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

## Product Identifier

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

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

<table>
<thead>
<tr>
<th>Relevant identified uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ospolot™ is indicated as an anticonvulsant for behavioural disorders associated with epilepsy; hyperkinetic behaviour; temporal lobe epilepsy; myoclonic seizures; grand mal attacks; Jacksonian seizures.</td>
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</tbody>
</table>

## 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

<table>
<thead>
<tr>
<th>Association / Organisation</th>
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<tr>
<td>Emergency telephone numbers</td>
<td>+61 401 264 004</td>
</tr>
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<td>Other emergency telephone numbers</td>
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# SECTION 2 HAZARDS IDENTIFICATION

## Classification of the substance or mixture

### Poisons Schedule

S4

### Classification [1]

Carcinogenicity Category 1A, Reproductive Toxicity Category 2

### Legend:


## Label elements

### Hazard pictogram(s)

| SIGNAL WORD | DANGER |

## Hazard statement(s)

| H350 | May cause cancer. |
| H361 | Suspected of damaging fertility or the unborn child. |

## Precautionary statement(s) Prevention

| P201 | Obtain special instructions before use. |
| P281 | Use personal protective equipment as required. |

## Precautionary statement(s) Response

| P308+P313 | IF exposed or concerned: Get medical advice/attention. |

## Precautionary statement(s) Storage

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Continued...
Precautionary statement(s) Disposal

P405 Store locked up.

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>
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<tr>
<td>61-56-3</td>
<td>51.5</td>
<td>Sulthiame</td>
</tr>
<tr>
<td>9005-25-8</td>
<td>26.5</td>
<td>starch</td>
</tr>
<tr>
<td>63-42-3</td>
<td>12.9</td>
<td>alpha-lactose</td>
</tr>
<tr>
<td>14807-96-6</td>
<td>4.6</td>
<td>talc</td>
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<tr>
<td>7631-86-9</td>
<td>1.2</td>
<td>silica amorphous</td>
</tr>
<tr>
<td>9004-65-3</td>
<td>1.2</td>
<td>Hydroxypropyl methyl Cellulose USP</td>
</tr>
<tr>
<td>9000-70-8</td>
<td>0.52</td>
<td>gelatine</td>
</tr>
<tr>
<td>557-04-0</td>
<td>0.52</td>
<td>magnesium stearate</td>
</tr>
<tr>
<td>25322-68-3</td>
<td>0.41</td>
<td>polyethylene glycol 4000</td>
</tr>
<tr>
<td>13463-67-7</td>
<td>0.41</td>
<td>titanium dioxide</td>
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</tbody>
</table>

SECTION 4 FIRST AID MEASURES

Description of first aid measures

Eye Contact
If this product comes in contact with the eyes:
- Wash out immediately with fresh running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Seek medical attention without delay; if pain persists or recurs 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.

Inhalation
If fumes or combustion products are inhaled remove from contaminated area.
- Lay patient down. Keep warm and rested.
- Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.
- Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.
- Transport to hospital, or doctor.

Ingestion
If swallowed do NOT induce vomiting.
- If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.
- Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
- Seek medical advice.

Indication of any immediate medical attention and special treatment needed

For anticonvulsants:
- It is recommended that the physician withdraw the drug slowly on the appearance of unusual depression, aggressiveness, or other behavioral alterations.
- As with other anticonvulsants, it is important to proceed slow when increasing or decreasing dosage, as well as when adding or eliminating other medication. Abrupt withdrawal of anticonvulsant medication may precipitate absence (petit mal) status.
- Treat symptomatically.

In cases of recent sulfonamide overdose the stomach should be emptied by aspiration and lavage. If kidney function is adequate, a saline purgative, such as sodium sulfate, 30 g in 250 ml water, may be given to promote peristalsis and elimination of sulfonamide in the urine may be assisted by giving alkalis, such as sodium bicarbonate and increasing fluid intake. Severe crystalluria may require ureteric catheterisation and irrigation with warm 2.5% sodium bicarbonate solution. Treatment should be continued until it can be assumed that the sulfonamide has been eliminated. The majority of sulfonamides are metabolised to acetylated derivatives which retain the toxicity of the parent compound and thus may indicate more active removal when adverse effects are very severe. Active measures may include forced diuresis, peritoneal dialysis and charcoal haemoperfusion.

[Martindale: The Extra Pharmacopoeia, 28th Ed]

SECTION 5 FIREFIGHTING MEASURES

Extinguishing media
- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.
- Water spray or fog - Large fires only.

