

Ospolot™, Sulthiame 50mg Tablet

Phebra Pty Ltd

Chemwatch Hazard Alert Code: 3

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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	Ospolot™, Sulthiame 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	Ospolot™ is indicated as an anticonvulsant for behavioural disorders associated with epilepsy; hyperkinetic behaviour; temporal lobe epilepsy; myoclonic seizures; grand mal attacks; Jacksonian seizures.
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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]	Carcinogenicity Category 1A, Reproductive Toxicity 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)	
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SIGNAL WORD	DANGER
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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.
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Precautionary statement(s) Storage

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

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

Eye Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ 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	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ 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 slowly 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

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Fire Incompatibility

▶ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▶ 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. <p>Slight hazard when exposed to heat, flame and oxidisers.</p>
Fire/Explosion Hazard	<ul style="list-style-type: none"> ▶ 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. <p>For starch/ air mixtures Starch is a class St1 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)</p> <p>Dust Explosion Hazard Class 1</p> <p>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 speciality 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.</p> <p>* Kst - a normalised expression of the burning dust pressure rise rate over time.</p> <p>Dusts with Minimum Ignition Energies (MIEs) ranging between 20 and 100 mJ may be sensitive to ignition. They require that:</p> <ul style="list-style-type: none"> - plant is grounded - personnel might also need to be grounded - the use of high resistivity materials (such as plastics) should be restricted or avoided during handling or in packaging <p>The majority of ignition accidents occur within or below this range.</p> <p>The MIE of a dust/air mix depends on the particle size the water content and the temperature of the dust. The finer and the dryer the dust the lower the MIE. Higher temperatures cause lower MIE and an increased risk of dust explosion.</p> <p>Quoted values for MIE generally are only representative. Characteristics may change depending upon the process and conditions of use or any changes made to the dust during use, including further grinding or mixing with other products. In order to obtain more specific data for dust, as used, it is recommended that further characterisation testing is performed.</p> <p>Combustion products include:</p> <ul style="list-style-type: none"> ’ carbon monoxide (CO) ’ carbon dioxide (CO2) ’ hydrogen cyanide ’ nitrogen oxides (NOx) ’ sulfur oxides (SOx) ’ other pyrolysis products typical of burning organic material. <p>May emit poisonous fumes. May emit corrosive fumes.</p>
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	<p>Environmental hazard - contain spillage.</p> <ul style="list-style-type: none"> ▶ Clean up waste regularly and abnormal spills immediately. ▶ Avoid breathing dust and contact with skin and eyes. ▶ Wear protective clothing, gloves, safety glasses and dust respirator. ▶ Use dry clean up procedures and avoid generating dust. ▶ Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use). ▶ Dampen with water to prevent dusting before sweeping. ▶ Place in suitable containers for disposal.
Major Spills	<p>Minor hazard.</p> <ul style="list-style-type: none"> ▶ Clear area of personnel. ▶ Alert Fire Brigade and tell them location and nature of hazard.

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- ▶ 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	<ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ Store away from incompatible materials.

Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> ▶ 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	<p>Cellulose and its derivatives may react vigorously with calcium oxide, bleaching powder, perchlorates, perchloric acid, sodium chlorate, fluorine, nitric acid, sodium nitrate and sodium nitrite.</p> <p>May be incompatible with aminacrine hydrochloride, chlorocresol, mercuric chloride, phenol, resorcinol, tannic acid and silver nitrate.</p> <ul style="list-style-type: none"> ▶ Avoid reaction with oxidising agents

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	talc	Talc, (containing no asbestos fibres)	2.5 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	talc	Soapstone (respirable dust)	3 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Precipitated silica	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Silica gel	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Diatomaceous earth (uncalcined)	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Diatomaceous earth (uncalcined)	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Precipitated silica	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Silica gel	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Fumed silica (respirable dust)	2 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Fumed silica (respirable dust)	2 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Silica, fused	Not Available	Not Available	Not Available	Not Available
Australia Exposure Standards	magnesium stearate	Stearates	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	titanium dioxide	Titanium dioxide	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
talc	Talc	6 mg/m3	66 mg/m3	400 mg/m3
silica amorphous	Silica gel, amorphous synthetic	18 mg/m3	200 mg/m3	1,200 mg/m3
silica amorphous	Silica, amorphous fumed	18 mg/m3	100 mg/m3	630 mg/m3
silica amorphous	Siloxanes and silicones, dimethyl, reaction products with silica; (Hydrophobic silicon dioxide, amorphous)	120 mg/m3	1,300 mg/m3	7,900 mg/m3
silica amorphous	Silica, amorphous fume	45 mg/m3	500 mg/m3	3,000 mg/m3
silica amorphous	Silica amorphous hydrated	18 mg/m3	220 mg/m3	1,300 mg/m3
polyethylene glycol 4000	Tetraethylene glycol	87 mg/m3	960 mg/m3	5,700 mg/m3


