

Pro-Cid™, Probenecid 500mg Tablet

Phebra Pty Ltd

Chemwatch Hazard Alert Code: 2

Chemwatch: 25-9465

Issue Date: 27/06/2017

Version No: 2.1.1.1

Print Date: 07/03/2018

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	Pro-Cid™, Probenecid 500mg 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	Pro-Cid™ is indicated for: Gout Probenecid is a uricosuric agent for the treatment of hyperuricaemia in all stages of gout and gouty arthritis except an acute attack. Asymptomatic hyperuricaemia seems to occur in a significant percentage of relatives of gouty patients. Probenecid may be given prophylactically to these people to forestall gouty attacks and urate deposition in tissues. By virtue of its effective uricosuric activity, probenecid may be used to control the hyperuricaemia induced or aggravated by many diuretics employed for the treatment of oedema and hypertension (eg thiazides and similar diuretics). B- Lactam Antibiotic Therapy Probenecid is indicated for the elevation and prolongation of plasma levels by whatever route the antibiotic is given. A two-to-fourfold increase in plasma levels has been demonstrated for benzylpenicillin, phenoxymethylpenicillin, the synthetic penicillins, ampicillin, methicillin, oxacillin, cloxacillin, nafcillin, carbenicillin, and for the cephamycin, MEFOXINTM (cefotaxime sodium, MSD), and the cephalosporins, cephalothin, cephalexin and cephaloglycin. Because of its mechanism of action, probenecid is not recommended in conjunction with a B-lactam antibiotic in the presence of known renal impairment. Concurrent Treatment with Cidofovir for CMV retinitis in HIV patients. Probenecid is recommended to be administered concomitantly with cidofovir, as the combination reduces the potential for nephrotoxicity associated with cidofovir..
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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, Skin Corrosion/Irritation Category 2, Eye Irritation Category 2A, Carcinogenicity Category 2, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation)
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	WARNING
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Hazard statement(s)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H351	Suspected of causing cancer.

H335	May cause respiratory irritation.
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Precautionary statement(s) Prevention

P201	Obtain special instructions before use.
P271	Use only outdoors or in a well-ventilated area.
P281	Use personal protective equipment as required.
P261	Avoid breathing dust/fumes.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statement(s) Response

P308+P313	IF exposed or concerned: Get medical advice/attention.
P362	Take off contaminated clothing and wash before reuse.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice/attention.
P301+P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P304+P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P330	Rinse mouth.

Precautionary statement(s) Storage

P405	Store locked up.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.

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
57-66-9	74.6	<u>probenecid</u>
9004-34-6	8.6	<u>cellulose</u>
9063-38-1	3.9	<u>sodium carboxymethoxy starch</u>
9005-25-8	3.6	<u>starch</u>
Not Available	2.7	OPADRY YS-12063 yellow
57-11-4	2.4	<u>stearic acid</u>
9003-39-8	1.9	<u>vinylpyrrolidone homopolymer</u>
7631-86-9	0.5	<u>silica amorphous</u>
557-04-0	0.3	<u>magnesium stearate</u>
117698-04-1	0.3	<u>Opadry YS-1-7006</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, without delay.

Ingestion

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

Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:

- ▶ **INDUCE** vomiting with fingers down the back of the throat, **ONLY IF CONSCIOUS**. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

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

Indication of any immediate medical attention and special treatment needed

As in all cases of suspected poisoning, follow the ABCDEs of emergency medicine (airway, breathing, circulation, disability, exposure), then the ABCDEs of toxicology (antidotes, basics, change absorption, change distribution, change elimination).

For poisons (where specific treatment regime is absent):

BASIC TREATMENT

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

ADVANCED TREATMENT

- ▶ Consider orotracheal or nasotracheal intubation for airway control in unconscious patient or where respiratory arrest has occurred.
- ▶ Positive-pressure ventilation using a bag-valve mask might be of use.
- ▶ Monitor and treat, where necessary, for arrhythmias.
- ▶ 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**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**

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

Slight hazard when exposed to heat, flame and oxidisers.

Fire/Explosion Hazard

- ▶ Non combustible.
 - ▶ Not considered a significant fire risk, however containers may burn.
- Decomposition may produce toxic fumes of:

carbon dioxide (CO₂)

nitrogen oxides (NO_x)

sulfur oxides (SO_x)

other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

May emit corrosive fumes.

