



# MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.1

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

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CHEMTREC (24 hours): 1-800-424-9300

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ChemSafe (24 hours): +44 (0)208 762 8322

### 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

### Hazardous

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

Ingredient	CAS Number	EU EINECS List	%
Mannitol	69-65-8	200-711-8	*
Povidone	9003-39-8	Not listed	*

**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

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**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



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**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 Dichloride Monohydrate** mg/kg

Rat Oral LD 50 >800 mg/kg  
Mouse Oral Minimum Lethal Dose 1700 mg/kg  
Rat Intravenous LD 50 ~210 mg/kg  
Mouse Intravenous LD 50 155 (M) mg/kg

#### **Magnesium stearate**

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

#### **Mannitol**

Rat Oral LD 50 13500 mg/kg  
Mouse Oral LD 50 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 Dichloride Monohydrate**

Skin Irritation Rabbit Non-irritating

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

#### **Pramipexole Dichloride 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 Dichloride 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 Dichloride Monohydrate**

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative  
Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative

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Micronucleus Not specified Negative  
Mammalian Cell Mutagenicity HGPRT Negative

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

#### **Pramipexole Dichloride 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

## **12. ECOLOGICAL INFORMATION**

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

## **13. DISPOSAL CONSIDERATIONS**

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

## **14. TRANSPORT INFORMATION**

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

## **15. REGULATORY INFORMATION**

**EU Indication of danger:** Not classified

#### **OSHA Label:**

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

#### **Canada - WHMIS: Classifications**

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## 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 Dichloride Monohydrate

Standard for the Uniform Scheduling  
for Drugs and Poisons:

Schedule 4

## Corn Starch

Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):  
EU EINECS List

XU  
Present  
232-679-6

## Mannitol

Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):  
EU EINECS List

Present  
Present  
200-711-8

## Povidone

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

XU  
Present

## Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):  
EU EINECS List

Present  
Present  
209-150-3

## Silicon dioxide, colloidal NF

Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):  
EU EINECS List

Present  
Present  
231-545-4

## 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