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polyethylene glycol 4000	Polyethylene glycol	30 mg/m3	1,300 mg/m3	7,700 mg/m3
titanium dioxide	Titanium oxide; (Titanium dioxide)	30 mg/m3	330 mg/m3	2,000 mg/m3

Ingredient	Original IDLH	Revised IDLH
Sulthiame	Not Available	Not Available
starch	Not Available	Not Available
alpha-lactose	Not Available	Not Available
talc	1000 mg/m3	Not Available
silica amorphous	3000 mg/m3	Not Available
Hydroxypropyl methyl Cellulose USP	Not Available	Not Available
gelatine	Not Available	Not Available
magnesium stearate	Not Available	Not Available
polyethylene glycol 4000	Not Available	Not Available
titanium dioxide	5000 mg/m3	Not Available

Exposure controls

Appropriate engineering controls	<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> <p>Assess operations based upon available dust explosion information to determine the suitability of preventative or protective systems as precautionary measures against possible dust explosions. If prevention is not possible, consider protection by use of containment, venting or suppression of dust handling equipment. Where explosion venting is considered to be the most appropriate method of protection, vent areas should preferably be calculated based on Kst rather than an St value. If nitrogen purging is considered as the protective system, it must operate with an oxygen level below the limiting oxygen concentration. The system should include an oxygen monitoring and shut-down facility in the event of excessive oxygen being detected.</p> <p>The maximum surface temperature of enclosures potentially exposed to this material should be based on values obtained by taking 2/3 of the minimum ignition temperature (MIE) of the dust cloud. The effect of dust layers should be reviewed.</p> <p>An isolated (insulated) human body can readily produce electrostatic discharges in excess of 50 mJ, but have been recorded up to 100 mJ.</p>
Personal protection	
Eye and face protection	<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"> ▶ 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. <p>No special equipment required due to the physical form of the product.</p>
Skin protection	See Hand protection below
Hands/feet protection	<ul style="list-style-type: none"> ▶ 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. <p>No special equipment required due to the physical form of the product.</p>
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none"> ▶ 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 ▶ Overalls. ▶ P.V.C. apron. ▶ Barrier cream.

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	<ul style="list-style-type: none"> ▶ Skin cleansing cream. ▶ Eye wash unit.
Thermal hazards	Not Available

Respiratory protection

- ▶ Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- ▶ The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- ▶ Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- ▶ Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- ▶ Use approved positive flow mask if significant quantities of dust becomes airborne.
- ▶ Try to avoid creating dust conditions.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES**Information on basic physical and chemical properties**

Appearance	Ospolot™ Tablets are white, round, slightly domed film coated tablets, diameter 6 mm, upper punch: imprint "50".		
Physical state	Manufactured	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Applicable
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water (g/L)	Not Available	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

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	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

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	<p>population.</p> <p>There is some evidence from animal testing that exposure to this material may result in reduced fertility.</p> <p>Some workers may develop chronic occupational dermatitis (generally mild) through the handling of starch products.</p> <p>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.</p> <p>Prolonged oral treatment with sulfonamides has caused nausea, vomiting, diarrhoea, abdominal pain, loss of appetite, inflammation of the mouth cavity, impaired folic acid absorption, exacerbation of porphyria, acidosis, liver damage with impaired blood clotting, jaundice and inflammation of the pancreas.</p> <p>Effects on the kidney include blood and crystals in the urine, painful and frequent urination or lack of urine with nitrogen retention.</p> <p>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.</p> <p>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.</p>
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	TOXICITY	IRRITATION
Ospolot™, Sulthiame 50mg Tablet	Not Available	Not Available
Sulthiamine	Oral (rat) LD50: >5000 mg/kg ^[2]	Not Available
starch	Not Available	Skin (human): 0.3 mg/3d-I mild
alpha-lactose	Oral (rat) LD50: >10000 mg/kg ^[2]	Not Available
talc	Not Available	Skin (human): 0.3 mg/3d-I mild
silica amorphous	Dermal (rabbit) LD50: >5000 mg/kg ^[2] Inhalation (rat) LC50: >0.139 mg/l/14h**[Grace] ^[2] Oral (rat) LD50: 3160 mg/kg ^[2]	Eye (rabbit): non-irritating * Skin (rabbit): non-irritating *
Hydroxypropyl methyl Cellulose USP	Oral (rat) LD50: >10000 mg/kg ^[2]	Not Available
gelatine	Not Available	Not Available
magnesium stearate	Not Available	Not Available
polyethylene glycol 4000	Dermal (rabbit) LD50: >20000 mg/kg ^[2] Oral (rat) LD50: 600 mg/kg ^[2]	Eye (rabbit): 500 mg/24h - mild Skin (rabbit): 500mg (open) mild
titanium dioxide	Inhalation (rat) LC50: >2.28 mg/14 h ^[1] Oral (rat) LD50: >2000 mg/kg ^[1]	Skin (human): 0.3 mg /3D (int)-mild *

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.

