



MATERIAL SAFETY DATA SHEET

SECTION 1 - CHEMICAL PRODUCT & COMPANY IDENTIFICATION

Pfizer Inc	Emergency telephone	212-573-2222
Pfizer Pharmaceuticals Group	Hours of operation	24 hours
235 E 42nd Street	Telephone	212-573-2222
New York, NY 10017		

Product name Hydroxyzine hydrochloride tablets

Synonyms ATARAX® tablets; Hydroxyzine hydrochloride tablets

Chemical family Benzhydrylpiperazine agent

Therapeutic use Tranquilizer (minor)

Description 10 mg : Orange, triangular tablets, scored on one side with "ATARAX 10" and "560" on other side.
25 mg : Dark green, triangular tablets, scored on one side with "ATARAX 25" and "561" on other side.
50 mg : Yellow, triangular tablets, scored on one side with "ATARAX 50" and "562" on other side.
100 mg: Red, triangular tablets, scored on one side with "ATARAX 100" and "563" on other side.

SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Hazardous Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Calcium phosphate dibasic, anhydrous	7757-93-9	Trade Secret
Hydroxyzine hydrochloride	2192-20-3	Trade Secret
Starch NF	9005-25-8	Trade Secret
Alginate Acid	9005-32-7	Trade Secret
Lactose	63-42-3	Trade Secret
Polyethylene Glycol	68130-99-4	Trade Secret
Magnesium stearate	557-04-0	Trade Secret

SECTION 3 - HAZARDS IDENTIFICATION

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

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

Signal word CAUTION!

Statements of hazard ACCIDENTAL OR INCIDENTAL INGESTION OF LARGE AMOUNTS OF THIS MATERIAL MAY BE HARMFUL; SEE ADVERSE EFFECTS UNDER INGESTION.

MAY CAUSE CENTRAL NERVOUS SYSTEM EFFECTS.

Eye

SECTION 3 - HAZARDS IDENTIFICATION continued

Short term effects	None known or expected.
Long term effects	None known or expected.
Skin	
Short term effects	None known or expected.
Long term effects	None known or expected.
Inhalation	
Short term effects	None known or expected.
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 clinical use including drowsiness, dry mouth, blurred vision, low blood pressure, ringing in the ear, euphoria and involuntary motor activity. The most common manifestation of overdosage of this material is hypersedation.
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 spill or leak. Scoop spilled material into a labeled container for recovery or disposal. Clean spill area thoroughly with detergent and water.
Clean up - large spill	Review Section 3 and 8 before proceeding with clean up. Scoop or shovel spilled material into a labeled container for recovery or disposal. 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 absorbent material and transfer to labeled container for treatment and disposal.

SECTION 7 - HANDLING AND STORAGE

General handling	Keep away from heat. Avoid creating dust when handling. Use with adequate ventilation. IF TABLETS OR CAPSULES ARE CRUSHED AND/OR BROKEN, AVOID CONTACT WITH EYES, SKIN AND CLOTHING. AVOID BREATHING DUST. When handling, use proper personal protective equipment specified in Section 8.
Storage	Keep container tightly closed when not in use. 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
	Hydroxyzine hydrochloride	Pfizer	TWA-8	Not established
	Magnesium stearate	ACGIH	TWA-8	10 mg/m ³ (Stearates)
	Starch NF	ACGIH	TWA-8	10 mg/m ³
		OSHA	TWA-8	5 mg/m ³ (respirable fraction)
		OSHA	TWA-8	15 mg/m ³ (total dust)
Exposure information	See exposure limits for components listed above.			
Ventilation	General room ventilation is adequate unless the process generates airborne dust or fumes.			
Eye protection	None required under normal and foreseeable conditions of use.			
Skin protection	None required under normal and foreseeable conditions of use.			
Hand protection	None required under normal and foreseeable conditions of use.			
Respiratory protection	None required under normal and foreseeable conditions. Use dust mask for dusty conditions.			

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical form	Tablet
Color	Red, yellow, orange, green.
Odor	Odorless.
Molecular weight	Not applicable

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES continued

Molecular formula	Not applicable
pH	Not known
Melting point	Not known
Pour point	Not known
Vapor pressure	Not known
Water solubility	No data available.
Solvent solubility	No data available.

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	Stable.
Conditions to avoid	None known.
Incompatibilities	Strong oxidizers.
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	950 mg/kg
	LD50	IP	Mouse	122 mg/kg
	LD50	IP	Rat	126 mg/kg
	LD50	IV	Mouse	48.9 mg/kg
	LD50	IV	Rat	45 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	Rats receiving oral doses up to 50 mg Atarax/100 gm of food for 24 weeks showed no adverse effects.			
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	Hydroxyzine, when administered to the pregnant mouse, rat and rabbit, induced fetal abnormalities in the rat and mouse at doses substantially above the human therapeutic dose.			
At increased risk from exposure	Individuals with a history of hypersensitivity to this material or other materials in its chemical class may be susceptible to the toxicity of			

SECTION 11 - TOXICOLOGY INFORMATION continued

overexposure. Individuals taking central nervous system depressants (alcohol, hypnotics, narcotics, barbiturates) should avoid exposure to this material.

Additional data Since this material may affect the developing fetus (based on animal data), females planning to have a child and pregnant women should avoid exposure to this material. It is also advisable for nursing mothers to exercise caution regarding exposure.

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.

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.

SECTION 14 - TRANSPORTATION INFORMATION

Proper shipping name Hydroxyzine hydrochloride tablets
General shipping instructions Non-regulated

SECTION 15 - REGULATORY INFORMATION

TSCA status No
SARA section 302 No
SARA section 313 No
California proposition 65 No
Summary Not applicable

SECTION 16 - OTHER

Summary Not applicable
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