Special hazards arising from the substrate or mixture

Continued...
Advice for firefighters

Fire Fighting
- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use water delivered as a fine spray to control fire and cool adjacent 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
- Combustible.
- Slight fire hazard when exposed to heat or flame.
- Heating may cause expansion or decomposition leading to violent rupture of containers.
- On combustion, may emit toxic fumes of carbon monoxide (CO).
- May emit acrid smoke.
- Mists containing combustible materials may be explosive.

For starch/air mixtures
- Starch is a Class 1 dust at normal moisture level:
  - Minimum Ignition Temperature (MIE): >30 mJ at normal moisture level
  - Pmax 9.5 Bar
  - Kst 170 bar/m/s
  - Autoignition Temperature: 170 deg C (above this temperature starch will self-heat)

Dust Explosion Hazard Class 1

Dusts fall into one of three Kst* classes. Class 1 dusts; Kst 1-200 m3/sec; Class 2 dusts; 201-299 m3/sec. Class 3 dusts; Kst 300 or more. Most agricultural dusts (grains, flour etc.) are Class 1; pharmaceuticals and other specialty chemicals are typically Class 1 or 2; most unoxidised metallic dusts are Class 3. The higher the Kst, the more energetically the dust will burn and the greater is the explosion risk and the greater is the speed of the explosion.

Standard test conditions, used to derive the Kst, are representative of industrial conditions, but do not represent an absolute worst case. Increased levels of turbulence increase the speed of the explosion dramatically.

* Kst - a normalised expression of the burning dust pressure rise rate over time.

Combustion products include:
- carbon monoxide (CO)
- carbon dioxide (CO2)
- hydrogen cyanide
- 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 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

#### 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>
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<tbody>
<tr>
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<td>Starch</td>
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#### EMERGENCY LIMITS

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<td>Silica, amorphous fumed</td>
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<td>7,900 mg/m3</td>
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### 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 fume balanced ventilation enclosure is recommended for weighing or 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 enclosed enclosures. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment laboratory using appropriate barriers.

**Personal 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.

**Eye and face protection**

- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- 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 up to 500 gram a laboratory coat may be suitable.
- 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.
- Wash hands immediately after removing gloves.
- Protective shoe covers. [AS/NZS 2210]
- Head covering.

**Skin protection**

See Hand protection below.

**Hands/feet 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 manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- 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
- Overalls.
- PVC apron.
- Barrier cream.

**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 manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- Eye wash unit.
- For Emergencies: Vinyl suit
- Overalls.
- PVC apron.
- Barrier cream.
SECTION 10 STABILITY AND REACTIVITY

Reactivity

Chemical stability

Possibility of hazardous reactions

Conditions to avoid

Incompatible materials

Hazardous decomposition products

SECTION 11 TOXICOLOGICAL INFORMATION

Information on toxicological effects

Inhaled

Inhalation of vapours or aerosols (mists, fumes), generated by the material during the course of normal handling, may be damaging to the health of the individual.

Ingestion

Accidental ingestion of the material may be damaging to the health of the individual. Antiepileptic drugs (AEDs) act as anticonvulsants and increase the risk of suicidal thoughts or behaviour in patients taking these drugs for any indication, as such, should be monitored carefully. However, this is limited to 24 weeks study and there is no gender or age barrier to these effects.

Skin Contact

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. There is some evidence to suggest that the material may cause mild but significant inflammation of the skin either following direct contact or after a delay of some time. Repeated exposure can cause contact dermatitis which is characterised by redness, swelling and blistering.

Eye

There is some evidence to suggest that this material can cause eye irritation and damage in some persons.

Chronic

Based on experience with animal studies, exposure to the material may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother.

Substance accumulation, in the human body, may occur and may cause some concern following repeated or long term occupational exposure. There is some evidence that inhaling this product is more likely to cause a sensitisation reaction in some persons compared to the general population.

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.
population.
There is some evidence from animal testing that exposure to this material may result in reduced fertility. Some workers may develop chronic occupational dermatitis (generally mild) through the handling of starch products. When starch is used as a lubricant in surgical gloves, small amounts, released into the patient during the course of surgery, have resulted in granulomas and peritonitis. Prolonged oral treatment with sulfonamides has caused nausea, vomiting, diarrhoea, loss of appetite, inflammation of the mouth cavity, impaired folate acid absorption, exacerbation of porphyria, acidosis, liver damage with impaired blood clotting, jaundice and inflammation of the pancreas. Effects on the kidney include blood and crystals in the urine, painful and frequent urination or lack of urine with nitrogen retention. Dusts produced by proteins can sometimes sensitise workers like other foreign bodies. Symptoms include asthma appearing soon after exposure, with wheezing, narrowing of the airways and breathing difficulties. Inhalation studies using animals have shown that cellulose fibres can cause lung scarring, and humans exposed to cellulose at work are more likely to develop asthma and obstructive lung disease. The substance may also induce the production of free radicals in human white blood cells.

