PTU™, Propylthiouracil 50mg Tablet

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

Product Identifier

<table>
<thead>
<tr>
<th>Product name</th>
<th>PTU™, Propylthiouracil 50mg Tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonyms</td>
<td>Not Available</td>
</tr>
<tr>
<td>Other means of identification</td>
<td>Not Available</td>
</tr>
</tbody>
</table>

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses

PTU™ Tablets are indicated for the total treatment of hyperthyroidism or in the treatment of the thyrotoxic patient prior to surgery or radioactive-iodine therapy.

Details of the supplier of the safety data sheet

Registered company name: Phebra

Address: 19 Orion Road, Lane Cove West, NSW 2066 Australia

Telephone: +61 2 9420 9199 | 1800 720 020

Fax: +61 2 9420 9177

Website: www.phebra.com

Email: info@phebra.com

Emergency telephone number

Association / Organisation: Not Available

Emergency telephone numbers: +61 401 264 004

Other emergency telephone numbers: N/A

SECTION 2 HAZARDS IDENTIFICATION

Classification of the substance or mixture

Poenis Schedule: S4

Classification: Acute Toxicity (Oral) Category 4, Germ cell mutagenicity Category 2, Carcinogenicity Category 2, Specific target organ toxicity - repeated exposure Category 2


Label elements

Hazard pictogram(s)

SIGNAL WORD: WARNING

Hazard statement(s)

H302 Harmful if swallowed.

H341 Suspected of causing genetic defects.

H351 Suspected of causing cancer.

H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statement(s) Prevention

P201 Obtain special instructions before use.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P281 Use personal protective equipment as required.

P264 Wash all exposed external body areas thoroughly after handling.
Precautionary statement(s) Response

- **P308+P313**: IF exposed or concerned: Get medical advice/attention.
- **P314**: Get medical advice/attention if you feel unwell.
- **P301+P312**: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
- **P330**: Rinse mouth.

Precautionary statement(s) Storage

- **P405**: Store locked up.

Precautionary statement(s) Disposal

- **P501**: Dispose of contents/container in accordance with local regulations.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

**Substances**

See section below for composition of Mixtures

**Mixtures**

<table>
<thead>
<tr>
<th>CAS No</th>
<th>%[weight]</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>51-52-5</td>
<td>54.6</td>
<td>propylthiouracil</td>
</tr>
<tr>
<td>9005-25-8</td>
<td>19.5</td>
<td>starch</td>
</tr>
<tr>
<td>63-42-3</td>
<td>18</td>
<td>alpha-lactose</td>
</tr>
<tr>
<td>9003-39-8</td>
<td>5.2</td>
<td>vinylpyrrolidone homopolymer</td>
</tr>
<tr>
<td>151-21-3</td>
<td>1.6</td>
<td>sodium lauryl sulfate</td>
</tr>
<tr>
<td>557-04-0</td>
<td>1.1</td>
<td>magnesium stearate</td>
</tr>
</tbody>
</table>

SECTION 4 FIRST AID MEASURES

**Description of first aid measures**

**Eye Contact**

If this product comes in contact with eyes:
- Wash out immediately with water.
- If irritation continues, seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

**Skin Contact**

If skin contact occurs:
- Immediately remove all contaminated clothing, including footwear.
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.
- Other measures are usually unnecessary.

**Inhalation**

- **IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.**
  - For advice, contact a Poison Information Centre or a doctor.
  - Urgent hospital treatment is likely to be needed.
  - In the mean time, qualified first aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition.
  - If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the SDS should be provided. Further action will be the responsibility of the medical specialist.
  - If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the SDS.

  Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:
  - INDUCE vomiting with fingers down the back of the throat, ONLY IF CONSCIOUS. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

  **NOTE:** Wear a protective glove when inducing vomiting by mechanical means.

**Indication of any immediate medical attention and special treatment needed**

As in all cases of suspected poisoning, follow the ABCDEs of emergency medicine (airway, breathing, circulation, disability, exposure), then the ABCDEs of toxicology (antidotes, basics, change absorption, change distribution, change elimination). For poisons (where specific treatment regime is absent):

**BASIC TREATMENT**

- Establish a patent airway with suction where necessary.
- Watch for signs of respiratory insufficiency and assist ventilation as necessary.
- Administer oxygen by non-rebreather mask at 10 to 15 L/min.
- Monitor and treat, where necessary, for pulmonary oedema.
- Monitor and treat, where necessary, for shock.
- Anticipate seizures.
- DO NOT use emetics. Where ingestion is suspected rinse mouth and give up to 200 ml water (5 ml/kg recommended) for dilution where patient is able to swallow, has a strong gag reflex and does not drool.
ADVANCED TREATMENT

- Consider orotracheal or nasotracheal intubation for airway control in unconscious patient or where respiratory arrest has occurred.
- Positive-pressure ventilation using a bag-valve-mask might be of use.
- Monitor and treat, where necessary, for arrhythmias.
- If signs of hypovolaemia are present use lactated Ringers solution. Fluid overload might create complications.
- Drug therapy should be considered for pulmonary oedema.
- Hypotension with signs of hypovolaemia requires the cautious administration of fluids. Fluid overload might create complications.
- Treat seizures with diazepam.
- Proparacaine hydrochloride should be used to assist eye irrigation.

SECTION 5 FIREFIGHTING MEASURES

Extinguishing media
- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

Special hazards arising from the substrate or mixture

<table>
<thead>
<tr>
<th>Fire Incompatibility</th>
<th>Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result</th>
</tr>
</thead>
</table>

Advice for firefighters

**Fire Fighting**
- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves in the event of a fire.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use fire fighting procedures suitable for surrounding area.
- **DO NOT** approach containers suspected to be hot.
- Cool fire exposed containers with water spray from a protected location.
- If safe to do so, remove containers from path of fire.
- Equipment should be thoroughly decontaminated after use.
- Slight hazard when exposed to heat, flame and oxidisers.

**Fire/Explosion Hazard**
- Non combustible.
- Not considered a significant fire risk, however containers may burn.
- Decomposition may produce toxic fumes of:
  - carbon dioxide (CO2)
  - nitrogen oxides (NOx)
  - sulfur oxides (SOx)
  - other pyrolysis products typical of burning organic material.
- May emit poisonous fumes.
- May emit corrosive fumes.

HAZCHEM: Not Applicable

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures
See section 8

Environmental precautions
See section 12

Methods and material for containment and cleaning up

**Minor Spills**
- Clean up all spills immediately.
- Secure leak if safe to do so.
- Bundle/collect recoverable product.
- Collect remaining material in containers with covers for disposal.

**Major Spills**
- Minor hazard.
- Clear area of personnel.
- Alert Fire Brigade and tell them location and nature of hazard.
- Control personal contact with the substance, by using protective equipment as required.
- Prevent spillage from entering drains or water ways.
- Contain spill with sand, earth or vermiculite.
- Collect recoverable product into labelled containers for recycling.
- Absorb remaining product with sand, earth or vermiculite and place in appropriate containers for disposal.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

**Safe handling**
- Avoid all personal contact, including inhalation.
Wear protective clothing when risk of exposure occurs. 
Use in a well-ventilated area. 
Prevent concentration in hollows and sumps. 
DO NOT enter confined spaces until atmosphere has been checked. 
DO NOT allow material to contact humans, exposed food or food utensils. 
Avoid contact with incompatible materials. 
When handling, DO NOT eat, drink or smoke.

Other information 
Store away from incompatible materials.

Conditions for safe storage, including any incompatibilities

Suitable container 
Glass container is suitable for laboratory quantities 
Polyethylene or polypropylene container.

Packing as recommended by manufacturer. 
Check all containers are clearly labelled and free from leaks.

Storage incompatibility 
Protect from light. 
Avoid reaction with oxidising agents.

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

OCCUPATIONAL EXPOSURE LIMITS (OEL)

<table>
<thead>
<tr>
<th>Source</th>
<th>Ingredient</th>
<th>Material name</th>
<th>TWA</th>
<th>STEL</th>
<th>Peak</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia Exposure Standards</td>
<td>starch</td>
<td>Starch</td>
<td>10 mg/m³</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>Australia Exposure Standards</td>
<td>magnesium stearate</td>
<td>Stearates</td>
<td>10 mg/m³</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
</tbody>
</table>

EMERGENCY LIMITS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Material name</th>
<th>TEEL-1</th>
<th>TEEL-2</th>
<th>TEEL-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>starch</td>
<td>Thydene; (Amylodextrin)</td>
<td>30 mg/m³</td>
<td>360 mg/m³</td>
<td>2,000 mg/m³</td>
</tr>
<tr>
<td>vinylpyrrolidone homopolymer</td>
<td>Poly(1-vinyl-2-pyrrolidinone) homopolymer; (Polyvinylpyrrolidone; Plasdone)</td>
<td>51 mg/m³</td>
<td>560 mg/m³</td>
<td>20,000 mg/m³</td>
</tr>
<tr>
<td>sodium lauryl sulfate</td>
<td>Sodium lauryl sulfate</td>
<td>3.9 mg/m³</td>
<td>43 mg/m³</td>
<td>260 mg/m³</td>
</tr>
</tbody>
</table>

Exposure controls

Appropriate engineering controls 
Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation. 
HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours. 
Barrier protection or laminar flow cabinets should be considered for laboratory scale handling. 
A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg. 
When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. 
Quantities up to 1 kilogram may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment laboratory using appropriate barrier/ containment technology. 
Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies.

Personal protection

Eye and face protection 
When handling very small quantities of the material eye protection may not be required. 
For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs: 
 Chemical goggles. 
 Face shield. Full face shield may be required for supplementary but never for primary protection of eyes. 
 Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available.

Skin protection 
See Hand protection below

Hands/feet protection 
Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference. 
Double gloving should be considered. 
PVC gloves. 
Change gloves frequently and when contaminated, punctured or torn.
PTU™, Propylthiouracil 50mg Tablet

Information on toxicological effects

Inhaled
The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

Ingestion
Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.
Side effects from the usage of antithyroid agents include nausea, vomiting, distress, headache, skin rashes, hives, and itching. Other effects include fever, joint pain, lupus, inflammation of blood vessels, liver inflammation, and hair loss.

Skin Contact
Skin contact is not thought to produce harmful health effects (as classified under EC Directives using animal models). Systemic harm, however, has been identified following exposure of animals by at least one other route and the material may still produce health damage following entry through wounds, lesions or abrasions.
Open cuts, abraded or irritated skin should not be exposed to this material. Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

Eye
Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).

Chronic
There has been concern that this material can cause cancer or mutations, but there is not enough data to make an assessment. Repeated or long-term occupational exposure is likely to produce cumulative health effects involving organs or biochemical systems.

There is some evidence that inhaling this product is more likely to cause a sensitisation reaction in some persons compared to the general population.

For Emergencies: Vinyl suit

For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers. For quantities up to 500 grams a laboratory coat may be suitable. For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.

For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.

For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.

Eye wash unit.
Ensure there is ready access to an emergency shower.

Wash hands immediately after removing gloves.
Head covering.
Protective shoe covers. [AS/NZS 2210]

Body protection

See Other protection below

Other protection

For quantities up to 500 grams a laboratory coat may be suitable.
For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
Eye wash unit.
Ensure there is ready access to an emergency shower.
For Emergencies: Vinyl suit

Thermal hazards
Not Available

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>PTU™ Tablets are round, white and biconvex. One side is debossed with “PRESTAB” while the other side is plain.</td>
</tr>
<tr>
<td>Physical state</td>
<td>Manufactured</td>
</tr>
<tr>
<td>Odour</td>
<td>Not Available</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>Not Available</td>
</tr>
<tr>
<td>pH (as supplied)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Melting point/freezing point (°C)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Initial boiling point and boiling range (°C)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Flash point (°C)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Flammability</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Flammability</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Flammability</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Upper Explosive Limit (%)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Lower Explosive Limit (%)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Vapour pressure (kPa)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Solubility in water (g/L)</td>
<td>Immiscible</td>
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<tr>
<td>Vapour density (Air = 1)</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

SECTION 10 STABILITY AND REACTIVITY

Reactivity
See section 7

Chemical stability
Product is considered stable and hazardous polymerisation will not occur.

Possibility of hazardous reactions
See section 7

Conditions to avoid
See section 7

Incompatible materials
See section 7

Hazardous decomposition products
See section 5

SECTION 11 TOXICOLOGICAL INFORMATION

Information on toxicological effects

Inhaled
The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

Ingestion
Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.
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Eye
Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).

Chronic
There has been concern that this material can cause cancer or mutations, but there is not enough data to make an assessment. Repeated or long-term occupational exposure is likely to produce cumulative health effects involving organs or biochemical systems. There is some evidence that inhaling this product is more likely to cause a sensitisation reaction in some persons compared to the general population.
PTU™, Propylthiouracil 50mg Tablet

<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity</th>
<th>Irritation</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTU™, Propylthiouracil 50mg Tablet</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>propylthiouracil</td>
<td>Oral (rat) LD50: 1250 mg/kg[^2]</td>
<td>Not Available</td>
</tr>
<tr>
<td>starch</td>
<td>Oral (rat) LD50: &gt;10000 mg/kg[^2]</td>
<td>Not Available</td>
</tr>
<tr>
<td>alpha-lactose</td>
<td>Oral (rat) LD50: &gt;10000 mg/kg[^2]</td>
<td>Not Available</td>
</tr>
<tr>
<td>vinylpyrrolidone homopolymer</td>
<td>Inhalation (rat) LC50: &gt;5.2 mg/l/4h[^2]</td>
<td>Eye (rabbit): non-irritating (Draize)*</td>
</tr>
<tr>
<td>sodium lauryl sulfate</td>
<td>Oral (rat) LD50: 1288 mg/kg[^2]</td>
<td>Eye (rabbit): 100 mg/24 hr - moderate</td>
</tr>
<tr>
<td>magnesium stearate</td>
<td>Oral (rat) LD50: 960 mg/kg[^2]</td>
<td>Not Available</td>
</tr>
</tbody>
</table>

**Legend:**
1. Value obtained from Europe ECHA Registered Substances - Acute toxicity: 2. Value obtained from manufacturer’s SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

### PTU™, Propylthiouracil 50mg Tablet
For alkyl sulfates: alkane sulfonates and alpha-olefin sulfonates.
Most chemicals of this category are not defined substances, but mixtures of homologues with different alkyl side chains. Common physical and/or biological pathways result in structurally similar breakdown products, and are, together with the surfactant properties, responsible for similar environmental behavior and essentially identical hazard profiles with regard to human health.
Acute toxicity: These substances are well absorbed after ingestion; penetration through the skin is however, poor. After absorption, these chemicals are distributed mainly to the liver.
In animals, signs of poisoning by mouth include lethargy, hair standing up, decreased motor activity and breathing rate, and diarrhea. Poisoning from skin contact caused irritation, tremor, tonic-clonic convulsions, breathing failure, and weight loss. The C-12-alkyl sulfate sodium salt caused the greatest effect.
In eye irritation tests, C-12 containing alkyl sulfates at greater than 10% concentration were severely irritating and produced irreversible effects on the cornea.

### PROPYTHIOURACIL
**WARNING:** This substance has been classified by the IARC as Group 2B: Possibly Carcinogenic to Humans.

### STARCH
The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.

### ALPHA-LACTOSE
Equivalent tumorigenic agent by RTECS criteria.

### VINYL/PYRROLIDONE HOMOPOLYMER
The substance is classified by IARC as Group 3: NOT classifiable as to its carcinogenicity to humans.

### MAGNESIUM STEARATE
Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compounds. Main criteria for diagnosing RADS include the absence of previous asthma disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficult breathing, cough and mucus production. Fatty acid salts of low acute toxicity. Their potential to irritate the skin and eyes is dependent on chain length.

