



# SAFETY DATA SHEET

## 1. Identification

|                                                        |                                                                                         |                 |
|--------------------------------------------------------|-----------------------------------------------------------------------------------------|-----------------|
| Product identifier                                     | <b>Pramipexole Dihydrochloride Monohydrate</b>                                          |                 |
| 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<br>Rockville<br>MD<br>20852-1790<br>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

### Substance

### Hazardous components

| Chemical name                           | Common name and synonyms | CAS number  | %   |
|-----------------------------------------|--------------------------|-------------|-----|
| Pramipexole Dihydrochloride Monohydrate |                          | 191217-81-9 | 100 |

## 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.  |

|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Most important symptoms/effects, acute and delayed</b>                     | Not available.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Indication of immediate medical attention and special treatment needed</b> | 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.                       |
| <b>General information</b>                                                    | 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

|                                                                      |                                                                                                                                                                                        |
|----------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Suitable extinguishing media</b>                                  | Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.                                                                                  |
| <b>Unsuitable extinguishing media</b>                                | None known.                                                                                                                                                                            |
| <b>Specific hazards arising from the chemical</b>                    | No unusual fire or explosion hazards noted.                                                                                                                                            |
| <b>Special protective equipment and precautions for firefighters</b> | Wear suitable protective equipment.                                                                                                                                                    |
| <b>Fire-fighting equipment/instructions</b>                          | 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. |
| <b>Specific methods</b>                                              | Cool containers exposed to flames with water until well after the fire is out.                                                                                                         |

## 6. Accidental release measures

|                                                                            |                                                                                                                                                                                                                                                                       |
|----------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Personal precautions, protective equipment and emergency procedures</b> | 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. |
| <b>Methods and materials for containment and cleaning up</b>               | 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

|                                                                     |                                                                                                                                                                                                                                                                                                                                                                                       |
|---------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Precautions for safe handling</b>                                | 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. |
| <b>Conditions for safe storage, including any incompatibilities</b> | 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

#### Industrial Use

| Material                                                  | Type | Value            | Form       |
|-----------------------------------------------------------|------|------------------|------------|
| Pramipexole Dihydrochloride Monohydrate (CAS 191217-81-9) | STEL | 42 micrograms/m3 | 15 minutes |
|                                                           | TWA  | 24 micrograms/m3 | 60 minutes |
|                                                           |      | 6 micrograms/m3  |            |

|                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Biological limit values</b>          | No biological exposure limits noted for the ingredient(s).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Appropriate engineering controls</b> | 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.<br>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

|                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|---------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Eye/face protection</b>            | Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Skin protection</b>                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Hand protection</b>                | 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. |
| <b>Other</b>                          | 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Respiratory protection</b>         | 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).                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Thermal hazards</b>                | Not available.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>General hygiene considerations</b> | 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

|                                                     |                                                                                                       |
|-----------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| <b>Appearance</b>                                   | White to off-white powder.                                                                            |
| <b>Physical state</b>                               | Solid.                                                                                                |
| <b>Form</b>                                         | Powder.                                                                                               |
| <b>Odor</b>                                         | Odorless.                                                                                             |
| <b>Odor threshold</b>                               | Not available.                                                                                        |
| <b>pH</b>                                           | Not available.                                                                                        |
| <b>Melting point/freezing point</b>                 | 519.8 °F (271 °C) ; 296 - 301 ° C (decomposes)                                                        |
| <b>Initial boiling point and boiling range</b>      | Not available.                                                                                        |
| <b>Flash point</b>                                  | Not available.                                                                                        |
| <b>Evaporation rate</b>                             | Not available.                                                                                        |
| <b>Flammability (solid, gas)</b>                    | Not applicable.                                                                                       |
| <b>Upper/lower flammability or explosive limits</b> |                                                                                                       |
| <b>Flammability limit - lower (%)</b>               | Not available.                                                                                        |
| <b>Flammability limit - upper (%)</b>               | Not available.                                                                                        |
| <b>Explosive limit - lower (%)</b>                  | Not available.                                                                                        |
| <b>Explosive limit - upper (%)</b>                  | Not available.                                                                                        |
| <b>Vapor pressure</b>                               | Not available.                                                                                        |
| <b>Vapor density</b>                                | Not available.                                                                                        |
| <b>Relative density</b>                             | Not available.                                                                                        |
| <b>Solubility in water</b>                          | Freely soluble in water.                                                                              |
| <b>Partition coefficient (n-octanol/water)</b>      | -1                                                                                                    |
| <b>Auto-ignition temperature</b>                    | 815 °F (435 °C)                                                                                       |
| <b>Decomposition temperature</b>                    | Not available.                                                                                        |
| <b>Viscosity</b>                                    | Not available.                                                                                        |
| <b>Other information</b>                            |                                                                                                       |
| <b>Chemical family</b>                              | Aminobenzothiazole derivative.                                                                        |
| <b>Molecular formula</b>                            | C10H17N3S.2HCl.H2O                                                                                    |
| <b>Molecular weight</b>                             | 302.26                                                                                                |
| <b>Solubility (other)</b>                           | Soluble in methanol; slightly soluble in ethanol 95% (v/v); practically insoluble in dichloromethane. |

