

# PTU™, Propylthiouracil 50mg Tablet

Phebra Pty Ltd

Chemwatch Hazard Alert Code: 2

Chemwatch: 25-9467

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Safety Data Sheet according to WHS and ADG requirements

S.GHS.AUS.EN

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

### Product Identifier

Product name	PTU™, Propylthiouracil 50mg Tablet
Synonyms	Not Available
Other means of identification	Not Available

### 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.
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### 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

Poisons Schedule	S4
Classification [1]	Acute Toxicity (Oral) Category 4, Germ cell mutagenicity Category 2, Carcinogenicity Category 2, Specific target organ toxicity - repeated exposure Category 2
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HSIS ; 3. Classification drawn from EC Directive 1272/2008 - Annex VI

### Label elements

Hazard pictogram(s)	
SIGNAL WORD	<b>WARNING</b>

### 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.

P270	Do not eat, drink or smoke when using this product.
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**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.
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**Precautionary statement(s) Disposal**

P501	Dispose of contents/container in accordance with local regulations.
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**SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS****Substances**

See section below for composition of Mixtures

**Mixtures**

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

**SECTION 4 FIRST AID MEASURES****Description of first aid measures**

<b>Eye Contact</b>	<p>If this product comes in contact with eyes:</p> <ul style="list-style-type: none"> <li>▶ Wash out immediately with water.</li> <li>▶ If irritation continues, seek medical attention.</li> <li>▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>
<b>Skin Contact</b>	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> <li>▶ Immediately remove all contaminated clothing, including footwear.</li> <li>▶ Flush skin and hair with running water (and soap if available).</li> <li>▶ Seek medical attention in event of irritation.</li> </ul>
<b>Inhalation</b>	<ul style="list-style-type: none"> <li>▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area.</li> <li>▶ Other measures are usually unnecessary.</li> </ul>
<b>Ingestion</b>	<ul style="list-style-type: none"> <li>▶ <b>IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.</b></li> <li>▶ For advice, contact a Poisons Information Centre or a doctor.</li> <li>▶ Urgent hospital treatment is likely to be needed.</li> <li>▶ 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.</li> <li>▶ 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.</li> <li>▶ If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the SDS.</li> </ul> <p><b>Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:</b></p> <ul style="list-style-type: none"> <li>▶ <b>INDUCE</b> vomiting with fingers down the back of the throat, <b>ONLY IF CONSCIOUS</b>. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.</li> </ul> <p><b>NOTE:</b> Wear a protective glove when inducing vomiting by mechanical means.</p>

**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):

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**BASIC TREATMENT**  
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- ▶ 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.

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 ADVANCED TREATMENT  
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- ▶ 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.
- ▶ Start an IV D5W TKO. 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.

BRONSTEIN, A.C. and CURRANCE, P.L.

EMERGENCY CARE FOR HAZARDOUS MATERIALS EXPOSURE: 2nd Ed. 1994

Treat symptomatically.

## 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

<b>Fire Incompatibility</b>	▶ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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### Advice for firefighters

<b>Fire Fighting</b>	<ul style="list-style-type: none"> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Wear breathing apparatus plus protective gloves in the event of a fire.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water courses.</li> <li>▶ Use fire fighting procedures suitable for surrounding area.</li> <li>▶ <b>DO NOT</b> approach containers suspected to be hot.</li> <li>▶ Cool fire exposed containers with water spray from a protected location.</li> <li>▶ If safe to do so, remove containers from path of fire.</li> <li>▶ Equipment should be thoroughly decontaminated after use.</li> </ul> <p>Slight hazard when exposed to heat, flame and oxidisers.</p>
<b>Fire/Explosion Hazard</b>	<ul style="list-style-type: none"> <li>▶ Non combustible.</li> <li>▶ Not considered a significant fire risk, however containers may burn.</li> </ul> <p>Decomposition may produce toxic fumes of:</p> <ul style="list-style-type: none"> <li>, carbon dioxide (CO<sub>2</sub>)</li> <li>, nitrogen oxides (NO<sub>x</sub>)</li> <li>, sulfur oxides (SO<sub>x</sub>)</li> <li>, other pyrolysis products typical of burning organic material.</li> </ul> <p>May emit poisonous fumes. May emit corrosive fumes.</p>
<b>HAZCHEM</b>	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