<table>
<thead>
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<th>Ospolot™, Sulthiame 50mg Tablet</th>
<th>TOXICITY</th>
<th>IRRITATION</th>
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<tr>
<td>Sulthiame</td>
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</tr>
<tr>
<td>starch</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>alpha-lactose</td>
<td>Not Available</td>
<td>Skin (human): 0.3 mg/3d I mild</td>
</tr>
<tr>
<td>talc</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td>silica amorphous</td>
<td>Dermal (rabbit) LD50: &gt;5000 mg/kg^2</td>
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</tr>
<tr>
<td>Hydroxypropyl methyl Cellulose USP</td>
<td>Oral (rat) LD50: &gt;6000 mg/kg^2</td>
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<td>gelatine</td>
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<td>magnesium stearate</td>
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<td>Not Available</td>
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<td>polyethylene glycol 4000</td>
<td>Dermal (rabbit) LD50: &gt;20000 mg/kg^2</td>
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<tr>
<td>titanium dioxide</td>
<td>Inhalation (rat) LC50: &gt;2280 mg/l</td>
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</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

**ALPHA-LACTOSE**
- Equivocal tumorigenic agent by RTECS criteria.

**TALC**
- The overuse of talc in nursing infants has resulted in respiratory damage causing fluid in the lungs and lung inflammation which may lead to death within hours of inhalation.
- Long-term exposure can also cause a variety of respiratory symptoms.

**SILICA AMORPHOUS**
- For silica amorphous: When experimental animals inhale synthetic amorphous silica (SAS) dust, it dissolves in the lung fluid and is rapidly eliminated. If swallowed, the vast majority of SAS is excreted in the faeces and there is little accumulation in the body. Following absorption across the gut, SAS is eliminated via urine without modification in animals and humans. SAS is not expected to be broken down (metabolised) in mammals. After ingestion, there is limited accumulation of SAS in body tissues and rapid elimination occurs. Intestinal absorption has not been calculated, but appears to be insignificant in animals and humans. SASs injected subcutaneously are subjected to rapid dissolution and removal. There is no indication of metabolism of SAS in animals or humans based on chemical structure and available data. Reports indicate high/prolonged exposures to amorphous silicas induced lung fibrosis in experimental animals; in some experiments these effects were reversible. [PATTYS]

**MAGNESIUM STEARATE**
- 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></th>
<th>ENDPOINT</th>
<th>TEST DURATION (HR)</th>
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<th>VALUE</th>
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<tr>
<td><strong>starch</strong></td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td><strong>alpha-lactose</strong></td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td><strong>talc</strong></td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
<td>Not Available</td>
</tr>
<tr>
<td><strong>silica amorphous</strong></td>
<td>LC50 96</td>
<td>Fish</td>
<td>ca.2000mg/L</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC50 48</td>
<td>Crustacea</td>
<td>ca.7600mg/L</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

#### SECTION 12 ECOLOGICAL INFORMATION

**Acute Toxicity**
- Data available but does not fill the criteria for classification

**Skin Irritation/Corrosion**
- Data available to make classification

**Serious Eye Damage/Irritation**
- Data available to make classification

**Respiratory or Skin sensitisation**
- Data Not Available to make classification

**Mutagenicity**
- Data available to make classification

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

---

For polyethylene glycols: 
Pure polyethylene glycols have essentially similar toxicity, with the lighter species being more toxic. Absorption from the digestive tract decreases with increasing molecular weight. 
Polyethylene glycols do not have sensitizing and irritating properties on skin, however, allergic reactions (which can present as hives), sometimes delayed, may occur with some lighter species. 
The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

**TITANIUM DIOXIDE**
The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. 
Exposure to titanium dioxide is via inhalation, swallowing or skin contact. When inhaled, it may deposit in lung tissue and lymph nodes causing dysfunction of the lungs and immune system. Absorption by the stomach and intestines depends on the size of the particle. It penetrated only the outermost layer of the skin, suggesting that healthy skin may be an effective barrier. There is no substantive data on genetic damage, though cases have been reported in experimental animals. Studies have differing conclusions on its cancer-causing potential.

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

* IUCLID

**Ospolot™, Sulthiame 50mg Tablet & TALC & GELATINE**
No significant acute toxicological data identified in literature search.

