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

Material Name: Pramipexole Dihydrochloride Tablets
Trade Name: Mirapex; Mirapexin
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of Parkinson's disease

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pramipexole Dichloride Monohydrate</td>
<td>104632-26-0</td>
<td>Not listed</td>
<td>0.2 - 0.5</td>
</tr>
<tr>
<td></td>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Silicon dioxide, colloidal NF</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mannitol</td>
<td>69-65-8</td>
<td>200-711-8</td>
<td>*</td>
</tr>
<tr>
<td>Povidone</td>
<td>9003-39-8</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.

3. HAZARDS IDENTIFICATION

Appearance: White tablets

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information: Short Term: Not a skin irritant, Not acutely toxic (based on components). Ingestion may cause lowering of blood pressure. Long Term: Animal studies indicate that this material may cause adverse effects on the eyes. Known Clinical Effects: Adverse effects most commonly reported in clinical use include hallucinations, drowsiness, sleepiness, dizziness, sedation, and gastrointestinal disturbance. EU Indication of danger: Not classified
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.

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.

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: 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:** Ground and bond all bulk transfer equipment. 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).

**Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames. Protect from light.

**Storage Temperature:** 25°C (77°F)

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Pramipexole Dihydrochloride Monohydrate

- **Pfizer OEL TWA-8 Hr:** 7 ug/m³

#### Corn Starch

- **OSHA - Final PELs - TWAs:**
  - total = 15 mg/m³ TWA
  - = 5 mg/m³ TWA

- **ACGIH Threshold Limit Value (TWA):**
  - = 10 mg/m³ TWA
  - = 10 mg/m³ TWA

#### Magnesium stearate

- **ACGIH Threshold Limit Value (TWA):**
  - = 10 mg/m³ TWA
  - = 10 mg/m³ TWA

- **Australia TWA**
  - except stearates of toxic metals

#### Silicon dioxide, colloidal NF

- **OSHA - Final PELs - Table Z-3 Mineral D:**
  - (80)/(% SiO₂) mg/m³ TWA
  - = 20 mppcf TWA
  - = 2 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

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

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**Personal Protective Equipment:**

- **Hands:** Not required for the normal use of this product. Wear protective gloves when working with large quantities.

- **Eyes:** Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

- **Skin:** Not required for the normal use of this product. Wear protective clothing when working with large quantities.

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

### 10. STABILITY AND REACTIVITY
**Stability:** Stable under normal conditions of use.

**Conditions to Avoid:** None known

**Incompatible Materials:** Not applicable

### 11. TOXICOLOGICAL INFORMATION

**General Information:** The following information is available for the individual ingredients.

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

**Pramipexole Dihydrochloride Monohydrate**
- mg/kg
- Rat, Oral: LD50 >800 mg/kg
- Mouse, Oral: Minimum Lethal Dose 1700 mg/kg
- Rat, Intravenous: LD50 ~210 mg/kg
- Mouse, Intravenous: LD50 155 (M) mg/kg

**Magnesium stearate**
- Rat, Oral: LD50 > 2000 mg/kg
- Rat, Inhalation: LC50 > 2000 mg/m³

**Mannitol**
- Rat, Oral: LD50 13500 mg/kg
- Mouse, Oral: LD50 22 g/kg

**Povidone**
- Rat, Oral: LD50 100 g/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)

**Pramipexole Dihydrochloride Monohydrate**
- Skin Irritation: Rabbit, Non-irritating

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

**Pramipexole Dihydrochloride Monohydrate**
- 13 Week(s), Rat, No route specified: 25 mg/kg/day, LOAEL, Eyes
- 2 Year(s), Rat, Oral: 2 mg/kg/day, LOAEL, Eyes
- 2 Year(s), Rat, Oral: 8 mg/kg/day, NOAEL, No effects at maximum dose
- 2 Year(s), Mouse, No route specified: 10 mg/kg/day, NOAEL, No effects at maximum dose
- 12 Month(s), Non-human Primate, Oral: 0.1 mg/kg/day, NOAEL, No effects at maximum dose

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

**Pramipexole Dihydrochloride Monohydrate**
- Reproductive & Fertility, Rat: 2.5 mg/kg, LOAEL, Fertility
- Reproductive & Fertility, Rat: 1.5 mg/kg/day, LOAEL, Fetotoxicity
- Embryo / Fetal Development, Rabbit: 10 mg/kg/day, NOAEL, No effects at maximum dose
- Prenatal & Postnatal Development, Rat: 0.5 mg/kg/day, LOAEL, Neonatal toxicity

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

**Pramipexole Dihydrochloride Monohydrate**
- Bacterial Mutagenicity (Ames): Salmonella, E. coli, Negative
- Chromosome Aberration: Chinese Hamster Ovary (CHO) cells, Negative
Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

**Pramipexole Dihydrochloride Monohydrate**

- **2 Year(s) Mouse**
  - No route specified
  - 10 mg/kg/day NOAEL
  - Not carcinogenic

- **2 Year(s) Rat**
  - No route specified
  - 8 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. See below

**Povidone**

- **IARC:** Group 3

**Silicon dioxide, colloidal NF**

- **IARC:** Group 3

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**12. ECOLOGICAL INFORMATION**

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

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**13. DISPOSAL CONSIDERATIONS**

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations.

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**14. TRANSPORT INFORMATION**

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

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**15. REGULATORY INFORMATION**

**EU Indication of danger:** Not classified

**OSHA Label:**

Non-hazardous in accordance with international standards for workplace safety.

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**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.

Pramipexole Dihydrochloride Tablets

16. OTHER INFORMATION

Reasons for Revision:
Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

Prepared by:
Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet