



MATERIAL SAFETY DATA SHEET

Revision date: 26-Apr-2011

Version: 3.1

Page 1 of 7

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

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Material Name: Doxazosin mesylate tablets

Trade Name: CARDURA®
Chemical Family: Quinazoline derivative
Intended Use: high blood pressure (hypertension); benign prostatic hyperplasia

2. HAZARDS IDENTIFICATION

Appearance: Tablets: (1 mg) white; (2 mg) yellow; (4 mg) orange

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 : heart.
Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including dizziness, fatigue, hypotension (low blood pressure), edema and dyspnea.

EU Indication of danger: Not classified

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

Additional Information: For a more detailed discussion of potential health hazards and toxicity see Section 11.
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	EU Classification	%
Doxazosin mesylate	77883-43-3	Not Listed	Xn;R48/22	1.0 - 4.0
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*

MATERIAL SAFETY DATA SHEET

Material Name: Doxazosin mesylate tablets
Revision date: 26-Apr-2011

Page 2 of 7
Version: 3.1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Yellow lake blend	MIXTURE	Not Listed	Not Listed	*
Magnesium stearate/sodium lauryl sulfate blend	MIXTURE	Not Listed	Not Listed	*
Green lake blend	MIXTURE	Not Listed	Not Listed	*
Lactose NF, anhydrous	63-42-3	200-559-2	Not Listed	*
Sodium starch glycolate	9063-38-1	Not Listed	Not Listed	*
FD&C yellow No.6 aluminum lake	15790-07-5	239-888-1	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: Not determined

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.

MATERIAL SAFETY DATA SHEET

Material Name: Doxazosin mesylate tablets
Revision date: 26-Apr-2011

Page 3 of 7
Version: 3.1

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.

Doxazosin mesylate

Pfizer OEL TWA-8 Hr: 30µg/m³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m ³ TWA
Australia TWA	10 mg/m ³
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 ³ total 5 mg/m ³
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed

Analytical Method:

Analytical method available for Doxazosin. Contact Pfizer Inc for further information.

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.

MATERIAL SAFETY DATA SHEET

Material Name: Doxazosin mesylate tablets
Revision date: 26-Apr-2011

Page 4 of 7
Version: 3.1

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablet	Color:	White, yellow, orange, or green
Odor:	Odorless	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.

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

Microcrystalline cellulose

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

Doxazosin mesylate

Mouse Oral LD50 > 1000 mg/kg
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

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))

MATERIAL SAFETY DATA SHEET

Material Name: Doxazosin mesylate tablets
Revision date: 26-Apr-2011

Page 5 of 7
Version: 3.1

11. TOXICOLOGICAL INFORMATION

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

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 is expected. Long-term adverse effects to aquatic organisms are possible.

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

Doxazosin mesylate

<i>Daphnia magna</i> (Water Flea)	NPDES	LC50	48 Hours	> 5 mg/L
<i>Mysidopsis bahia</i> (Mysid Shrimp)	NPDES	LC50	48 Hours	3.8 mg/L
<i>Pimephales promelas</i> (Fathead Minnow)	NPDES	LC50	48 Hours	> 5 mg/L
<i>Cyprinodon variegatus</i> (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

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.

MATERIAL SAFETY DATA SHEET

Material Name: Doxazosin mesylate tablets
Revision date: 26-Apr-2011

Page 6 of 7
Version: 3.1

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

15. REGULATORY INFORMATION

EU Symbol: None required
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

Lactose NF, anhydrous

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

Sodium starch glycolate

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

FD&C yellow No.6 aluminum lake

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	239-888-1

Microcrystalline cellulose

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

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.

Data Sources: Pfizer proprietary drug development information.

MATERIAL SAFETY DATA SHEET

Material Name: Doxazosin mesylate tablets
Revision date: 26-Apr-2011

Page 7 of 7
Version: 3.1

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

Prepared by: Product Stewardship Hazard Communications
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