<b>Minor Spills</b>	<ul style="list-style-type: none"> <li>▶ Clean up all spills immediately.</li> <li>▶ Secure load if safe to do so.</li> <li>▶ Bundle/collect recoverable product.</li> <li>▶ Collect remaining material in containers with covers for disposal.</li> </ul>
<b>Major Spills</b>	<p>Minor hazard.</p> <ul style="list-style-type: none"> <li>▶ Clear area of personnel.</li> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Control personal contact with the substance, by using protective equipment as required.</li> <li>▶ Prevent spillage from entering drains or water ways.</li> <li>▶ Contain spill with sand, earth or vermiculite.</li> <li>▶ Collect recoverable product into labelled containers for recycling.</li> <li>▶ Absorb remaining product with sand, earth or vermiculite and place in appropriate containers for disposal.</li> </ul>

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

## SECTION 7 HANDLING AND STORAGE

### Precautions for safe handling

<b>Safe handling</b>	▶ Avoid all personal contact, including inhalation.
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	<ul style="list-style-type: none"> <li>▶ Wear protective clothing when risk of exposure occurs.</li> <li>▶ Use in a well-ventilated area.</li> <li>▶ Prevent concentration in hollows and sumps.</li> <li>▶ <b>DO NOT enter confined spaces until atmosphere has been checked.</b></li> <li>▶ <b>DO NOT allow material to contact humans, exposed food or food utensils.</b></li> <li>▶ Avoid contact with incompatible materials.</li> <li>▶ <b>When handling, DO NOT eat, drink or smoke.</b></li> </ul>
<b>Other information</b>	<ul style="list-style-type: none"> <li>▶ Store away from incompatible materials.</li> </ul>

**Conditions for safe storage, including any incompatibilities**

<b>Suitable container</b>	<ul style="list-style-type: none"> <li>▶ Glass container is suitable for laboratory quantities</li> <li>▶ Polyethylene or polypropylene container.</li> <li>▶ Packing as recommended by manufacturer.</li> <li>▶ Check all containers are clearly labelled and free from leaks.</li> </ul>
<b>Storage incompatibility</b>	<ul style="list-style-type: none"> <li>▶ Protect from light.</li> <li>▶ Avoid reaction with oxidising agents</li> </ul>

**SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION****Control parameters****OCCUPATIONAL EXPOSURE LIMITS (OEL)****INGREDIENT DATA**


Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	starch	Starch	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	magnesium stearate	Stearates	10 mg/m3	Not Available	Not Available	Not Available

**EMERGENCY LIMITS**

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
starch	Thyodene; (Amylodextrin)	30 mg/m3	330 mg/m3	2,000 mg/m3
vinylpyrrolidone homopolymer	Poly(1-vinyl-2-pyrrolidinone) homopolymer; (Polyvinylpyrrolidone; Plasdone)	51 mg/m3	560 mg/m3	20,000 mg/m3
sodium lauryl sulfate	Sodium lauryl sulfate	3.9 mg/m3	43 mg/m3	260 mg/m3

Ingredient	Original IDLH	Revised IDLH
propylthiouracil	Not Available	Not Available
starch	Not Available	Not Available
alpha-lactose	Not Available	Not Available
vinylpyrrolidone homopolymer	Not Available	Not Available
sodium lauryl sulfate	Not Available	Not Available
magnesium stearate	Not Available	Not Available

