MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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CHEMTREC (24 hours): 1-800-262-8200

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Prazosin hydrochloride/polythiazide capsules

Trade Name: Not determined
Synonyms: MINIZIDE® capsules
Chemical Family: Quinazoline derivative and benzothiadiazine agent
Intended Use: Antihypertensive/Diuretic agents

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Starch	9005-25-8	232-679-6	*
Magnesium stearate	557-04-0	209-150-3	*
Sucrose	57-50-1	200-334-9	*
Prazosin hydrochloride	19237-84-4	242-903-4	*
Polythiazide	346-18-9	206-468-4	*

Additional Information: * Proprietary

3. HAZARDS IDENTIFICATION

Appearance: 1.0 mg/0.5 mg: Blue green top and blue green body lock-capsules 2.0 mg/0.5 mg: Blue green top and pink body lock-capsules 5.0 mg/0.5 mg: blue green top and light blue body lock-capsules

Signal Word: CAUTION

Statement of Hazard: Accidental ingestion of large amounts of this material may be harmful; see known clinical effects, below May cause cardiovascular and central nervous system effects

Eye Contact: None known
Skin Contact: None known
Inhalation: None known
Ingestion: None known

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including hypotension (low blood pressure), dizziness, headache and drowsiness. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. Get medical attention.

Skin Contact: Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, oxides of nitrogen, sulfur oxides, hydrogen chloride and other chlorine-, florine-, and sulfur-containing compounds

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of the spill or leak. Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Review Sections 3, 8 and 12 before proceeding with clean up. Vacuum or sweep material into appropriate recovery container. Close container and move it to a secure holding area.

7. HANDLING AND STORAGE

General Handling: Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Minimize dust generation and accumulation. Use only in a well-ventilated area. IF TABLETS OR CAPSULES ARE CRUSHED AND/OR BROKEN, AVOID BREATHING DUST AND AVOID CONTACT WITH EYES, SKIN AND CLOTHING.

Storage Conditions: Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at room temperature.

Storage Temperature 15-30°C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Starch

OSHA - Final PELS - TWAs	15 mg/m³ total dust 5 mg/m³ respirable fraction
ACGIH Threshold Limit Value (TWA)	10 mg/m³ TWA

Sucrose

OSHA - Final PELS - TWAs	15 mg/m³ total dust 5 mg/m³ respirable fraction
ACGIH Threshold Limit Value (TWA)	10 mg/m³ TWA

Prazosin hydrochloride

Pfizer OEL TWA-8 Hr: 0.02 mg/m³

Analytical Method: Prazosin hydrochloride: CAM-JWT-95-03; STP P 122.8 (Contact Pfizer for additional details)

Engineering Controls: Good general ventilation should be sufficient to control airborne levels.

Personal Protective Equipment:

Hands:	None required under normal and foreseeable conditions of use.
Eyes:	Not required under normal conditions of use.
Skin:	None required under normal and foreseeable conditions of use.
Respiratory protection:	None required under normal conditions of use. Use dust mask for dusty conditions.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Capsule	**Color:**	Blue-green, blue-green/pink, and blue-green/blue
Odor:	Odorless	**Molecular Formula:**	Mixture
Molecular Weight:	Mixture		

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: Strong acids and oxidizers

Hazardous Decomposition Products: No data available See Section 5 - under Hazardous combustion products.
Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the active ingredient.

NTP:	Not classified
IARC:	Not classified
OSHA:	No

Sucrose
Rat Oral LD50 29.7 g/kg

Starch
Mouse IP LD50 6600 mg/kg

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Polythiazide
Mouse Oral LD50 > 5 g/kg
Rat Oral LD50 > 10g/kg

Prazosin hydrochloride
Mouse (M) Oral LD50 > 5000 mg/kg
Rat (M) Oral LD50 > 2000mg/kg

Ingestion Acute Toxicity The acute oral LD50s of a 2:1 blend of prazosin/polythiazide are reported to be > 5000 mg/kg and > 2000 mg/kg in mice and male rats, respectively.

Subchronic Effects Refer to Chronic Section.

Chronic Toxicity Chronic toxicity was evaluated in a 2:1 blend of prazosin/polythiazide in rats and dogs at dose levels up to 25 mg/kg/day for 3 months. Findings in rats showed no drug-related effects other than slight ptosis and a manifestation of prazosin adrenolytic activity. Findings in dogs revealed no adverse effects other than pharmacological effects that are characteristic of the individual components.

Chronic Effects/Carcinogenicity No data available on mixture. However, individual components showed no evidence of carcinogenic potential.

Reproductive Effects No effects on fertility or fetal abnormalities were observed in rats administered a 2:1 blend of prazosin/polythiazide. However there was a slight increase in gestation length, an increase in number of still births, and a decrease in survival of pups from birth to day 4.

Teratogenicity No evidence of embrytoxicity or teratogenicity was observed in rats or rabbits administered a 2:1 blend of prazosin/polythiazide at dose levels up to 132.5 mg/kg. High dosed rats showed ptosis, increased diuresis, and slight delayed growth of fetus.

Mutagenicity No evidence of mutagenic potential in in vivo genetic toxicity studies.

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

At increase risk from exposure: Individuals who have shown hypersensitivity to this material or other materials in its chemical class and individuals with liver and/or kidney dysfunction or impairment may be more susceptible to toxicity in cases of overexposure.

Additional Information: FDA PREGNANCY CATEGORY C. No adequate and well-controlled studies in pregnant women. Animal studies have shown adverse effects on the fetus. In clinical usage, it is considered that potential therapeutic benefits to the pregnant women may be acceptable despite the risk to the fetus.

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.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Incineration is the recommended method of disposal for this material. This material may also be disposed in landfills. Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

Not regulated

Proper shipping name: Prazosin hydrochloride/polythiazide capsules

15. REGULATORY INFORMATION

OSHA Label:
CAUTION
Accidental ingestion of large amounts of this material may be harmful; see known clinical effects, below May cause cardiovascular and central nervous system effects

Canada - WHMIS: Classifications

WHMIS hazard class:
None required

Starch

EU EINECS List	232-679-6
Inventory - United States TSCA - Sect. 8(b)	Listed

Magnesium stearate

EU EINECS List	209-150-3
Inventory - United States TSCA - Sect. 8(b)	Listed

Sucrose

EU EINECS List	200-334-9
Inventory - United States TSCA - Sect. 8(b)	Listed

Prazosin hydrochloride

EU EINECS List	242-903-4

Polythiazide

EU EINECS List	206-468-4

16. OTHER INFORMATION

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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.

End of Safety Data Sheet