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

Material Name: Pirmenol Hydrochloride Capsules

Trade Name: Pimenol
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of cardiac arrhythmias

2. HAZARDS IDENTIFICATION

Appearance: White capsules
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.

Additional Hazard Information:
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver, heart, spleen, and kidneys.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include taste abnormalities, dizziness, headache, dry mouth, fatigue, and chest pain.

EU Classification
EU Indication of danger: Harmful

EU Risk Phrases: R22 - Harmful if swallowed.


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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pirmenol Hydrochloride</td>
<td>61477-94-9</td>
<td>Not listed</td>
<td>Xn;R22</td>
<td>50mg/100mg***</td>
</tr>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</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>Sodium lauryl sulfate</td>
<td>151-21-3</td>
<td>205-788-1</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>

### Additional Information:
- * Proprietary
- *** per tablet/capsule/lozenge/suppository
- 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 immediately.

- **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:** Not available

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

- **Fire / Explosion Hazards:** Not applicable

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). 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.

**Pirmenol Hydrochloride**

**Pfizer OEL TWA-8 Hr:** 200 µg/m³

**Corn Starch**

ACGIH Threshold Limit Value (TWA) 10 mg/m³ TWA
Australia TWA 10 mg/m³
Belgium OEL - TWA Listed
Bulgaria OEL - TWA Listed
Czech Republic OEL - TWA Listed
Greece OEL - TWA Listed
Ireland OEL - TWAs Listed
OSHA - Final PELS - TWAs: 15 mg/m³ total
Spain OEL - TWA Listed

**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
Spain OEL - TWA Listed

**Sodium lauryl sulfate**

Pfizer OEL TWA-8 Hr: 0.3 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Material Name:** Pirmenol Hydrochloride Capsules

**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:** Capsule
- **Color:** White
- **Molecular Weight:** Mixture

10. STABILITY AND REACTIVITY

- **Chemical Stability:** Stable under normal conditions of use.
- **Conditions to Avoid:** Not determined
- **Incompatible Materials:** None identified

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)

- **Pirmenol Hydrochloride**
  - Rat Oral LD50 360 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)

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

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

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

Pirmenol Hydrochloride

In Vitro Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative
In Vitro Mammalian Cell Mutagenicity Hamster Lung Cells Negative
In Vivo Micronucleus Mouse Rat Bone Marrow Negative
In Vitro Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Negative
11. TOXICOLOGICAL INFORMATION

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

Pirmenol Hydrochloride
2 Year(s)  Mouse  Oral, in feed  50 mg/kg/day  NOAEL  Not carcinogenic
2 Year(s)  Rat  Oral, in feed  50 mg/kg/day  NOAEL  Not carcinogenic

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

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

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

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

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Harmful

EU Risk Phrases: R22 - Harmful if swallowed.

EU Safety Phrases: S22 - Do not breathe dust.

OSHA Label:
WARNING
Harmful if swallowed.

Canada - WHMIS: Classifications
15. REGULATORY INFORMATION

WHMIS hazard class:
D1b toxic materials

Corn Starch
- Inventory - United States TSCA - Sect. 8(b): Listed
- Australia (AICS): Listed
- REACH - Annex IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List: 232-679-6

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

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

Gelatin
- Inventory - United States TSCA - Sect. 8(b): Listed
- Australia (AICS): Listed
- EU EINECS/ELINCS List: 232-554-6

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
R22 - Harmful if swallowed.

Data Sources:
Pfizer proprietary drug development information. Publicly available toxicity information.

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

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End of Safety Data Sheet