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POLYETHYLENE GLYCOL 4000	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 anticonvulsant 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 anticonvulsant drugs is unclear and unsubstantiated by study till date. Exposure in utero has lead to high frequency of "anticonvulsant 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 anticonvulsant 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.

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 fill the criteria for classification

✓ – Data available to make classification

☒ – Data Not Available to make classification

SECTION 12 ECOLOGICAL INFORMATION

Toxicity

	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Ospolot™, Sulthiame 50mg Tablet	Not Available	Not Available	Not Available	Not Available
Sulthiame	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
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
talc	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
silica amorphous	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	LC50	96	Fish	ca.2000mg/L	1
	EC50	48	Crustacea	ca.7600mg/L	1

Continued...

Ospolot™, Sulthiame 50mg Tablet

	EC50	72	Algae or other aquatic plants	440mg/L	1
	EC10	72	Algae or other aquatic plants	140mg/L	1
	NOEC	72	Algae or other aquatic plants	60mg/L	1
Hydroxypropyl methyl Cellulose USP	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
gelatine	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
magnesium stearate	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
polyethylene glycol 4000	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	LC50	96	Fish	>1000mg/L	4
titanium dioxide	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	LC50	96	Fish	155mg/L	2
	EC50	48	Crustacea	>10mg/L	2
	EC50	72	Algae or other aquatic plants	5.83mg/L	4
	EC20	72	Algae or other aquatic plants	1.81mg/L	4
	NOEC	336	Fish	0.089mg/L	4

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

Toxic to soil organisms.

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
alpha-lactose	LOW	LOW
silica amorphous	LOW	LOW
polyethylene glycol 4000	LOW	LOW
titanium dioxide	HIGH	HIGH

Bioaccumulative potential

Ingredient	Bioaccumulation
alpha-lactose	LOW (LogKOW = -5.1249)
silica amorphous	LOW (LogKOW = 0.5294)
polyethylene glycol 4000	LOW (LogKOW = -1.1996)
titanium dioxide	LOW (BCF = 10)

Mobility in soil

Ingredient	Mobility
alpha-lactose	LOW (KOC = 10)
silica amorphous	LOW (KOC = 23.74)
polyethylene glycol 4000	HIGH (KOC = 1)
titanium dioxide	LOW (KOC = 23.74)

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

Product / Packaging disposal	<ul style="list-style-type: none"> ▶ 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 wherever 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.
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Continued...

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

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 Inventory of Chemical Substances (AICS)

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 Inventory of Chemical Substances (AICS)

Australia Hazardous Substances Information System - Consolidated Lists

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(557-04-0) 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

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

Australia Inventory of Chemical Substances (AICS)

National Inventory	Status
Australia - AICS	N (Sulthiame)
Canada - DSL	N (Sulthiame)
Canada - NDSL	N (talc; alpha-lactose; gelatine; magnesium stearate; Sulthiame; polyethylene glycol 4000; Hydroxypropyl methyl Cellulose USP)
China - IECSC	N (Sulthiame)
Europe - EINEC / ELINCS / NLP	N (Hydroxypropyl methyl Cellulose USP)
Japan - ENCS	N (gelatine)
Korea - KECI	N (Sulthiame)
New Zealand - NZIoC	Y
Philippines - PICCS	N (Sulthiame)
USA - TSCA	N (Sulthiame)
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**

Ospolot™, Sulthiame 50mg Tablet

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
silica amorphous	7631-86-9, 112945-52-5, 67762-90-7, 68611-44-9, 68909-20-6, 112926-00-8, 61790-53-2, 60676-86-0, 91053-39-3, 69012-64-2, 844491-94-7
Hydroxypropyl methyl Cellulose USP	9004-65-3, 8063-82-9
titanium dioxide	13463-67-7, 1317-70-0, 1317-80-2, 12188-41-9, 1309-63-3, 100292-32-8, 101239-53-6, 116788-85-3, 12000-59-8, 12701-76-7, 12767-65-6, 12789-63-8, 1344-29-2, 185323-71-1, 185828-91-5, 188357-76-8, 188357-79-1, 195740-11-5, 221548-98-7, 224963-00-2, 246178-32-5, 252962-41-7, 37230-92-5, 37230-94-7, 37230-95-8, 37230-96-9, 39320-58-6, 39360-64-0, 39379-02-7, 416845-43-7, 494848-07-6, 494848-23-6, 494851-77-3, 494851-98-8, 55068-84-3, 55068-85-4, 552316-51-5, 62338-64-1, 767341-00-4, 97929-50-5, 98084-96-9

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
 BCF: BioConcentration Factors
 BEI: Biological Exposure Index

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