MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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New York, New York 10017
1-212-573-2222

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

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International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Prazosin hydrochloride XL tablets

Trade Name: MINIPRESS
Synonyms: MINIPRESS® XL tablets
Chemical Family: Quinazoline antihypertensive
Intended Use: Antihypertensive

2. HAZARDS IDENTIFICATION

Appearance: Round, red-brown and off-white bilayer tablets

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
Short Term: Antihypertensive drug: has blood pressure-lowering properties

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver, testes, developing fetus.

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.

EU Classification
EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%

3. COMPOSITION/INFORMATION ON INGREDIENTS

Prazosin hydrochloride	19237-84-4	242-903-4	Repr. Cat.3;R63 Xn;R48/22	<1.0
Ferric oxide red	1309-37-1	215-168-2	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Polyethylene oxide NF	25322-68-3	Not Listed	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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 spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling:	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Storage Conditions:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Prazosin hydrochloride

Pfizer OEL TWA-8 Hr:	20µg/m^3

Ferric oxide red

ACGIH Threshold Limit Value (TWA)	5 mg/m^3
Australia TWA	5 mg/m^3 10 mg/m^3
Austria OEL - MAKs	5 mg/m^3 10 mg/m^3
Belgium OEL - TWA	2 ppm 5 mg/m^3
Bulgaria OEL - TWA	5.0 mg/m^3
Denmark OEL - TWA	3.5 mg/m^3
Estonia OEL - TWA	3.5 mg/m^3
Finland OEL - TWA	5 mg/m^3
France OEL - TWA	5 mg/m^3
Greece OEL - TWA	10 mg/m^3
Hungary OEL - TWA	6 mg/m^3
Ireland OEL - TWAs	5 mg/m^3 10 mg/m^3 4 mg/m^3
Lithuania OEL - TWA	3.5 mg/m^3
OSHA - Final PELS - TWAs:	10 mg/m^3 15 mg/m^3
Poland OEL - TWA	5 mg/m^3
Portugal OEL - TWA	5 mg/m^3
Romania OEL - TWA	5 mg/m^3
Slovakia OEL - TWA	1.5 mg/m^3
Spain OEL - TWA	5 mg/m^3
Sweden OEL - TWAs	3.5 mg/m^3

Polyethylene oxide NF

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Austria OEL - MAKs	1000 mg/m^3
Germany - TRGS 900 - TWAs	1000 mg/m^3
Germany (DFG) - MAK	1000 mg/m^3 average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m^3
Slovenia OEL - TWA	1000 mg/m^3

Sodium chloride

Latvia OEL - TWA	5 mg/m^3
Lithuania OEL - TWA	5 mg/m^3

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Lithuania OEL - TWA	5 mg/m^3
Sweden OEL - TWAs	5 mg/m^3

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

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Tablet **Color:** Red brown to off-white
Molecular Formula: Mixture **Molecular Weight:** Mixture

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity: (Species, Route, End Point, Dose)

Sodium chloride
Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m^3

Hydroxypropyl methylcellulose
Rat Oral LD50 > 10,000 mg/kg

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

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Polyethylene oxide NF
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Sodium chloride
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Subchronic toxicity was evaluated in dogs at oral doses ranging from 40 mg/kg/day for one month. drug-related pharmacologic responses were apparent at all doses. However, toxicity was observed only at the high dose level of 40 mg/kg/day with animals exhibiting ocular inflammation, vomiting, ataxia, diarrhea, anorexia, and histologic evidence of liver toxicity. In a one-month oral toxicity study in rats at doses up to 160 mg/kg/day, no evidence of toxicity was seen among treated animals. Chronic toxicity was evaluated in rats and dogs at oral dose levels ranging from 5 to 150 mg/kg/day for 18 months and 2 to 25 mg/kg/day for one year, respectively. Testicular atrophy and hepatocellular degeneration were noted in rats at dose levels of 25 mg/kg or greater.

Chronic Effects/Carcinogenicity No evidence of carcinogenic potential was seen in an 18-month oral rat study at dose levels up to 75 mg/kg/day.

Reproductive Effects Fertility and reproductive performance were evaluated in rats at doses up to 75 mg/kg/day. Decreased fertility was seen at the high-dose, but no adverse effects were noted at the mid-dose (25 mg/kg/day). Decreased body weight gain was seen among the rat pups in Phase II of the study at the lowest dose of 5 mg/kg/day. A peri- and postnatal study was conducted in rats at doses up to 75 mg/kg/day. This study revealed decreased survival rate in rat pups and decreased litter size in animals receiving the high-dose.

Teratogenicity No evidence of teratologic potential was observed in rats or rabbits at dose levels up to 75 mg/kg/day or in monkeys at dose levels up to 4 mg/kg/day.

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

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Ferric oxide red
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

Prazosin hydrochloride

Australia (AICS):	Present
EU EINECS/ELINCS List	242-903-4

Ferric oxide red

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	215-168-2

15. REGULATORY INFORMATION

Polyethylene oxide NF

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3

Sodium chloride

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3

Hydroxypropyl methylcellulose

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R63 - Possible risk of harm to the unborn child.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

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 warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet