

# MATERIAL SAFETY DATA SHEET

Boehringer Ingelheim Pharmaceuticals, Inc.  
900 Ridgebury Rd  
Ridgefield, CT 06877  
(203) 798-5521 9AM - 4PM EST

Product name: Mirapex  
DATE ISSUED: December 1, 2003

EMERGENCY TELEPHONE NUMBER  
CHEMTREC - 24 hours  
1-800-424-9300

## 1. SUBSTANCE IDENTIFICATION

CHEMICAL NAME: (S)-4,5,6,7-tetrahydro-N6-propyl-2,6-benzothiazolodiamine  
dihydrochloride monohydrate

CAS TYPE: 1

MOLECULAR FORMULA: C<sub>10</sub>H<sub>17</sub>N<sub>3</sub>S • 2HCl • H<sub>2</sub>O

TRADEMARK:

MOLECULAR WEIGHT: 302.27

CHEMICAL FAMILY: - Dopamine Receptor Agonist CAS NUMBER: 104632-26-0

PRODUCT USE: Anti-Parkinsons Disease, Schizophrenia, Depression

SYNONYMS: Pramipexole dichloride monohydrate

## 2. COMPONENTS PER UNIT DOSE

MATERIAL	EXPOSURE LIMITS
Active Ingredient: PRAMIPEXOLE	BIEL Value: 6 µg/m <sup>3</sup>
Inactive Ingredients:	
Mannitol	
Corn starch	
Colloidal silicon dioxide	
Povidone	
Magnesium stearate	

BIEL is the BI Exposure Limit. Where lower governmentally imposed limits are in effect, such limits should take precedence.

## 3. HAZARD IDENTIFICATION

### EMERGENCY OVERVIEW

**White, odorless powder. Mild irritant and mild sensitizer. Dust can combine with air to form an explosive mixture.**

Active Ingredient:

ROUTES OF ENTRY: Inhalation, ingestion, eye and skin contact.

TARGET ORGANS: Central Nervous System

ACUTE EXPOSURE: May cause: Mild skin irritation. Mild sensitizer.

SIGNS AND SYMPTOMS OF EXPOSURE: Possible side effects could include: Low Blood Pressure, Paleness, Fainting, Weakness, Fatigue, Malaise, Dizziness, Headache, Nausea

CHRONIC EXPOSURE: Not known

MEDICAL CONDITIONS POTENTIALLY AGGRAVATED BY EXPOSURE: Impaired renal function.

CARCINOGENICITY: Not listed/listed as carcinogen or potential carcinogen by NTP, IARC Monographs or OSHA.

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## 4. EMERGENCY FIRST AID PROCEDURES

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**INHALATION:** Remove from area to fresh air. Seek medical attention if respiratory irritation develops or if breathing becomes difficult.

**INGESTION:** Give 3-4 glasses of water, but **DO NOT** induce vomiting. If vomiting occurs, give fluids again. Get medical attention to determine whether vomiting or evacuation of stomach is necessary. Do not give anything by mouth to an unconscious or convulsing person.

**SKIN CONTACT:** Remove contaminated clothing. Wash affected areas with plenty of water, and soap if available, for several minutes. Seek medical attention if irritation or rash develops and persists.

**INJECTION:** In case of accidental injection, wash and thoroughly disinfect, get medical attention.

**EYE CONTACT:** Flush eyes with large amounts of running water for 15 minutes. Get immediate medical attention.

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## 5. FIRE AND EXPLOSION HAZARD DATA

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Flash Point	Auto Ignition Temperature	Flammable Limits	
		Upper	Lower
ND	435 °C Active Ingredient	ND	ND

FIRE EXTINGUISHING MEDIA: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

**SPECIAL FIRE FIGHTING PROCEDURES:** Evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use water spray to keep fire-exposed containers cool and protect against all exposures.

**UNUSUAL FIRE AND EXPLOSION HAZARDS:** This material presents a dust explosion hazard. It can burn in a fire, producing flammable fumes including acid gases and oxides of carbon, nitrogen and sulfur. **Minimum Ignition Energy** 42 mJ at 22.5 °C

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## 6. SPILL AND ACCIDENTAL RELEASE MEASURES

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**STEPS TO BE TAKEN IN THE EVENT OF A SPILL:** Wear approved respirator and chemically compatible gloves if containers have been compromised. Vacuum or sweep up spillage. Avoid creating dust. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before reuse. Ventilate area; wash down spill site and control wash water.

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## 7. PRECAUTIONS FOR SAFE HANDLING AND USE

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**HANDLING AND STORAGE PRECAUTIONS:** Avoid contact with eyes, skin or clothing. Avoid breathing dust. Avoid generating dust. Store in tight, light-resistant containers at a temperature less than 30 deg C.

**OTHER PRECAUTIONS:** Wash thoroughly after handling material. Wear fresh clothing daily. Wash contaminated clothing before reuse.

