Material Safety Data Sheet

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PROPYLTHIOURACIL

Catalog Number:  1578000
Package Size:  200 mg
Revision Date:  September 18, 2000

SECTION 1 - IDENTIFICATION

Common Name: Propylthiouracil
Synonym: 6-Propyl-2-thiouracil
Chemical Name: 4(1H)-Pyrimidinone, 2,3-dihydro-6-propyl-2-thioxo-
CAS Number: 51-52-5
RTECS Number: YR1400000
Chemical Family: A 2,4(1H,3H)-Pyrimidinedione derivative
Therapeutic Category: Thyroid inhibitor

SECTION 2 - INGREDIENT INFORMATION

<table>
<thead>
<tr>
<th>Principle Components</th>
<th>Percent</th>
<th>Exposure Limits</th>
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<tbody>
<tr>
<td>Propylthiouracil</td>
<td>Pure Material</td>
<td>n/f</td>
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SECTION 3 - HEALTH HAZARD INFORMATION

Usual Adult Dose: The usual oral adult dose of propylthiouracil is 50 to 600 mg a day as one to four divided daily doses.
Adverse Effects: Adverse effects may include fever, throat infection, mouth sores, skin rash, itching, chills, cough or hoarseness, dizziness, nausea or vomiting, stomach pain, painful or swollen joints, numbness or tingling of fingers, toes, or face, and general feeling of discomfort, illness, or weakness. Possible allergic reaction to material if inhaled, ingested or in contact with skin.
Overdose Effects: Signs of overdose include menstrual changes, constipation, chills, dry, puffy skin, headache, listlessness or drowsiness, muscle aches, unusual tiredness or weakness, severe nausea or vomiting, weight gain, and
swelling in the front of the neck.

**Acute:** Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

**Chronic:** Possible hypersensitization, hypothyroidism, and cancer.

**Inhalation:** May cause irritation. Remove to fresh air.

**Eye:** May cause irritation. Flush with copious quantities of water.

**Skin:** May cause irritation. Flush with copious quantities of water.

**Ingestion:** May cause irritation and bitter taste. Flush out mouth with water. This material is rapidly absorbed following ingestion.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to the material and impaired liver function.

**Cross Sensitivity:** Persons sensitive to other antithyroid agents may be sensitive to this material also.

**Pregnancy Comments:** Propylthiouracil can cause adverse effects (hypothyroidism, goiter) in the fetus, although the actual risk appears to be low, especially if maternal doses are low.

**Pregnancy Category:** D

### SECTION 4 - FIRST AID MEASURES

**General:** Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

**Overdose Treatment:** For current information about the treatment of overdose, consult a certified Regional Poison Control Center by calling the number listed in your local telephone directory.

### SECTION 5 - TOXICOLOGICAL INFORMATION

**Oral Rat:** LD50: 1250 mg/kg

**Oral Mouse:** LD50: n/f

**Irritancy Data:** n/f

**Target Organ(s):** Thyroid gland

**Listed as a Carcinogen?** NTP: Yes IARC: Yes OSHA: No

**Other:** Thyroid hyperplasia and carcinoma have occurred in laboratory animals treated with propylthiouracil for longer than 1 year. [USP DI 20th ed. 2000]

### SECTION 6 - FIREFIGHTING MEASURES

**Flash Point:** n/f

**Auto-Ignition Temperature:** n/f

**Extinguisher Media:** Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

**Fire and Explosion Hazards:** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

**Firefighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
SECTION 7 - PHYSICAL HAZARDS

Conditions to Avoid: Avoid exposure to light.
Incompatibilities: Oxidizing agents.
Decomposition Products: When heated to decomposition material emits toxic fumes of SOx and NOx. Emits toxic fumes under fire conditions.
Stable? Yes
Hazardous Polymerization? No

SECTION 8 - HANDLING / SPILL / DISPOSAL MEASURES

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. Wash thoroughly after handling.
Storage: Store in tight, light-resistant container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.
Spill Response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Wash spill site. Place spillage and all contaminated cleanup materials in a thick plastic hazardous waste disposal bag or leakproof container and label it CAUTION: HAZARDOUS CHEMICAL WASTE.
Disposal: Place material in a thick plastic hazardous waste disposal bag or leakproof container and label it CAUTION: HAZARDOUS CHEMICAL WASTE. Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 9 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory Protection: Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.
Ventilation: Recommended.
Gloves: Rubber
Eye Protection: Safety Goggles
Protective Clothing: Protect exposed skin.

SECTION 10 - PHYSICAL AND CHEMICAL PROPERTIES

NOTE: The data reported below is general information, and is not specific to the USP Reference Standard Lot provided!

Appearance and Odor: White crystalline powder.
Melting Point: 219 - 221° C
Solubility in Water: Very slightly soluble
Boiling Point: n/f
Specific Gravity: n/f
Vapor Pressure: n/f
Vapor Density: n/f
Evaporation Rate: n/f
Reactivity in Water: n/f
% Volatile by Volume: n/f