**Exposure controls**

<b>Appropriate engineering controls</b>	<p>Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.</p> <p>HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.</p> <p>Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.</p> <p>A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg.</p> <p>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.</p> <p>Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies.</p>
<b>Personal protection</b>	
<b>Eye and face protection</b>	<p>When handling very small quantities of the material eye protection may not be required.</p> <p>For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:</p> <ul style="list-style-type: none"> <li>▶ Chemical goggles.</li> <li>▶ Face shield. Full face shield may be required for supplementary but never for primary protection of eyes.</li> <li>▶ 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.</li> </ul>
<b>Skin protection</b>	See Hand protection below
<b>Hands/feet protection</b>	<ul style="list-style-type: none"> <li>▶ Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference.</li> <li>▶ Double gloving should be considered.</li> <li>▶ PVC gloves.</li> <li>▶ Change gloves frequently and when contaminated, punctured or torn.</li> </ul>

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	<ul style="list-style-type: none"> <li>▶ Wash hands immediately after removing gloves.</li> <li>▶ Protective shoe covers. [AS/NZS 2210]</li> <li>▶ Head covering.</li> </ul>
<b>Body protection</b>	See Other protection below
<b>Other protection</b>	<ul style="list-style-type: none"> <li>▶ For quantities up to 500 grams a laboratory coat may be suitable.</li> <li>▶ 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.</li> <li>▶ For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.</li> <li>▶ For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.</li> <li>▶ Eye wash unit.</li> <li>▶ Ensure there is ready access to an emergency shower.</li> <li>▶ For Emergencies: Vinyl suit</li> </ul>
<b>Thermal hazards</b>	Not Available

## SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

## Information on basic physical and chemical properties

<b>Appearance</b>	PTU™ Tablets are round, white and biconvex. One side is debossed with "PRESTAB" while the other side is plain.		
<b>Physical state</b>	Manufactured	<b>Relative density (Water = 1)</b>	Not Available
<b>Odour</b>	Not Available	<b>Partition coefficient n-octanol / water</b>	Not Available
<b>Odour threshold</b>	Not Available	<b>Auto-ignition temperature (°C)</b>	Not Applicable
<b>pH (as supplied)</b>	Not Applicable	<b>Decomposition temperature</b>	Not Applicable
<b>Melting point / freezing point (°C)</b>	Not Applicable	<b>Viscosity (cSt)</b>	Not Applicable
<b>Initial boiling point and boiling range (°C)</b>	Not Applicable	<b>Molecular weight (g/mol)</b>	Not Applicable
<b>Flash point (°C)</b>	Not Applicable	<b>Taste</b>	Not Available
<b>Evaporation rate</b>	Not Applicable	<b>Explosive properties</b>	Not Available
<b>Flammability</b>	Not Applicable	<b>Oxidising properties</b>	Not Available
<b>Upper Explosive Limit (%)</b>	Not Applicable	<b>Surface Tension (dyn/cm or mN/m)</b>	Not Applicable
<b>Lower Explosive Limit (%)</b>	Not Applicable	<b>Volatile Component (%vol)</b>	Not Applicable
<b>Vapour pressure (kPa)</b>	Not Applicable	<b>Gas group</b>	Not Available
<b>Solubility in water (g/L)</b>	Immiscible	<b>pH as a solution (1%)</b>	Not Applicable
<b>Vapour density (Air = 1)</b>	Not Applicable	<b>VOC g/L</b>	Not Available

## SECTION 10 STABILITY AND REACTIVITY

<b>Reactivity</b>	See section 7
<b>Chemical stability</b>	Product is considered stable and hazardous polymerisation will not occur.
<b>Possibility of hazardous reactions</b>	See section 7
<b>Conditions to avoid</b>	See section 7
<b>Incompatible materials</b>	See section 7
<b>Hazardous decomposition products</b>	See section 5

## SECTION 11 TOXICOLOGICAL INFORMATION

## Information on toxicological effects

<b>Inhaled</b>	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.
<b>Ingestion</b>	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.
<b>Skin Contact</b>	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.
<b>Eye</b>	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).
<b>Chronic</b>	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.




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	There is limited evidence that, skin contact with this product is more likely to cause a sensitisation reaction in some persons compared to the general population. Prolonged exposure to high doses of thyroid inhibitors cause severe enlargement of the thyroid and reduced levels of circulating thyroid hormone.	
PTU™, Propylthiouracil 50mg Tablet	<b>TOXICITY</b>	<b>IRRITATION</b>
	Not Available	Not Available
propylthiouracil	<b>TOXICITY</b>	<b>IRRITATION</b>
	Oral (rat) LD50: 1250 mg/kg <sup>[2]</sup>	Not Available
starch	<b>TOXICITY</b>	<b>IRRITATION</b>
	Not Available	Skin (human): 0.3 mg/3d-I mild
alpha-lactose	<b>TOXICITY</b>	<b>IRRITATION</b>
	Oral (rat) LD50: >10000 mg/kg <sup>[2]</sup>	Not Available
vinylpyrrolidone homopolymer	<b>TOXICITY</b>	<b>IRRITATION</b>
	Inhalation (rat) LC50: >5.2 mg/l4h** <sup>[2]</sup>	Eye (rabbit):non-irritating (Draize)*
	Oral (rat) LD50: >100,000 mg/kg <sup>[2]</sup>	Skin (rabbit):non-irritating(Draize)**
sodium lauryl sulfate	<b>TOXICITY</b>	<b>IRRITATION</b>
	Oral (rat) LD50: 1288 mg/kg <sup>[2]</sup>	Eye (rabbit):100 mg/24 hr-moderate
		Skin (human): 25 mg/24 hr - mild
magnesium stearate	<b>TOXICITY</b>	<b>IRRITATION</b>
	Not Available	Not Available

**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.
PROPYLTHIOURACIL	<b>WARNING:</b> This substance has been classified by the IARC as Group 2B: Possibly Carcinogenic to Humans. Oral (woman) LDLo: 84 mg/kg/2W-I Nil reported Oral (woman) LDLo: 480 mg/kg/9W-I Oral (woman) TDLo: 900 mg/kg/21W-I Oral (man) TDLo: 116 mg/kg/11W-I
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	Equivocal tumorigenic agent by RTECS criteria.
VINYLPYRROLIDONE HOMOPOLYMER	The substance is classified by IARC as Group 3: <b>NOT</b> classifiable as to its carcinogenicity to humans. Evidence of carcinogenicity may be inadequate or limited in animal testing. Chronic toxicity ** Genetic toxicity: No mutagenic effect was found in various tests with microorganisms and mammalian cell culture. The substance was not mutagenic in studies with mammals. Carcinogenicity: In long-term animal studies in which the substance was given in high doses by feed, a carcinogenic effect was not observed. Developmental toxicity/teratogenicity: No indications of a developmental toxic / teratogenic effect were seen in animal studies * ISP MSDS **BASF MSDS
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 compound. Main criteria for diagnosing RADS include the absence of previous airways 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 due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty 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.

Acute Toxicity	✓	Carcinogenicity	✓
Skin Irritation/Corrosion	⊘	Reproductivity	⊘
Serious Eye Damage/Irritation	⊘	STOT - Single Exposure	⊘
Respiratory or Skin sensitisation	⊘	STOT - Repeated Exposure	✓
Mutagenicity	✓	Aspiration Hazard	⊘

Legend:  - Data available but does not meet the criteria for classification  
 - Data available to make classification  
 - Data Not Available to make classification

## SECTION 12 ECOLOGICAL INFORMATION

## Toxicity

PTU™, Propylthiouracil 50mg Tablet	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
propylthiouracil	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	LC50	96	Fish	>100mg/L	6
starch	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
alpha-lactose	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
vinylpyrrolidone homopolymer	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
sodium lauryl sulfate	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	LC50	96	Fish	0.59mg/L	4
	EC50	48	Crustacea	0.67mg/L	4
	EC50	96	Algae or other aquatic plants	1.2mg/L	4
	BCF	1	Fish	0.85mg/L	4
	EC15	24	Crustacea	0.17mg/L	4
magnesium stearate	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available

**Legend:** *Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data*

**DO NOT** discharge into sewer or waterways.

## Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
propylthiouracil	HIGH	HIGH
alpha-lactose	LOW	LOW
vinylpyrrolidone homopolymer	LOW	LOW
sodium lauryl sulfate	HIGH	HIGH