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## 8. CONTROL MEASURES

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**ENGINEERING CONTROLS:** Minimize dust generation. Use closed equipment where possible. Use spot ventilation to remove dust from the work area. If operations generate dusts, use explosion-proof ventilation equipment to control airborne levels. Use appropriate respiratory protection based on an industrial hygiene survey.

**RESPIRATORY PROTECTION:** A qualified person should determine the need for respiratory protection. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

### PERSONAL PROTECTIVE EQUIPMENT

Eye Protection: Safety glasses with side shields or goggles	Hand Protection: Chemical protective gloves
Protective Clothing: Laboratory coats or disposable coveralls	Other: Eye wash & safety shower

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## 9. PHYSICAL/CHEMICAL CHARACTERISTICS

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**APPEARANCE AND ODOR OF ACTIVE INGREDIENT :** White, odorless powder

Boiling Point: N/D

Vapor Pressure (mm Hg): N/A

Vapor Density: N/A

Water Solubility: greater than 10% (20 C)

Specific Gravity: N/D

Melting Point: 271 °C

Evaporation Rate: N/A

Volatiles, %: N/A

## 10. REACTIVITY DATA

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STABILITY: Stable. Settled dust produces no reaction at 360°C

CONDITIONS TO AVOID: Take precautionary measures against static discharge. Keep away from heat and sources of ignition. Is slightly sensitive to friction.

INCOMPATIBLE MATERIALS: Strong oxidizers

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: When heated to decomposition or under fire conditions, material emits toxic fumes including acid gases and oxides of nitrogen, carbon and sulfur.

HAZARDOUS POLYMERIZATION: Will not occur.

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## 11. TOXICOLOGICAL INFORMATION

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ACUTE TOXICITY for ACTIVE INGREDIENT:

LOWEST PUBLISHED TOXIC DOSE/CONC

*Child*

TDLo - ROUTE: Oral; DOSE: 91 ug/kg

TOXIC EFFECTS: *Behavioral* - Somnolence (general depressed activity) *Gastrointestinal* - Nausea or vomiting

LOWEST PUBLISHED LETHAL DOSE/CONC

*Mouse*

LDLo - ROUTE: Oral; DOSE: 1700 mg/kg

TOXIC EFFECTS: *Behavioral* – Tremor, Convulsions or effect on seizure threshold, Ataxia

LD50/LC50

*Rat*

LD50 - ROUTE: Oral; DOSE: 809 mg/kg (Male)

TOXIC EFFECTS: *Behavioral* – Tremor, Convulsions or effect on seizure threshold, Ataxia

LD 50- Route: Oral: LD50: 548 mg/kg (Female)

Sensitization: Maximization Test (GPMT) mild sensitizing potential (guinea pig)

Ames Test: Negative

### Reproductive Toxicity for Active ingredient

Doses of Pramipexole of 2.5 mg/kg/day (5.4 times the highest human dose on a surface area basis) prolonged estrous cycles and inhibited implantation. This is a common effect of dopamine agonists in rats and does not necessarily translate to humans. Treatment of pregnant rats after implantation with Pramipexole 1.5 mg/kg/d resulted in an increase in embryo resorptions. Serum concentrations of Pramipexole at this dose were more than four times the concentrations achieved in humans on therapy.

In pregnant rabbits, administration of 10 mg/kg/d did not produce adverse pregnancy effects. Serum concentrations were 71 times those achieved in humans on therapy. The rabbit, like the human, does not rely on prolactin for successful pregnancy.

In the rat nidation study, an increase in early resorptions occurred in most dams. However the surviving fetuses, as well as the progeny of the intermediate and low dose groups, were normal. The high dose of the active ingredient led to severe maternotoxicity.

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## 12. ECOLOGICAL INFORMATION

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For Active Ingredient: Water danger class 3 (German Self-assessment): extremely hazardous for water. Do not allow product to reach ground water, water bodies or sewage system.

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## 13. DISPOSAL CONSIDERATIONS

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WASTE DISPOSAL CONSIDERATIONS: WASTE DISPOSAL CONSIDERATIONS: Dispose of in accordance with local, state and federal regulations. Recommended method is incineration.

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## 14. TRANSPORT INFORMATION

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Not regulated by the United States Department of Transportation. Ship according to state and local regulations, if applicable.

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## 15. REGULATORY INFORMATION

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This material is **not** listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

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## 16. OTHER INFORMATION

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### ABBREVIATIONS:

N/E: Not Established  
N/A: Not Applicable  
N/D: Not Determined

Prepared by: Environmental Affairs & Safety  
Prepared: December 1, 2003  
Replaces: New

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### REFERENCES:

Physician's Desk Reference<sup>®</sup>, 1974-2003  
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BI MSDS for Pramipexole Dihydrochloride – 11/4/2003