MATERIAL SAFETY DATA SHEET

SECTION 1 - CHEMICAL PRODUCT & COMPANY IDENTIFICATION

Pfizer Inc
Pfizer Pharmaceuticals Group
235 E 42nd Street
New York, NY 10017

Emergency telephone	212-573-2222
Hours of operation	24 hours
Telephone	212-573-2222

Product name	**Meclizine hydrochloride chewable tablets**
Synonyms	BONINE® chewable tablets; Meclizine hydrochloride chewable tablets
Chemical family	Benzhydrylpiperazine agent
Therapeutic use	Anti-emetic drug
Description	Pink mottled tablet.

SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Ingredient	CAS Number	Amount
Lactose	63-42-3	Trade Secret
Meclizine **hydrochloride**	31884-77-2	Trade Secret
Starch NF	9005-25-8	Trade Secret
Talc	14807-96-6	Trade Secret
Purified Siliceous Earth NF (celite)	61790-53-2	Trade Secret
Sodium Saccharin USP	128-44-9	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

CAUTION!

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

Signal word

Statements of hazard MAY CAUSE CENTRAL NERVOUS SYSTEM EFFECTS.

Eye

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.

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SECTION 3 - HAZARDS IDENTIFICATION continued

Short term effects	None known or expected
Long term effects	None known or expected.

Ingestion

Short term effects	Accidental or incidental ingestion of large amounts of this material may cause drowsiness, dry mouth, and blurred vision.
Long term effects	Not known; see short-term effects above.

SECTION 4 - FIRST AID MEASURES

Eyes	Immediately flush eyes with plenty of water. If irritation occurs or persists, 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.
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	PEL	Type	Value
Magnesium stearate	ACGIH	TWA-8	10 mg/m^3 (Stearates)
Meclizine hydrochloride	**Pfizer**	TWA-8	Not established
Purified Siliceous Earth NF (celite)	OSHA	TWA-8	6 mg/m^3 (<1% crystalline silica)
	ACGIH	TWA-8	3 mg/m^3 (respirable particulate)
	ACGIH	TWA-8	10 mg/m^3 (total dust; <1% quartz)
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)
Talc	**ACGIH**	TWA-8	2 mg/m^3 (particulate)

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 forseeable 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 forseeable conditions. Use **dust mask for** dusty conditions.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical form Tablet

Color **pink**

Odor **Odorless.**

Molecular weight Not applicable

Molecular formula Not applicable

oH Not known

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES continued

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	1600 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	Subchronic toxicity studies in dogs and rats for six months showed no abnormal symptoms or changes.
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	Epidemological studies in pregnant women revealed no increase risk of abnormalities due to meclizine treatment. However, animal studies in mice, rats, and rabbits showed specific developmental abnormalities at maternally toxic doses.
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 overexposure. Individuals with asthma, glaucoma, or enlarged prostate gland and individuals taking central nervous system depressants (alcohol, hypnotics, narcotics, barbiturates) should avoid exposure to this material.
Additional data	FDA PREGNANCY CATEGORY B. Reproduction studies in rats have shown cleft palates. Epidemiological studies in pregnant women, however, Do not indicate that meclizine increases the risk of abnormalities when

SECTION 11 - TOXICOLOGY INFORMATION continued

administered during pregnancy. Despite the animal finidings, it would appear that the possibility of fetal harm is remote.

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	Meclizine hydrochloride chewable 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
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.**