**Ospolot™, Sulthiame 50mg Tablet & SULTHIAMINE**
Reports suggest an association between the use of anti-convulsant drugs by women with epilepsy and an elevated incidence of birth defects in children born to these women. However, whether the abnormalities are caused by the maternal epilepsy itself or by exposure to anti-convulsant drugs is unclear and unsubstantiated by study till date. Exposure in utero has lead to high frequency of "anti-convulsant embryopathy" characterised by growth retardation, and hypoplasia of the mid face and fingers. As such, pregnant patients with seizure disorders should be carefully considered before administering anti-convulsant therapy.

**STARCH & POLYETHYLENE GLYCOL 4000 & TITANIUM DIOXIDE**
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.

**TALC & 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.

**TALC & SILICA AMORPHOUS**
The substance is classified by IARC as Group 3: NOT classifiable as to its carcinogenicity to humans. Evidence of carcinogenicity may be inadequate or limited in animal testing.
## EC50
- 72 Algae or other aquatic plants 440mg/L 1
- 72 Algae or other aquatic plants 140mg/L 1
- 72 Algae or other aquatic plants 60mg/L 1

## EC10
- 72 Algae or other aquatic plants 140mg/L 1

## NOEC
- 72 Algae or other aquatic plants 60mg/L 1

### 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

### Persistence and degradability

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Persistence: Water/Soil</th>
<th>Persistence: Air</th>
</tr>
</thead>
<tbody>
<tr>
<td>alpha-lactose</td>
<td>LOW</td>
<td>LOW</td>
</tr>
<tr>
<td>silica amorphous</td>
<td>LOW</td>
<td>LOW</td>
</tr>
<tr>
<td>polyethylene glycol 4000</td>
<td>LOW</td>
<td>LOW</td>
</tr>
<tr>
<td>titanium dioxide</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>alpha-lactose</td>
<td>LOW (LogKOW = -5.1249)</td>
</tr>
<tr>
<td>silica amorphous</td>
<td>LOW (LogKOW = 0.5294)</td>
</tr>
<tr>
<td>polyethylene glycol 4000</td>
<td>LOW (LogKOW = -1.1996)</td>
</tr>
<tr>
<td>titanium dioxide</td>
<td>LOW (BCF = 10)</td>
</tr>
</tbody>
</table>

### Mobility in soil

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Mobility</th>
</tr>
</thead>
<tbody>
<tr>
<td>alpha-lactose</td>
<td>LOW (KOC = 10)</td>
</tr>
<tr>
<td>silica amorphous</td>
<td>LOW (KOC = 23.74)</td>
</tr>
<tr>
<td>polyethylene glycol 4000</td>
<td>HIGH (KOC = 1)</td>
</tr>
<tr>
<td>titanium dioxide</td>
<td>LOW (KOC = 23.74)</td>
</tr>
</tbody>
</table>

### SECTION 13 DISPOSAL CONSIDERATIONS

#### Waste treatment methods

- **Product / Packaging disposal**
  - 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 / GGGSee): 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

SULTHIAMINE(61-56-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Not Applicable

STARCH(9005-25-8) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Inventory of Chemical Substances (AICS)

ALPHA-LACTOSE(63-42-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

TALC(14807-96-6) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Hazardous Substances Information System - Consolidated Lists

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

SILICA AMORPHOUS(7631-86-9) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Hazardous Substances Information System - Consolidated Lists

Australia Inventory of Chemical Substances (AICS)

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

HYDROXYPROPYL METHYL CELLULOSE USP(9004-65-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

GELATINE(9000-70-8) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

MAGNESIUM STEARATE(657-04-0) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Inventory of Chemical Substances (AICS)

POLYETHYLENE GLYCOL 4000(25322-68-3) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

TITANIUM DIOXIDE(13463-67-7) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Inventory of Chemical Substances (AICS)

National Inventory

<table>
<thead>
<tr>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia - AICS</td>
</tr>
<tr>
<td>Canada - DSL</td>
</tr>
<tr>
<td>Canada - NDSL</td>
</tr>
<tr>
<td>China - IEOCS</td>
</tr>
<tr>
<td>Europe - EINEC / ELINCS / NLP</td>
</tr>
<tr>
<td>Japan - ENCS</td>
</tr>
<tr>
<td>Korea - KECI</td>
</tr>
<tr>
<td>New Zealand - NZIoC</td>
</tr>
<tr>
<td>Philippines - PICCS</td>
</tr>
<tr>
<td>USA - TSCA</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

Other information

Ingredients with multiple cas numbers
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
silica amorphous 7631-86-9, 112945-52-5, 67762-90-7, 68611-44-9, 68909-20-6, 112926-00-8, 61790-53-2, 60053-39-3, 69012-64-2, 84449-94-7
Hydroxypropyl methyl Cellulose USP 9004-65-3, 8063-82-9

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
- BEI: Biological Exposure Index

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