1. Identification

Product identifier: Pramipexole Dihydrochloride Monohydrate

Other means of identification:
- Catalog number: 1553859
- Chemical name: (S)-2-amino-4,5,6,7-tetrahydro-6-(propylamino)benzothiazole dihydrochloride monohydrate

Recommended use:
Specified quality tests and assay use only.

Recommended restrictions:
Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information:
- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway, Rockville, MD 20852-1790, US
- Telephone: RS Technical Services 301-816-8129
- Website: www.usp.org
- E-mail: RSTECH@usp.org

Emergency phone number:
- CHEMTREC within US & Canada: 1-800-424-9300
- CHEMTREC outside US & Canada: +1 703-527-3887

2. Hazard(s) identification

Physical hazards:
Not classified.

Health hazards:
- Acute toxicity, oral: Category 4

OSHA hazard(s):
- Not classified.

Label elements:
- Signal word: Warning
- Hazard statement: Harmful if swallowed.
- Precautionary statement:
  - Prevention: Wash thoroughly after handling. Do not eat, drink or smoke when using this product.
  - Response: If swallowed: Call a poison center/doctor/medical professional if you feel unwell. Rinse mouth.
  - Storage: Not available.
  - Disposal: Dispose of contents/container to an approved disposal site.

Hazard(s) not otherwise classified (HNOC):
- Not classified.

3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pramipexole Dihydrochloride Monohydrate</td>
<td>191217-81-9</td>
<td>100</td>
</tr>
</tbody>
</table>

4. First-aid measures

Inhalation:
Remove to fresh air. Call a physician if symptoms develop or persist.

Skin contact:
Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact:
Rinse with water. Get medical attention if irritation develops and persists.

Ingestion:
Rinse mouth. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
Most important symptoms/effects, acute and delayed
Indication of immediate medical attention and special treatment needed

Administer activated charcoal as an aqueous slurry, unless contraindicated. Perform gastric lavage. For hypotension, infuse 10-20 mL/kg isotonic fluid. Administer dopamine or norepinephrine if hypotension persists. For dystonias and dyskinetic movements, administer diazepam, diphenhydramine, or benztropine. For dysrhythmia treat with standard anti-arrhythmic drugs. Hemodialysis is unlikely to be of benefit. (Poisindex) (Drugdex) Provide general supportive measures and treat symptomatically.

General information
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures
Suitable extinguishing media
Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters
Wear suitable protective equipment.

Fire-fighting equipment/instructions
Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods
Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures
Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

7. Handling and storage
Precautions for safe handling
As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.

Conditions for safe storage, including any incompatibilities
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection
Exposure limit values

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pramipexole Dihydrochloride Monohydrate (CAS 191217-81-9)</td>
<td>STEL</td>
<td>42 micrograms/m3</td>
<td>15 minutes</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>24 micrograms/m3</td>
<td>60 minutes</td>
</tr>
</tbody>
</table>

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls
Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Avoid any open handling of this material, particularly for grinding, crushing, weighing, or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.
Individual protection measures, such as personal protective equipment

**Eye/face protection**
Safety glasses with sideshields are recommended. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

**Skin protection**

**Hand protection**
Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. This material is extremely potent. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

**Other**
For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

**Respiratory protection**
Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

**Thermal hazards**
Not available.

**General hygiene considerations**
Wash hands after handling and before eating. Keep away from food and drink. Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

**Appearance**
White to off-white powder.

**Physical state**
Solid.

**Form**
Powder.

**Odor**
Odorless.

**Odor threshold**
Not available.

**pH**
Not available.

**Melting point/freezing point**
519.8 °F (271 °C); 296 - 301 °C (decomposes)

**Initial boiling point and boiling range**
Not available.

**Flash point**
Not available.

**Evaporation rate**
Not available.

**Flammability (solid, gas)**
Not applicable.

**Upper/lower flammability or explosive limits**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability limit - lower (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flammability limit - upper (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Explosive limit - lower (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Explosive limit - upper (%)</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

**Vapor pressure**
Not available.

**Vapor density**
Not available.

**Relative density**
Not available.

**Solubility in water**
Freely soluble in water.

**Partition coefficient (n-octanol/water)**
-1

**Auto-ignition temperature**
815 °F (435 °C)

**Decomposition temperature**
Not available.

**Viscosity**
Not available.

**Other information**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical family</td>
<td>Aminobenzothiazole derivative.</td>
</tr>
<tr>
<td>Molecular formula</td>
<td>C10H17N3S.2HCl.H2O</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>302.26</td>
</tr>
<tr>
<td>Solubility (other)</td>
<td>Soluble in methanol; slightly soluble in ethanol 95% (v/v); practically insoluble in dichloromethane.</td>
</tr>
</tbody>
</table>

10. Stability and reactivity

**Reactivity**
No reactivity hazards known.

**Chemical stability**
Stable at normal conditions.
Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.

Conditions to avoid
None under normal conditions.

