

# SAFETY DATA SHEET

### 1. Identification

Product identifier Propylthiouracil

Other means of identification

Catalog number 1578000 CAS number 51-52-5

**Synonyms** 6-Propyl-2-thiouracil

Chemical name 4(1H)-Pyrimidinone, 2,3-dihydro-6-propyl-2-thioxo-

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

Manufacturer

Company name U. S. Pharmacopeia
Address 12601 Twinbrook Parkway

Rockville MD 20852-1790 United States

**Telephone** RS Technical Services 301-816-8129

Website www.usp.org
E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Acute toxicity, oral Category 4

Carcinogenicity Category 2
Reproductive toxicity Category 2

Specific target organ toxicity, single exposure Category 2 (thyroid gland)

Specific target organ toxicity, repeated Category 2 (liver)

exposure

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Warning

Hazard statement Harmful if swallowed. Suspected of causing cancer. Suspected of damaging fertility or the unborn

child. May cause damage to organs (thyroid gland). May cause damage to organs (liver) through

prolonged or repeated exposure.

Precautionary statement

**Prevention**Obtain special instructions before use. Do not handle until all safety precautions have been read

and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after

handling. Wear protective gloves/protective clothing/eye protection/face protection.

**Response** If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If exposed or concerned:

Call a poison center/doctor. Get medical advice/attention if you feel unwell.

Storage Store locked up.

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

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information Pharmacologically active material.

# 3. Composition/information on ingredients

**Substance** 

Chemical name	Common name and synonyms	CAS number	%
Propylthiouracil	6-Propyl-2-thiouracil	51-52-5	100

#### 4. First-aid measures

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

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

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

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Ingestion

Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head

Pharmacologically active material. Occupational exposure may cause physiological effects.

low so that stomach content doesn't get into the lungs.

Most important

symptoms/effects, acute and

delayed Indication of immediate

Provide general supportive measures and treat symptomatically.

medical attention and special treatment needed

**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. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding

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

Specific methods

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.

Use standard firefighting procedures and consider the hazards of other involved materials.

No unusual fire or explosion hazards noted. General fire hazards

#### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

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

thoroughly to remove residual contamination.

Avoid discharge into drains, water courses or onto the ground. **Environmental precautions** 

Material name: Propylthiouracil USP SDS US

### 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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

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

Occupational exposure limits No exposure limits noted for ingredient(s).

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

Appropriate engineering

controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

### Individual protection measures, such as personal protective equipment

**Eye/face protection** Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary.

Base the choice of protection on the job activity and potential for contact with eyes or face. An

emergency eye wash station should be available.

Skin protection

**Hand protection** Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved

or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of

skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do

not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

**Respiratory protection** Respirators are generally not required for laboratory operations. Use a tight-fitting full-face

respirator with HEPA filters for spill cleanup. Chose respiratory protection appropriate to the task

and the level of existing engineering controls.

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of reference standards.

Procedures for any other uses or quantities should be determined after an appropriate

assessment.

#### 9. Physical and chemical properties

Appearance Appearance descriptions are general information and not specific to any USP lot.

Physical state Solid.

**Form** Crystalline powder.

Color White.
Odor Odorless.
Odor threshold Not available.
pH Not available.

Melting point/freezing point 426.2 - 429.8 °F (219 - 221 °C)

Initial boiling point and boiling

range

Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

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 pressure < 0.0000001 kPa at 25 °C

Material name: Propylthiouracil
1578000 Version #: 04 Revision date: 09-20-2018 Issue date: 10-30-2006

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Slightly soluble.

**Solubility (other)** Alcohol: Sparingly soluble.

Ammonium hydroxide: Soluble. Benzene: Practically insoluble. Chloroform: Sparingly soluble.

Ether: Slightly soluble.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

**Chemical family** 2,4(1H,3H)-Pyrimidinedione derivative.

Molecular formula C7-H10-N2-O-S Molecular weight 170.23 g/mol

# 10. Stability and reactivity

**Reactivity**The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

**Incompatible materials** Strong oxidizing agents. Strong acids. Strong bases.

Hazardous decomposition

products

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

## 11. Toxicological information

Information on likely routes of exposure

InhalationKnowledge about health hazard is incomplete.Skin contactKnowledge about health hazard is incomplete.Eye contactKnowledge about health hazard is incomplete.