### Toxicity

<table>
<thead>
<tr>
<th>Acute Toxicity</th>
<th>Carcinogenicity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin Irritation/Corrosion</td>
<td>Reproductive</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Serious Eye Damage/Irritation</td>
<td>STOT - Single Exposure</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory or Skin sensitisation</td>
<td>STOT - Repeated Exposure</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>Aspiration Hazard</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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[^2]: Studies * ISP MSDS **BASF MSDS

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**Continued...**
## SECTION 12 ECOLOGICAL INFORMATION

### Toxicity

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>ENDPOINT</th>
<th>TEST DURATION (HR)</th>
<th>SPECIES</th>
<th>VALUE</th>
<th>SOURCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTU™, Propylthiouracil 50mg Tablet</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>propylthiouracil</td>
<td>LC50</td>
<td>96</td>
<td>Fish</td>
<td>&gt;100mg/L</td>
<td>6</td>
</tr>
<tr>
<td>starch</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>alpha-lactose</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>vinylpyrrolidone homopolymer</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>sodium lauryl sulfate</td>
<td>LC50</td>
<td>96</td>
<td>Fish</td>
<td>0.59mg/L</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>EC50</td>
<td>48</td>
<td>Crustacea</td>
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<td>4</td>
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<tr>
<td></td>
<td>EC50</td>
<td>96</td>
<td>Algae or other aquatic plants</td>
<td>1.2mg/L</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>BCF</td>
<td>1</td>
<td>Fish</td>
<td>0.85mg/L</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>EC15</td>
<td>24</td>
<td>Crustacea</td>
<td>0.17mg/L</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>NOEC</td>
<td>0.08</td>
<td>Fish</td>
<td>0.0000013mg/L</td>
<td>4</td>
</tr>
</tbody>
</table>

### Persistence and degradability

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Persistence: Water/Soil</th>
<th>Persistence: Air</th>
</tr>
</thead>
<tbody>
<tr>
<td>propylthiouracil</td>
<td>HIGH</td>
<td>HIGH</td>
</tr>
<tr>
<td>alpha-lactose</td>
<td>LOW</td>
<td>LOW</td>
</tr>
<tr>
<td>vinylpyrrolidone homopolymer</td>
<td>LOW</td>
<td>LOW</td>
</tr>
<tr>
<td>sodium lauryl sulfate</td>
<td>HIGH</td>
<td>HIGH</td>
</tr>
</tbody>
</table>

### Bioaccumulative potential

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Bioaccumulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>propylthiouracil</td>
<td>LOW (BCF = 38)</td>
</tr>
<tr>
<td>alpha-lactose</td>
<td>LOW (LogKOW = -5.1249)</td>
</tr>
<tr>
<td>vinylpyrrolidone homopolymer</td>
<td>LOW (LogKOW = 0.2484)</td>
</tr>
<tr>
<td>sodium lauryl sulfate</td>
<td>LOW (BCF = 7.15)</td>
</tr>
</tbody>
</table>

### Mobility in soil

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Mobility</th>
</tr>
</thead>
<tbody>
<tr>
<td>propylthiouracil</td>
<td>LOW (KOC = 271.5)</td>
</tr>
<tr>
<td>alpha-lactose</td>
<td>LOW (KOC = 10)</td>
</tr>
<tr>
<td>vinylpyrrolidone homopolymer</td>
<td>LOW (KOC = 40.46)</td>
</tr>
<tr>
<td>sodium lauryl sulfate</td>
<td>LOW (KOC = 10220)</td>
</tr>
</tbody>
</table>

---

**Legend:**

- Data available but does not fill the criteria for classification
- Data available to make classification
- Data Not Available to make classification

**DO NOT** discharge into sewer or waterways.
SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

Product / Packaging disposal

Containers may still present a chemical hazard/danger when empty.
Return to supplier for reuse/recycling if possible.
Otherwise:
If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then
puncture containers, to prevent re-use, and bury at an authorised landfill.
Where possible retain label warnings and SDS and observe all notices pertaining to the product.
DO NOT allow wash water from cleaning or process equipment to enter drains.
It may be necessary to collect all wash water for treatment before disposal.
In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
Where in doubt contact the responsible authority.
Recycle whenever possible or consult manufacturer for recycling options.
Consult State Land Waste Authority for disposal.
Bury or incinerate residue at an approved site.
Recycle containers if possible, or dispose of in an authorised landfill.