HAZCHEM

Not Applicable

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	<ul style="list-style-type: none"> ▶ Clean up all spills immediately. ▶ Secure load if safe to do so. ▶ Bundle/collect recoverable product. ▶ Collect remaining material in containers with covers for disposal.
Major Spills	<ul style="list-style-type: none"> ▶ Clear area of personnel and move upwind. ▶ 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 course. ▶ Stop leak if safe to do so. ▶ Contain spill with sand, earth or vermiculite. ▶ Collect recoverable product into labelled containers for recycling. ▶ Neutralise/decontaminate residue (see Section 13 for specific agent). ▶ Clean up all spills immediately. ▶ Wear protective clothing, safety glasses, dust mask, gloves. ▶ Secure load if safe to do so. Bundle/collect recoverable product. ▶ Use dry clean up procedures and avoid generating dust. ▶ Vacuum up (consider explosion-proof machines designed to be grounded during storage and use). ▶ Water may be used to prevent dusting. ▶ Collect remaining material in containers with covers for disposal. <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. ▶ 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"> ▶ 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	cellulose	Cellulose (paper fibre)	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	starch	Starch	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	stearic acid	Stearates	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	silica amorphous	Silica gel	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

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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	Precipitated silica	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
stearic acid	Octadecanoic acid, n-; (Stearic acid)	14 mg/m3	150 mg/m3	910 mg/m3
vinylpyrrolidone homopolymer	Poly(1-vinyl-2-pyrrolidone) homopolymer; (Polyvinylpyrrolidone; Plasdone)	51 mg/m3	560 mg/m3	20,000 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

Ingredient	Original IDLH	Revised IDLH
probenecid	Not Available	Not Available
cellulose	Not Available	Not Available
sodium carboxymethoxy starch	Not Available	Not Available
starch	Not Available	Not Available
OPADRY YS-12063 yellow	Not Available	Not Available
stearic acid	Not Available	Not Available
vinylpyrrolidone homopolymer	Not Available	Not Available
silica amorphous	3000 mg/m3	Not Available
magnesium stearate	Not Available	Not Available
Opadry YS-1-7006	Not Available	Not Available

Exposure controls

Appropriate engineering controls	<p>Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use.</p> <p>Employers may need to use multiple types of controls to prevent employee overexposure.</p> <p>General exhaust is adequate under normal operating conditions.</p>
Personal protection	
Eye and face protection	<ul style="list-style-type: none"> ▶ Safety glasses with side shields. ▶ Chemical goggles. ▶ 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. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. ▶ Safety glasses with side shields ▶ Chemical goggles. ▶ 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. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]
Skin protection	See Hand protection below
Hands/feet protection	<ul style="list-style-type: none"> ▶ Wear chemical protective gloves, e.g. PVC. ▶ Wear safety footwear or safety gumboots, e.g. Rubber <p>None required when handling small quantities.</p>
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none"> ▶ Overalls. ▶ P.V.C. apron. ▶ Barrier cream.

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

Respiratory protection

Type A-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required.

Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	A-AUS P2	-	A-PAPR-AUS / Class 1 P2
up to 50 x ES	-	A-AUS / Class 1 P2	-
up to 100 x ES	-	A-2 P2	A-PAPR-2 P2 ^