## Bioaccumulative potential

Ingredient	Bioaccumulation
propylthiouracil	LOW (BCF = 38)
alpha-lactose	LOW (LogKOW = -5.1249)
vinylpyrrolidone homopolymer	LOW (LogKOW = 0.2484)
sodium lauryl sulfate	LOW (BCF = 7.15)

## Mobility in soil

Ingredient	Mobility
propylthiouracil	LOW (KOC = 271.5)
alpha-lactose	LOW (KOC = 10)
vinylpyrrolidone homopolymer	LOW (KOC = 40.46)
sodium lauryl sulfate	LOW (KOC = 10220)

## SECTION 13 DISPOSAL CONSIDERATIONS

### Waste treatment methods

<b>Product / Packaging disposal</b>	<ul style="list-style-type: none"> <li>▶ Containers may still present a chemical hazard/ danger when empty.</li> <li>▶ Return to supplier for reuse/ recycling if possible.</li> </ul> <p>Otherwise:</p> <ul style="list-style-type: none"> <li>▶ 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.</li> <li>▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product.</li> <li>▶ <b>DO NOT allow wash water from cleaning or process equipment to enter drains.</b></li> <li>▶ It may be necessary to collect all wash water for treatment before disposal.</li> <li>▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.</li> <li>▶ Where in doubt contact the responsible authority.</li> <li>▶ Recycle wherever possible or consult manufacturer for recycling options.</li> <li>▶ Consult State Land Waste Authority for disposal.</li> <li>▶ Bury or incinerate residue at an approved site.</li> <li>▶ Recycle containers if possible, or dispose of in an authorised landfill.</li> </ul>
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## SECTION 14 TRANSPORT INFORMATION

### Labels Required

Marine Pollutant	NO
HAZCHEM	Not Applicable

**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

#### PROPYLTHIOURACIL(51-52-5) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)	International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs
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#### STARCH(9005-25-8) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards	Australia Inventory of Chemical Substances (AICS)
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#### ALPHA-LACTOSE(63-42-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)	
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#### VINYLPYRROLIDONE HOMOPOLYMER(9003-39-8) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)	International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs
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#### SODIUM LAURYL SULFATE(151-21-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Hazardous Substances Information System - Consolidated Lists	Australia Inventory of Chemical Substances (AICS)
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#### MAGNESIUM STEARATE(557-04-0) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards	Australia Inventory of Chemical Substances (AICS)
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National Inventory	Status
Australia - AICS	Y
Canada - DSL	N (propylthiouracil)
Canada - NDSL	N (alpha-lactose; sodium lauryl sulfate; magnesium stearate; vinylpyrrolidone homopolymer)
China - IECSC	N (propylthiouracil)
Europe - EINEC / ELINCS / NLP	N (vinylpyrrolidone homopolymer)
Japan - ENCS	Y
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	Y
<b>Legend:</b>	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



## Other information

### Ingredients with multiple cas numbers

Name	CAS No
starch	9005-25-8, 65996-63-6, 68441-21-4, 9005-84-9
alpha-lactose	63-42-3, 5989-81-1, 14641-93-1, 64044-51-5, 10039-26-6
vinylpyrrolidone homopolymer	9003-39-8, 25249-54-1, 111214-46-1, 116404-61-6, 132778-04-2, 132778-05-3, 132834-20-9, 153631-61-9, 29386-94-5, 41724-41-8, 496908-06-6, 53026-73-6, 53026-74-7, 53200-27-4, 61932-72-7, 65931-56-8, 862983-74-2, 9015-62-7, 9080-59-5
sodium lauryl sulfate	151-21-3, 1335-72-4, 3088-31-1, 9004-82-4

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  
TEEL: Temporary Emergency Exposure Limit,  
IDLH: Immediately Dangerous to Life or Health Concentrations  
OSF: Odour Safety Factor  
NOAEL :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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