**Ingestion** Harmful if swallowed.

Symptoms related to the physical, chemical, and

toxicological characteristics

Fever. Sore throat. Mouth sores. Skin rash. Itching. Chills. Coughing. Dizziness. Joint pain. Numbness or tingling in fingers, toes, or lips. Hearing problems. Change in menstrual cycle.

Drowsiness. Gastrointestinal disturbances.

#### Information on toxicological effects

Acute toxicity Harmful if swallowed.

Product Species Test Results

Propylthiouracil (CAS 51-52-5)

Acute Oral

irritation

LD50 Rat 1980 mg/kg

1250 mg/kg

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye Knowledge about health hazard is incomplete.

Respiratory or skin sensitization

Respiratory sensitization
Skin sensitization
Knowledge about health hazard is incomplete.
Knowledge about health hazard is incomplete.
Knowledge about mutagenicity is incomplete.

### Mutagenicity

Chromosome aberration

Result: Negative.

Mutagenicity: DNA synthesis inhibition (human lymphocytes)

Result: Positive.

#### Carcinogenicity

Suspected of causing cancer.

37 g/kg Carcinogenicity Result: Thyroid tumors. Species: Guinea pig Test Duration: 2 years 600 g/kg Carcinogenicity

Result: Chromophobe adenomas of the anterior pituitary and

carcinomas of the thyroid.

Species: Mouse

Test Duration: 72 weeks 653 g/kg Carcinogenicity

Result: Malignant thyroid lesions.

Species: Hamster Test Duration: 70 weeks

### IARC Monographs. Overall Evaluation of Carcinogenicity

Propylthiouracil (CAS 51-52-5) 2B Possibly carcinogenic to humans.

#### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

# US. National Toxicology Program (NTP) Report on Carcinogens

Propylthiouracil (CAS 51-52-5) Reasonably Anticipated to be a Human Carcinogen.

#### Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Propylthiouracil can cause goiter and hypothyroidism in the fetus and newborn. Hyperthyroidism may also occur as a compensatory mechanism. Following therapeutic use of propylthiouracil

during pregnancy, 1-5% of infants develop transient neonatal hypothyroidism.

May cause damage to organs (liver) through prolonged or repeated exposure.

#### Reproductivity

500 mg/kg Reproductivity

Result: Developmental abnormalities in the endocrine and

urogenital systems. Species: Rat

Specific target organ toxicity -

May cause damage to organs (thyroid gland).

single exposure

Specific target organ toxicity repeated exposure

**Aspiration hazard** 

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

Pharmacologically active material. Occupational exposure may cause physiological effects. **Further information** 

### 12. Ecological information

**Ecotoxicity** 

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

No data available. No data available.

Other adverse effects

Mobility in soil

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

# 13. Disposal considerations

**Disposal instructions** 

Dispose in accordance with all applicable regulations. 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.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

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

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

Material name: Propylthiouracil USP SDS US

## 14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to

Annex II of MARPOL 73/78 and

the IBC Code

**General information** It is the shipper's responsibility to determine the correct transport classification at the time of

shipment.

Not applicable.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)** 

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated

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

Not listed.

SARA 311/312 Hazardous

Yes

chemical

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA)

**US state regulations** 

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

Propylthiouracil (CAS 51-52-5) Listed: January 1, 1988

US - California Proposition 65 - CRT: Listed date/Developmental toxin

Propylthiouracil (CAS 51-52-5) Listed: July 1, 1990

#### **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)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
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

Country(s) or region Inventory name On inventory (yes/no)\*

Japan Inventory of Existing and New Chemical Substances (ENCS)

Yes

Korea Existing Chemicals List (ECL) Yes

New ZealandNew Zealand InventoryYesPhilippinesPhilippine Inventory of Chemicals and Chemical SubstancesYes

(PICCS)

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory Yes

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

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

 Issue date
 10-30-2006

 Revision date
 09-20-2018

Version # 04

**Disclaimer** USP Reference Standards are sold for chemical test and assay purposes only, and NOT for

human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained

herein.