SAFETY DATA SHEET

1. Identification

Product identifier **Thioridazine Hydrochloride**

Other means of identification

Catalog number 1663008

Chemical name 10H-Phenothiazine, 10-[2-(1-methyl-2-piperidinyl)ethyl]-2-(methylthio)-, monohydrochloride

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
Specific target organ toxicity, single exposure	Category 1 (heart)
Specific target organ toxicity, repeated exposure	Category 1 (nervous system)

OSHA hazard(s) Not classified.

Label elements

Signal word Danger

Hazard statement Harmful if swallowed. Causes damage to organs (heart). Causes damage to organs (nervous system) through prolonged or repeated exposure.

Precautionary statement

Prevention Wash thoroughly after handling.

Response If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If exposed: Call a poison center/doctor. Get medical advice/attention if you feel unwell.

Storage Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

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

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Thioridazine Hydrochloride		130-61-0	100

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and plenty of water. Get medical attention if irritation develops and persists.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth thoroughly. IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
Most important symptoms/effects, acute and delayed	Narcosis. Decrease in motor functions. Behavioral changes.
Indication of immediate medical attention and special treatment needed	Treatment of phenothiazine overdose should be symptomatic and supportive. 1. Do NOT induce vomiting. Perform gastric lavage. Administer activated charcoal as a slurry. 2. Control cardiac arrhythmias with intravenous phenytoin. Treat ventricular tachydysrhythmias with sodium bicarbonate. 3. For Torsades de Pointes, treat hemodynamically unstable patients with electrical cardioversion. Treat stable patients with magnesium and/or atrial overdrive pacing. Correct electrolyte abnormalities. 4. Treat hypotension with positioning, intravenous fluids, and norepinephrine or phenylephrine. Do NOT use epinephrine. 5. Treat convulsions with a benzodiazepine and phenytoin. Monitor ECG. Do NOT use barbiturates that may potentiate respiratory and CNS depression. 6. For parkinsonian effects or dystonia, administer benztropine or diphenhydramine. 7. Treat neuroleptic malignant syndrome with cooling and bromocriptine. 8. Monitor acid-base status, fluid and electrolyte balance, hepatic enzymes, renal function, urine output, and cardiac function. 9. Most phenothiazines are not removed by dialysis. [Meditext; USP DI]
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	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. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. 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

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	No exposure standards allocated.

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. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection	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.
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.
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	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White to slightly yellow, granular powder.
Physical state	Solid.
Form	Powder.
Odor	Faint odor.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	318.2 - 329 °F (159 - 165 °C)
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	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Freely soluble.
Partition coefficient (n-octanol/water)	5.637
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Piperidine phenothiazine.
Molecular formula	C21H26N2S2 . HCl
Molecular weight	407.04
pH in aqueous solution	4.2 - 5.2 (1% solution)

Solubility (other)	Freely soluble in ethanol, in methanol, and in chloroform; soluble in dimethyl sulfoxide; slightly soluble in benzene; insoluble in ether.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	SOx, NOx, HCl. 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	Due to lack of data the classification is not possible.
Symptoms related to the physical, chemical, and toxicological characteristics	For phenothiazines: Abnormal heartbeat. Sudden death. Involuntary movement (muscle spasms; uncontrolled body movements; difficulty breathing, speaking, or swallowing; loss of balance; trembling or shaking hands and fingers; shuffling walk; unusual facial expressions; eyelid spasms; twisting of neck, trunk, arms, or legs). Rigidity. Weakness. Incoordination. Dizziness. Drowsiness. Disorientation. Pinpoint pupils. Yellow eyes and/or skin. Dry mouth. Constipation. Nasal congestion. Decreased sweating. Difficulty urinating. Increased sensitivity of skin or eyes to sunlight. Skin rash. Skin discoloration. Changes in menstrual period. Swelling or pain in breasts or milk secretion. Weight gain. Vomiting. Convulsions. Coma.
Delayed and immediate effects of exposure	Phenothiazines: Coma. Extrapyramidal effects. Low blood pressure. Hypothermia or hyperthermia. Central nervous system toxicity. Cardiac toxicity. Respiratory depression. Sudden death.
Chronic effects	For phenothiazines: Skin and eye discoloration. Tardive dyskinesia.
Cross sensitivity	Persons sensitive to any other phenothiazine may be sensitive to this material also.
Medical conditions aggravated by exposure	Porphyria. Lowered levels of P450 2D6 isozyme activity. Phenothiazines: Active alcoholism. Blood, liver, kidney, respiratory, or cardiovascular disorders. Pheochromocytoma. History of convulsive disorders, brain damage, neuroleptic malignant syndrome, or dermatoses. Acquired immune deficiency syndrome (AIDS). Glaucoma. Parkinson's disease. Reye's syndrome. Breast cancer. Hypocalcemia. Exposure to extreme heat or phosphorus insecticides.
Acute toxicity	Harmful if swallowed.

Product	**Species**	**Test Results**
Thioridazine Hydrochloride (CAS 130-61-0)		
Acute		
Oral		
LD50	Dog	160 mg/kg
	Mouse	385 mg/kg
	Rabbit	1100 mg/kg
	Rat	1060 mg/kg

Skin corrosion/irritation	Due to lack of data the classification is not possible.
Serious eye damage/eye irritation	Due to lack of data the classification is not possible.
Respiratory sensitization	Due to lack of data the classification is not possible.
Skin sensitization	Due to lack of data the classification is not possible.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.

Mutagenicity

Drosophila heritable translocation assay
Result: Positive
In vitro studies with human lymphocytes
Result: No increase in the frequency of chromosome aberrations

Mutagenicity

In vivo studies in mice
Result: No increase in the frequency of chromosome aberrations in germ cells, micronucleii, or sperm head abnormalities.

Carcinogenicity

Based on available data, the classification criteria are not met.
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
Phenothiazines produce an elevation in prolactin concentrations. In vitro studies show about 1/3 of human breast cancers are prolactin-dependent. Studies in rodents found an increase in mammary tumors after long-term administration of antipsychotic medications. Early epidemiological studies did not show an association between chronic administration of antipsychotics and breast cancer in women. A later study found a modest dose-related increased risk of breast cancer in women using antipsychotic dopamine antagonists. The available evidence is inconclusive.

Reproductive toxicity

Based on available data, the classification criteria are not met.
There have been reports of prolonged jaundice, under or overactive reflexes, movement disorders, and withdrawal effects (runny nose, vomiting, difficulty breathing) in newborns exposed to phenothiazines in utero.
A related material did not cause birth defects in animal studies.

Specific target organ toxicity - single exposure

Causes damage to organs (heart).

Specific target organ toxicity - repeated exposure

Causes damage to organs (nervous system) through prolonged or repeated exposure.

Aspiration hazard

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

12. Ecological information

Ecotoxicity

Product		Species	Test Results
Thioridazine Hydrochloride (CAS 130-61-0)			
Acute			
Crustacea	EC50	Daphnia magna	0.76 mg/l, 24 hours

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 available.

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 - Yes 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

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
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)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
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

Issue date	04-25-2008
Revision date	07-21-2015
Version #	03
Further information	Not available.
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Revision Information	Hazard(s) identification: <INDENT>Response First-aid measures: General information Toxicological information: Medical conditions aggravated by exposure Toxicological information: Acute toxicity Toxicological information: Symptoms related to the physical, chemical, and toxicological characteristics Toxicological information: Delayed and immediate effects of exposure Regulatory Information: United States