## 10. Stability and reactivity

|                           |                              |
|---------------------------|------------------------------|
| <b>Reactivity</b>         | No reactivity hazards known. |
| <b>Chemical stability</b> | Stable at normal conditions. |

|                                           |                                                                                            |
|-------------------------------------------|--------------------------------------------------------------------------------------------|
| <b>Possibility of hazardous reactions</b> | No dangerous reaction known under conditions of normal use.                                |
| <b>Conditions to avoid</b>                | None under normal conditions.                                                              |
| <b>Incompatible materials</b>             | Strong oxidizing agents.                                                                   |
| <b>Hazardous decomposition products</b>   | NOx. SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. |

## 11. Toxicological information

### Information on likely routes of exposure

|                                                                                      |                                                                                                                                                                                                                                                                      |
|--------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Ingestion</b>                                                                     | Harmful if swallowed.                                                                                                                                                                                                                                                |
| <b>Inhalation</b>                                                                    | Due to lack of data the classification is not possible.                                                                                                                                                                                                              |
| <b>Skin contact</b>                                                                  | Due to lack of data the classification is not possible.                                                                                                                                                                                                              |
| <b>Eye contact</b>                                                                   | Based on available data, the classification criteria are not met.                                                                                                                                                                                                    |
| <b>Symptoms related to the physical, chemical, and toxicological characteristics</b> | Hallucinations. Headache. Compulsive behaviors. Confusion. Abnormal thoughts or dreams. Abnormal body movements. Weakness. Dizziness. Drowsiness. Insomnia. Nausea. Heartburn. Constipation. Loss of appetite. Weight loss. Dry mouth. Joint pain. Urinary problems. |
| <b>Medical conditions aggravated by exposure</b>                                     | Kidney disease. Dyskinesia. Sleep disorders. Hypotension.                                                                                                                                                                                                            |
| <b>Acute toxicity</b>                                                                | Harmful if swallowed.                                                                                                                                                                                                                                                |

| Product                                                   | Species | Test Results                             |
|-----------------------------------------------------------|---------|------------------------------------------|
| Pramipexole Dihydrochloride Monohydrate (CAS 191217-81-9) |         |                                          |
| Oral<br>LD50                                              |         |                                          |
|                                                           | Mouse   | 1700 mg/kg                               |
|                                                           | Rat     | 809 mg/kg, (male)<br>548 mg/kg, (female) |

**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 Carcinogenicity 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

|                                                                                                                                        |                                                                                                                                                                                                |                               |
|----------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| <b>SARA 311/312 Hazardous chemical</b>                                                                                                 | No                                                                                                                                                                                             |                               |
| <b>Other federal regulations</b>                                                                                                       |                                                                                                                                                                                                |                               |
| <b>Safe Drinking Water Act (SDWA)</b>                                                                                                  | Not regulated.                                                                                                                                                                                 |                               |
| <b>Food and Drug Administration (FDA)</b>                                                                                              | Not regulated.                                                                                                                                                                                 |                               |
| <b>US state regulations</b>                                                                                                            | 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. |                               |
| <b>International Inventories</b>                                                                                                       |                                                                                                                                                                                                |                               |
| <b>Country(s) or region</b>                                                                                                            | <b>Inventory name</b>                                                                                                                                                                          | <b>On inventory (yes/no)*</b> |
| Australia                                                                                                                              | Australian Inventory of Chemical Substances (AICS)                                                                                                                                             | No                            |
| Canada                                                                                                                                 | Domestic Substances List (DSL)                                                                                                                                                                 | No                            |
| Canada                                                                                                                                 | Non-Domestic Substances List (NDSL)                                                                                                                                                            | No                            |
| China                                                                                                                                  | Inventory of Existing Chemical Substances in China (IECSC)                                                                                                                                     | No                            |
| Europe                                                                                                                                 | European Inventory of Existing Commercial Chemical Substances (EINECS)                                                                                                                         | No                            |
| Europe                                                                                                                                 | European List of Notified Chemical Substances (ELINCS)                                                                                                                                         | No                            |
| Japan                                                                                                                                  | Inventory of Existing and New Chemical Substances (ENCS)                                                                                                                                       | No                            |
| Korea                                                                                                                                  | Existing Chemicals List (ECL)                                                                                                                                                                  | No                            |
| New Zealand                                                                                                                            | New Zealand Inventory                                                                                                                                                                          | No                            |
| Philippines                                                                                                                            | Philippine Inventory of Chemicals and Chemical Substances (PICCS)                                                                                                                              | No                            |
| United States & Puerto Rico                                                                                                            | Toxic Substances Control Act (TSCA) Inventory                                                                                                                                                  | No                            |
| *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

|                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Issue date</b>           | 02-01-2010                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Revision date</b>        | 11-16-2012                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Version #</b>            | 02                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Further information</b>  | Not available.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
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| <b>Revision Information</b> | This document has undergone significant changes and should be reviewed in its entirety.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |