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

Material Name: Cibenzoline Tablets

| Trade Name: | CIPRALAN; EXACOR |
| Chemical Family: | Not determined |
| Intended Use: | Pharmaceutical product used for cardiac arrhythmias |

2. HAZARDS IDENTIFICATION

Appearance: Tablet, film-coated
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.

Additional Hazard Information: Adverse effects most commonly reported in clinical use include chest pain, dizziness, fatigue, decreased blood sugar (hypoglycemia), and effects on cardiovascular system.

EU Classification
EU Indication of danger: Harmful

EU Hazard Symbols: Xn

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>Cibenzoline succinate</td>
<td>100678-32-8</td>
<td>Not Listed</td>
<td>Xn;R22</td>
<td>130mg***</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>418-260-2</td>
<td></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>Starch</td>
<td>9005-25-8</td>
<td>232-679-6</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>
<tr>
<td>Film coating</td>
<td>NOT ASSIGNED</td>
<td>Not Listed</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.

**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 thoroughly after handling. 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.

**Colloidal silicon dioxide**

<table>
<thead>
<tr>
<th>Country</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>0.1 mg/m³</td>
</tr>
<tr>
<td></td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>4 mg/m³ inhalable fraction</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td></td>
<td>2.4 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELs - Table Z-3 Mineral D:</td>
<td>20 mppcf</td>
</tr>
<tr>
<td></td>
<td>Listed</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>4.0 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>4 mg/m³</td>
</tr>
</tbody>
</table>

**Microcrystalline cellulose**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>4 mg/m³</td>
</tr>
</tbody>
</table>
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

**Material Name:** Cibenzoline Tablets

- **Physical State:** Film-coated tablets
- **Molecular Formula:** Mixture
- **Color:** No data available
- **Molecular Weight:** Mixture
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)

Lactose
Rat  Oral  LD50  > 10 g/kg

Stearic acid
Rat  Oral  LD50  > 4640 mg/kg
Rabbit  Dermal  LD50  > 5000 mg/kg

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

Cibenzoline succinate
Rat  Oral  LD50  359 mg/kg
Mouse  Oral  LD50  180 mg/kg

Magnesium stearate
Rat  Oral  LD50  > 2000 mg/kg
Rat  Inhalation  LC50  > 2000 mg/m³

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)

Stearic acid
Skin Irritation  Rabbit  Moderate
Eye Irritation  Rabbit  Mild

Microcrystalline cellulose
Skin Irritation  Rabbit  Non-irritating
Eye Irritation  Rabbit  Non-irritating

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

Stearic acid
30 Week(s)  Rat  Oral  300 ppm  LOAEL  Adipose tissue

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Cibenzoline succinate
Prenatal & Postnatal Development  Rat  Oral  50 mg/kg/day  NOAEL  Fetotoxicity
### 11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Category</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>Endpoint</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prenatal &amp; Postnatal Development</td>
<td>Rat</td>
<td>Intravenous</td>
<td>30 mg/kg/day</td>
<td>NOAEL</td>
<td>Not Teratogenic</td>
</tr>
<tr>
<td>Peri-/Postnatal Development</td>
<td>Rat</td>
<td>Intravenous</td>
<td>20 mg/kg/day</td>
<td>NOAEL</td>
<td>No effects at maximum dose</td>
</tr>
<tr>
<td>Prenatal &amp; Postnatal Development</td>
<td>Rabbit</td>
<td>Intravenous</td>
<td>10 mg/kg/day</td>
<td>NOAEL</td>
<td>No effects at maximum dose, Not Teratogenic</td>
</tr>
</tbody>
</table>

**Stearic acid**

- *In Vitro* Bacterial Mutagenicity (Ames) *Salmonella* Negative
- Unscheduled DNA Synthesis *E. coli* Negative

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

**Colloidal silicon dioxide**

| 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 Symbol:** Xn

**EU Indication of danger:** Harmful

**EU Risk Phrases:** R22 - Harmful if swallowed.
15. REGULATORY INFORMATION

S22 - Do not breathe dust.

OSHA Label:
WARNING
Harmful if swallowed.

Canada - WHMIS: Classifications
WHMIS hazard class:
D1b toxic materials

Colloidal silicon dioxide
  Inventory - United States TSCA - Sect. 8(b): Present
  Australia (AICS): Present
  EU EINECS/ELINCS List: 231-545-4, 418-260-2

Croscarmellose sodium
  Australia (AICS): Present

Lactose
  Inventory - United States TSCA - Sect. 8(b): Present
  Australia (AICS): Present
  REACH - Annex IV - Exemptions from the obligations of Register:
  EU EINECS/ELINCS List: 200-559-2

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

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

Stearic acid
  Inventory - United States TSCA - Sect. 8(b): Present
  Australia (AICS): Present
  EU EINECS/ELINCS List: 200-313-4

Magnesium stearate
15. REGULATORY INFORMATION

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

Carnauba wax

| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS): | Present |
| EU EINECS/ELINCS List | 232-399-4 |

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

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

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 8 - Exposure Controls / Personal Protection.

Prepared by: Product Stewardship 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