SECTION 14 TRANSPORT INFORMATION

Labels Required

<table>
<thead>
<tr>
<th>Marine Pollutant</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAZCHEM</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Transport in bulk according to Annex II of MARPOL and the IBC code
Not Applicable

SECTION 15 REGULATORY INFORMATION

Safety, health and environmental regulations / legislation specific for the substance or mixture

<table>
<thead>
<tr>
<th>PROPYLTHIOURACIL(51-52-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia Inventory of Chemical Substances (AICS)</td>
</tr>
<tr>
<td>International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>STARCH(9005-25-8) IS FOUND ON THE FOLLOWING REGULATORY LISTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia Exposure Standards</td>
</tr>
<tr>
<td>Australia Inventory of Chemical Substances (AICS)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ALPHA-LACTOSE(63-42-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia Inventory of Chemical Substances (AICS)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>VINYL PYRROLIDONE HOMOPOLYMER(9003-39-4) IS FOUND ON THE FOLLOWING REGULATORY LISTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia Inventory of Chemical Substances (AICS)</td>
</tr>
<tr>
<td>International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SODIUM LAURYL SULFATE(151-21-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia Hazardous Substances Information System - Consolidated Lists</td>
</tr>
<tr>
<td>Australia Inventory of Chemical Substances (AICS)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MAGNESIUM STEARATE(557-04-0) IS FOUND ON THE FOLLOWING REGULATORY LISTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia Exposure Standards</td>
</tr>
<tr>
<td>Australia Inventory of Chemical Substances (AICS)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>National Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia - AICS</td>
<td>Y</td>
</tr>
<tr>
<td>Canada - DSL</td>
<td>N (propylthiouracil)</td>
</tr>
<tr>
<td>Canada - NDSL</td>
<td>N (alpha-lactose; sodium lauryl sulfate; magnesium stearate; vinylpyrrolidone homopolymer)</td>
</tr>
<tr>
<td>China - IECSG</td>
<td>N (propylthiouracil)</td>
</tr>
<tr>
<td>Europe - ENEC / ELINCS / NLP</td>
<td>N (vinylpyrrolidone homopolymer)</td>
</tr>
<tr>
<td>Japan - ENCS</td>
<td>Y</td>
</tr>
<tr>
<td>Korea - KECI</td>
<td>Y</td>
</tr>
<tr>
<td>New Zealand - NZIoC</td>
<td>Y</td>
</tr>
<tr>
<td>Philippines - PICCS</td>
<td>Y</td>
</tr>
<tr>
<td>USA - TSCA</td>
<td>Y</td>
</tr>
</tbody>
</table>

Legend:
Y = All ingredients are on the inventory
N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing (see specific ingredients in brackets)

SECTION 16 OTHER INFORMATION
Ingredients with multiple cas numbers

<table>
<thead>
<tr>
<th>Name</th>
<th>CAS No</th>
</tr>
</thead>
<tbody>
<tr>
<td>starch</td>
<td>9005-25-8, 65996-63-6, 68441-21-4, 9005-84-9</td>
</tr>
<tr>
<td>alpha lactose</td>
<td>63-42-3, 5989-81-1, 14641-93-1, 64044-51-5, 10009-26-6</td>
</tr>
<tr>
<td>sodium lauryl sulfate</td>
<td>151-21-3, 1335-72-4, 3088-31-1, 9004-82-4</td>
</tr>
</tbody>
</table>

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

- PC—TWA: Permissible Concentration-Time Weighted Average
- PC—STEL: Permissible Concentration-Short Term Exposure Limit
- IARC: International Agency for Research on Cancer
- ACGIH: American Conference of Governmental Industrial Hygienists
- STEL: Short Term Exposure Limit
- IDLH: Immediately Dangerous to Life or Health Concentrations
- OSF: Odour Safety Factor
- NOEL: No Observed Adverse Effect Level
- LOAEL: Lowest Observed Adverse Effect Level
- TLV: Threshold Limit Value
- LOD: Limit Of Detection
- OTV: Odour Threshold Value
- BCF: BioConcentration Factors
- BEI: Biological Exposure Index

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