

**SAFETY DATA SHEET**

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 Date: 06/02/2016

Generic Name: Pramipexole Dihydrochloride Tablets, USP

 Brand Equivalent: Mirapex®  
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<b>SECTION 1: IDENTIFICATION</b>	
<b>Product Name</b>	Pramipexole Dihydrochloride Tablets
<b>Active substance</b>	Pramipexole Dihydrochloride
<b>Synonyms</b>	N/A
<b>Formula</b>	C <sub>10</sub> H <sub>17</sub> N <sub>3</sub> S.2HCl.H <sub>2</sub> O
<b>Intended Use</b>	Parkinson's disease and Restless Legs Syndrome (RLS)
<b>Chemical Name</b>	(S)-2-amino-4,5,6,7-tetrahydro-6-(propylamino)benzothiazole dihydrochloride monohydrate
<b>Manufacturer Name &amp; Address</b>	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
<b>Telephone No.</b>	631-434-2723

<b>2. Hazards Identification</b>	
<b>Appearance</b>	White tablets
<b>Statement of Hazard:</b>	Non-hazardous in accordance with international standards for workplace safety.
<b>Additional Hazard Information:</b> <b>Short Term:</b>	Not a skin irritant, Not acutely toxic (based on components) . Ingestion may cause lowering of blood pressure.
<b>Long Term:</b> <b>Known Clinical Effects:</b>	Animal studies indicate that this material may cause adverse effects on the eyes. Adverse effects most commonly reported in clinical use include hallucinations, drowsiness, sleepiness, dizziness, sedation, and gastrointestinal disturbance.
<b>EU Indication of danger</b>	Not classified

<b>3. Composition/Information on ingredients</b>		
<b>Components</b>	<b>CAS-No</b>	<b>Concentration (%w/w)</b>
Pramipexole Dihydrochloride Monohydrate	191217-81-9	0.417
Mannitol, USP ( Pearlitol 50 C)	69658	*
Corn Starch, NF (400 L Modified Food starch )	9005258	*
Povidone, USP (Kollidon 30)	9003398	*
Colloidal Silicon Dioxide, NF (Aerosil 200)	7631869	*
Magnesium Stearate, NF	557040	*

\* Proprietary, In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

<b>4. FIRST AID MEASURES</b>	
<b>General advice</b>	Remove from exposure, lie down. Immediately remove contaminated clothing. If danger of loss of consciousness, place patient in recovery position and transport accordingly. Apply artificial respiration if necessary. First aid personnel should pay attention to their own safety
<b>Eye contact</b>	Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist
<b>Skin contact</b>	Wash off thoroughly with ample water. Seek medical attention
<b>Inhalation</b>	Keep patient calm, remove to fresh air, and seek medical attention
<b>Ingestion</b>	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.

<b>5. FIRE-FIGHTING MEASURES</b>	
<b>Suitable extinguishing media</b>	Use extinguishing measures to suit surroundings., Water, Dry chemical, Foam, carbon dioxide
<b>Hazards during fire-fighting</b>	In case of fire and/or explosion do not breathe fumes. Can be released in case of fire:, nitrogen oxides, Sulfur oxides, Carbon oxides
<b>Further information</b>	Collect separately contaminated extinguishing water; do not allow to reach sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations

<b>6. ACCIDENTAL RELEASE MEASURES</b>	
<b>Personal precautions,</b>	Wear protective equipment. Keep unprotected persons away. Ensure adequate ventilation
<b>Environmental precautions</b>	Do not discharge into drains/surface waters/groundwater
<b>Methods for cleaning-up or taking-up</b>	For large amounts: Dampen, pick up mechanically and dispose of. Avoid raising dust. For residues: Use approved industrial vacuum cleaner for removal. Pack in tightly closed containers for disposal.
<b>Additional information</b>	Never return spills in original containers for re-use.

<b>7. HANDLING AND STORAGE</b>	
<b>Advice on safe handling</b>	Do not open until use. Provide good ventilation of working area (local exhaust ventilation if necessary). Keep away from sources of ignition - No smoking. Protect from moisture.
<b>Hygienic measures</b>	General safety and hygiene measures. Hands and/or face should be washed before breaks and at the end of the shift. Store work clothing separately
<b>Storage Conditions Requirements for storage rooms and vessels</b>	Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames. Protect from light. 25°C (77°F)
<b>Advice on storage compatibility</b>	Keep away from food, drink and animal feeding stuffs. Advice on Segregation

<b>8. Exposure controls/Personal protection</b>	
<b>Respiratory Protection</b>	Use NIOSH approved respirator if exposed to vapors/dust/aerosol.
<b>Hand protection</b>	Chemical resistant protective gloves
<b>Eye protection</b>	Safety glasses with side-shields
<b>Body protection</b>	Laboratory: laboratory coat.
<b>Additional information</b>	Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.
<b>General protective measures</b>	Handle in accordance with good industrial hygiene and safety practice. Do not breathe dust. Avoid contact with skin, eyes and clothing.

