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

Material Name: Doxazosin Mesylate Tablets, 8mg

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>CARDURA®; SUPRESSIN; PROSTADILAT; ALFADIL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Family:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Intended Use:</td>
<td>Pharmaceutical product for the treatment of high blood pressure (hypertension); benign prostatic hyperplasia</td>
</tr>
</tbody>
</table>

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.


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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>PZ01040</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.
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<thead>
<tr>
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<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doxazosin mesylate</td>
<td>77883-43-3</td>
<td>Not listed</td>
<td>N;R51/53</td>
<td>4</td>
</tr>
<tr>
<td>Sodium lauryl sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactose NF, anhydrous</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Green lake blend</td>
<td>MIXTURE</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium starch glycolate</td>
<td>9063-38-1</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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.
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/m³

Sodium lauryl sulfate
- Pfizer OEL TWA-8 Hr: 0.3 mg/m³

Microcrystalline cellulose
- ACGIH Threshold Limit Value (TWA): 10 mg/m³ TWA
- Australia TWA: 10 mg/m³
- 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/m³ total
- Portugal OEL - TWA: Listed
- Romania OEL - TWA: Listed
- Spain OEL - TWA: Listed

Magnesium stearate
- ACGIH Threshold Limit Value (TWA): 10 mg/m³ TWA
- Australia TWA: 10 mg/m³
- Belgium OEL - TWA: Listed
- Ireland OEL - TWAs: Listed
- Lithuania OEL - TWA: Listed
- Portugal OEL - TWA: Listed
- Spain OEL - TWA: Listed
- Sweden OEL - TWAs: Listed

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

- Physical State: Tablet
- Molecular Formula: Mixture
- Color: Green
- Molecular Weight: 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/m³

- **Sodium lauryl sulfate**
  - Rat Oral LD50 1288 mg/kg

- **Doxazosin mesylate**
  - Mouse Oral LD50 > 1000 mg/kg
11. TOXICOLOGICAL INFORMATION

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.
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.
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