Incompatible materials
Strong oxidizing agents.

Hazardous decomposition products
NOx. SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion
Harmful if swallowed.

Inhalation
Due to lack of data the classification is not possible.

Skin contact
Due to lack of data the classification is not possible.

Eye contact
Based on available data, the classification criteria are not met.

Symptoms related to the physical, chemical, and toxicological characteristics

Medical conditions aggravated by exposure

Acute toxicity
Harmful if swallowed.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pramipexole Dihydrochloride Monohydrate (CAS 191217-81-9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral LD50</td>
<td>Mouse</td>
<td>1700 mg/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>809 mg/kg, (male)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>548 mg/kg, (female)</td>
<td></td>
</tr>
</tbody>
</table>

Skin corrosion/irritation
Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation
Based on available data, the classification criteria are not met.

Local effects
Irritancy test
Result: Non-irritant.
Species: Rabbit
Organ: Eye
Irritancy test
Result: Non-irritant.
Species: Rabbit
Organ: Skin
Respiratory sensitization
Due to lack of data the classification is not possible.

Skin sensitization
Based on available data, the classification criteria are not met.

Sensitization
Maximization test
Result: Sensitizing.
Species: Guinea pig
Severity: Mild.

Germ cell mutagenicity
Based on available data, the classification criteria are not met.

Mutagenicity
Chromosomal aberration assay in Chinese hamster ovary cells
Result: Negative.
In vitro Ames assay
Result: Negative.
In vivo micronucleus assay
Result: Negative.
Species: Mouse
V79 gene mutation assay for HGPRT mutants
Result: Negative.

Carcinogenicity
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Based on available data, the classification criteria are not met.

10 mg/kg/day Carcinogenicity test
Result: No increase in tumors.
Species: Mouse
Test Duration: 2 years
8 mg/kg/day Carcinogenic test
Result: No increase in tumors.
Species: Rat
Test Duration: 2 years

**Reproductive toxicity**

Based on available data, the classification criteria are not met.

**Reproductivity**

10 mg/kg/day Reproductivity test
Result: No adverse effects on embryo-fetal development.
Species: Rabbit
2.5 mg/kg/day Reproductivity test
Result: Increased incidence of embryo resorption during gestation.
Species: Rat
25 mg/kg/day Reproductivity test
Result: Inhibited implantation.
Species: Rat

**Specific target organ toxicity - single exposure**

Due to lack of data the classification is not possible.

**Specific target organ toxicity - repeated exposure**

Due to lack of data the classification is not possible.

**Aspiration hazard**

Based on available data, the classification criteria are not met.

12. **Ecological information**

**Ecotoxicity**
Harmful to aquatic organisms. Readily biodegradable.

**Persistence and degradability**
No data is available on the degradability of this product.

**Bioaccumulative potential**
Not available.

**Mobility in soil**
Not available.

**Other adverse effects**
Not available.

13. **Disposal considerations**

**Disposal instructions**
This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose in accordance with all applicable regulations.

**Local disposal regulations**
Not available.

**Hazardous waste code**
Not regulated.

**Waste from residues / unused products**
Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging**
Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. **Transport information**

**DOT**
Not regulated as a hazardous material by DOT.

**IATA**
Not regulated as a dangerous good.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
No information available.

15. **Regulatory information**

**US federal regulations**
CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**Hazard categories**
Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

**SARA 302 Extremely hazardous substance**
No
SARA 311/312 Hazardous chemical
No

Other federal regulations
Safe Drinking Water Act (SDWA)
Not regulated.
Food and Drug Administration (FDA)
Not regulated.

US state regulations
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

Issue date: 02-01-2010
Revision date: 11-16-2012
Version #: 02
Further information: Not available.

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Revision Information
This document has undergone significant changes and should be reviewed in its entirety.