<b>9. PHYSICAL AND CHEMICAL PROPERTIES</b>	
<b>General Information</b>	
<i>Appearance</i>	
<b>Physical State</b>	Tablet
<b>Color</b>	white
<b>Form</b>	uncoated tablets
<i>Odour</i>	
<b>Odour</b>	Not available
<b>Odor Threshold</b>	Not available
<b>pH</b>	Not available
<i>Other information</i>	
<b>Bulk density</b>	Not available
<b>Evaporation rate</b>	Not available
<b>Molecular formula</b>	Not applicable
<b>Hydrolysis/Photolysis</b>	Not available
<b>Hygroscopicity</b>	Not available
<b>Molecular Weight</b>	Not applicable
<b>Log Octanol/Water Partition Coeff [log Kow]</b>	Not available
<b>Surface Tension</b>	Not available
<b>pKa</b>	Not available
<b>Particle Size</b>	Not available
<b>Solubility, Water</b>	Freely soluble
<b>Specific Gravity/ Relative Density</b>	Not available
<b>Viscosity, dynamic</b>	Not available
<b>Viscosity, kinematic</b>	Not available
<b>% Volatile</b>	Not available
<i>Thermal/Stability properties</i>	
<b>Autoignition temperature</b>	Not available
<b>Boiling Point</b>	Not available
<b>Thermal decomposition</b>	Not available
<b>Explosive Limits, LEL</b>	Not available
<b>Explosive limits, UEL</b>	Not available
<b>Explosiveness</b>	Not available
<b>Flammability</b>	Not available
<b>Flash point</b>	Not available
<b>Melting Point</b>	Not available
<b>Oxidizing Potential</b>	Not available
<i>Vapor Properties</i>	
<b>Vapor Density</b>	Not available

<b>Vapor Pressure</b>	Not available
<b>Saturated Vapor Concentration</b>	Not available

<b>10. Stability and Reactivity</b>	
<b>stability</b>	Stable under normal conditions of use.
<b>Conditions to Avoid</b>	None known
<b>Materials to Avoid</b>	Not available
<b>Hazardous Decomposition products</b>	Not available

<b>11. Toxicological Information</b>	
<b>Routes of Entry</b>	Ingestion, Inhalation, Eye contact, Skin contact
<b>Acute inhalation toxicity</b>	No data available
<b>Acute dermal toxicity</b>	No data available
<b>Skin irritation</b>	Non-irritant
<b>Eye irritation</b>	No eye irritation
<b>Genetic Toxicity</b>	No data available
<b>Carcinogenicity</b>	No data available.
<b>Reproductive Toxicity</b>	No data available
<b>Developmental Toxicity</b>	No data available
<b>Pharmacokinetics/Toxicokinetics</b>	No data available
<b>Other Toxicity Information</b>	No data available

<b>12. Ecological Information</b>	
<b>Ecotoxicity</b>	No ecotoxicity data noted for the ingredient(s).
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	Not available
<b>Mobility in soil</b>	Not available
<b>Other adverse effects</b>	Not available

<b>13. Disposal considerations</b>	
<b>Product</b>	Dispose of in accordance with local regulations

<b>Contaminated packaging</b>	Packs that cannot be cleaned should be disposed of in the same manner as the contents. Uncontaminated packaging can be recycled.
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<b>14. Transport Information</b>	
<b>Further information</b>	Not classified as dangerous in the meaning of transport regulations. For the internal transport: Use only released containers. Use only tightly closed containers. The container must be correctly labeled. Protect container against fall down

<b>15. Regulatory Information</b>	
<b>National legislation/regulations</b>	VWVWS
<b>Water hazard class</b>	WGK 1 slightly water endangering Annex 4 VwVwS (Germany) dated Mai, 17 th 1999

<b>16. Other information</b>	
<b>Recommended Restrictions for Use:</b>	Not available
<b>Prepared on</b>	06/02/2016
<b>Revision</b>	00
<b>Disclaimer</b>	The above information is believed to be correct but should only be used as a guide. ScieGen Pharmaceuticals, Inc. disclaims any express or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the above information.