	No data available. See Section 3 - HAZARD IDENTIFICATION, above.			
Inhalation	No data available. See Section 3 - HAZARD IDENTIFICATION, above.			
Ingestion	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.			
Mutagenicity	No data available.			
Subchronic effects	No data available.			
Chronic toxicity	See Chronic effects/Carcinogenicity below.			
Chronic effects/ Carcinogenicity	No long-term toxicity studies have been conducted to evaluate the chronic toxicity or carcinogenic potential of this material.			
OSHA carcinogen	No			
NTP carcinogen	Not classified			
IARC carcinogen	Not classified			
Reproductive effects	No data available.			
Teratogenicity	No data available.			
At increased risk from exposure	Individuals with cardiac conditions may be more susceptible to toxicity in cases of overexposure.			

SECTION 12 - ECOLOGICAL INFORMATION

Environmental overview	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.
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SECTION 13 - DISPOSAL INFORMATION

Disposal procedure	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.
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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.**