



# MATERIAL SAFETY DATA SHEET

Revision date: 08-Sep-2009

Version: 1.1

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

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-212-573-2222

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161  
Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

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

### Material Name: Doxazosin Mesylate Tablets, 8mg

**Trade Name:** CARDURA®; SUPRESSIN; PROSTADILAT; ALFADIL  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product for the treatment of high blood pressure (hypertension); benign prostatic hyperplasia

## 2. HAZARDS IDENTIFICATION

**Appearance:** Green tablets  
**Signal Word:** WARNING

**Statement of Hazard:** Harmful to aquatic life with long lasting effects.

### Additional Hazard Information:

**Short Term:** Dust may cause irritation. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on heart.  
**Known Clinical Effects:** The most common adverse effects reported with the therapeutic use of doxazosin include hypotension (low blood pressure), dizziness, sleepiness, malaise, and fatigue.

### EU Risk Phrases:

R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

### Australian Hazard Classification (NOHSC):

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 product or its ingredients 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	Classification	%
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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Doxazosin mesylate	77883-43-3	Not listed	N;R51/53 Xn;R48/22	4
Sodium lauryl sulfate	151-21-3	205-788-1	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Lactose NF, anhydrous	63-42-3	200-559-2	Not Listed	*
Green lake blend	MIXTURE	Not listed	Not Listed	*
Sodium starch glycolate	9063-38-1	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:** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other 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 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.

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**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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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.

**Doxazosin mesylate**  
Pfizer OEL TWA-8 Hr:

30µg/m<sup>3</sup>

**Sodium lauryl sulfate**  
Pfizer OEL TWA-8 Hr:

0.3 mg/m<sup>3</sup>

**Microcrystalline cellulose**  
ACGIH Threshold Limit Value (TWA)

10 mg/m<sup>3</sup> TWA

Australia TWA

10 mg/m<sup>3</sup>

Belgium OEL - TWA

Listed

Estonia OEL - TWA

Listed

France OEL - TWA

Listed

Ireland OEL - TWAs

Listed

Latvia OEL - TWA

Listed

OSHA - Final PELs - TWAs:

15 mg/m<sup>3</sup> total

5 mg/m<sup>3</sup>

Portugal OEL - TWA

Listed

Romania OEL - TWA

Listed

Spain OEL - TWA

Listed

**Magnesium stearate**

ACGIH Threshold Limit Value (TWA)

10 mg/m<sup>3</sup> TWA

Australia TWA

10 mg/m<sup>3</sup>

Belgium OEL - TWA

Listed

Ireland OEL - TWAs

Listed

Lithuania OEL - TWA

Listed

Portugal OEL - TWA

Listed

Spain OEL - TWA

Listed

Sweden OEL - TWAs

Listed

**Analytical Method:** Analytical method available for doxazosin mesylate. Contact Pfizer Inc for further information.

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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

<b>Physical State:</b>	Tablet	<b>Color:</b>	Green
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

**Polymerization:** Will not occur

### 10. STABILITY AND REACTIVITY

**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.

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

##### Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

##### Magnesium stearate

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

##### Sodium lauryl sulfate

Rat Oral LD50 1288 mg/kg

##### Doxazosin mesylate

Mouse Oral LD50 > 1000 mg/kg

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### 11. TOXICOLOGICAL INFORMATION

Rat Oral LD50 > 1200 mg/kg  
Mouse (M/F) IV LD50 9/14 mg/kg  
Rat (M/F) IV LD50 28/33 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)

##### **Microcrystalline cellulose**

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating

##### **Sodium lauryl sulfate**

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Severe

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### **Doxazosin mesylate**

12 Month(s) Rat Oral 10 mg/kg/day NOAEL Heart, Male reproductive system  
12 Month(s) Dog Oral 20 mg/kg/day NOAEL Heart  
3 Month(s) Dog Oral 16 mg/kg/day NOAEL No effects at maximum dose  
6 Month(s) Rat Oral 20 mg/kg/day NOAEL Heart Blood

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### **Doxazosin mesylate**

Reproductive & Fertility-Males Rat Oral 20 mg/kg/day LOAEL Fertility  
Fertility and Embryonic Development Rat Oral 5 mg/kg/day NOAEL Fertility, Not Teratogenic  
Embryo / Fetal Development Rabbit Oral 40 mg/kg/day NOAEL Not Teratogenic  
Peri-/Postnatal Development Rat Oral 2.5 mg/kg/day LOAEL Maternal Toxicity, Developmental toxicity  
Cardiovascular system

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### **Doxazosin mesylate**

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
*In Vitro* Cytogenetics Human Lymphocytes Negative  
*In Vivo* Cytogenetics Mouse Bone Marrow Negative

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### **Doxazosin mesylate**

18 Month(s) Mouse Oral, in feed 10 mg/kg/day NOAEL Not carcinogenic, Heart, Kidneys  
24 Month(s) Rat Oral, in feed 10 mg/kg/day NOAEL Not carcinogenic, Reproductive System, Heart

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

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater. Harmful effects to aquatic organisms could occur.

**Bioaccumulation and Toxicity:** Acute toxicity to aquatic organisms may occur. Long-term adverse effects to aquatic organisms are possible.

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### 12. ECOLOGICAL INFORMATION

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### Doxazosin mesylate

*Daphnia Magna* NPDES LC50 48 Hours > 5 mg/L

*Mysidopsis bahia* (Mysid Shrimp) NPDES LC50 48 Hours 3.8 mg/L

*Pimephales promelas* (Fathead Minnow) NPDES LC50 48 Hours > 5 mg/L

*Cyprinodon variegatus* (Sheepshead Minnow) NPDES LC50 48 Hours > 5 mg/L

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

### 13. DISPOSAL CONSIDERATIONS

#### Disposal Procedures:

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

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

### 15. REGULATORY INFORMATION

**EU Symbol:** None required

#### EU Risk Phrases:

R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

#### EU Safety Phrases:

S57 - Use appropriate containment to avoid environmental contamination.  
S22 - Do not breathe dust.

#### OSHA Label:

WARNING

Harmful to aquatic life with long lasting effects.

#### Canada - WHMIS: Classifications

##### WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

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### 15. REGULATORY INFORMATION

#### Lactose NF, anhydrous

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	200-559-2

#### Sodium lauryl sulfate

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	205-788-1

#### Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	232-674-9

#### Sodium starch glycolate

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

#### Magnesium stearate

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

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.  
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

**Prepared by:** Toxicology and Hazard Communication  
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**