^ - Full-face

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO₂), G = Agricultural chemicals, K = Ammonia(NH₃), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Pro-Cid™ Tablets are yellow, capsule shaped film coated tablets, bisected on one side with no embossing; does not mix with water.		
Physical state	Manufactured	Relative density (Water = 1)	Not Applicable
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Applicable
pH (as supplied)	Not Applicable	Decomposition temperature	Not Available
Melting point / freezing point (°C)	Not Applicable	Viscosity (cSt)	Not Applicable
Initial boiling point and boiling range (°C)	Not Applicable	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Applicable	Taste	Not Available
Evaporation rate	Not Applicable	Explosive properties	Not Available
Flammability	Not Applicable	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Applicable	Surface Tension (dyn/cm or mN/m)	Not Applicable
Lower Explosive Limit (%)	Not Applicable	Volatile Component (%vol)	Not Applicable
Vapour pressure (kPa)	Not Applicable	Gas group	Not Available
Solubility in water (g/L)	Immiscible	pH as a solution (1%)	Not Applicable
Vapour density (Air = 1)	Not Applicable	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	<p>The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage. 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.</p> <p>Cellulose, given via the windpipe, caused fibrosis in the alveoli and airways, with injuries of the lung cells. Some health effects associated with wood, cotton, flax, jute and hemp particles or fibres are not attributable to cellulose content but to other substances and/or impurities.</p>
Ingestion	<p>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.</p> <p>Large doses of cellulose may be administered orally as non-nutritive bulk, with doses of up to 30 g/day tolerated as bulk laxative while extremely large oral doses may produce disturbances to the gut.</p> <p>Adverse effects associated with the administration of central nervous system stimulants include labored breathing, coughing, narrowed airways, chest tightness, and throat spasm. Muscular involvement may produce contraction of small localised muscle fibres (visible through the skin) or seizures.</p>

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Skin Contact	This material can cause inflammation of the skin on contact in some persons. The material may accentuate any pre-existing dermatitis condition Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.
Eye	This material can cause eye irritation and damage in some persons.
Chronic	Long-term exposure to respiratory irritants may result in airways disease, involving difficulty breathing and related whole-body problems. 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. 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. There has been concern that this material can cause cancer or mutations, but there is not enough data to make an assessment.

Pro-Cid™, Probenecid 500mg Tablet	TOXICITY	IRRITATION
	Not Available	Not Available
probenecid	TOXICITY	IRRITATION
	Oral (rat) LD50: 1600 mg/kg ^[2]	Not Available
cellulose	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >2000 mg/kg ^[2]	Not Available
	Inhalation (rat) LC50: >5.8 mg/l/4h ^[2]	
	Oral (rat) LD50: >5000 mg/kg ^[2]	
sodium carboxymethoxy starch	TOXICITY	IRRITATION
	Not Available	Not Available
starch	TOXICITY	IRRITATION
	Not Available	Skin (human): 0.3 mg/3d-I mild
stearic acid	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >2000 mg/kg ^[1]	Skin (human): 75 mg/3d-I-mild
	Oral (rat) LD50: >2000 mg/kg ^[1]	Skin (rabbit):500 mg/24h-moderate
vinylpyrrolidone homopolymer	TOXICITY	IRRITATION
	Inhalation (rat) LC50: >5.2 mg/l/4h** ^[2]	Eye (rabbit):non-irritating (Draize)*
	Oral (rat) LD50: >100,000 mg/kg ^[2]	Skin (rabbit):non-irritating(Draize)**
silica amorphous	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >5000 mg/kg ^[2]	Eye (rabbit): non-irritating *
	Inhalation (rat) LC50: >0.139 mg/l/14h**[Grace] ^[2]	Skin (rabbit): non-irritating *
	Oral (rat) LD50: 3160 mg/kg ^[2]	
magnesium stearate	TOXICITY	IRRITATION
	Not Available	Not Available
Opadry YS-1-7006	TOXICITY	IRRITATION
	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

PROBENECID	Haemolysis recorded.
STEARIC ACID	Equivocal tumorigen by RTEC criteria
VINYLPYRROLIDONE HOMOPOLYMER	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
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

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	reversible. [PATTYS]
MAGNESIUM STEARATE	Fatty acid salts of low acute toxicity. Their potential to irritate the skin and eyes is dependent on chain length.
OPADRY YS-1-7006	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.
PROBENECID & STEARIC ACID & 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.
SODIUM CARBOXYMETHOXY STARCH & OPADRY YS-1-7006	No significant acute toxicological data identified in literature search.
STARCH & STEARIC ACID	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.
VINYLPYRROLIDONE HOMOPOLYMER & 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	✓
Skin Irritation/Corrosion	✓
Serious Eye Damage/Irritation	✓
Respiratory or Skin sensitisation	⊘
Mutagenicity	⊘
Carcinogenicity	✓
Reproductivity	⊘
STOT - Single Exposure	✓
STOT - Repeated Exposure	⊘
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

Pro-Cid™, Probenecid 500mg Tablet	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
probenecid	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
cellulose	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
sodium carboxymethoxy starch	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
stearic acid	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	EC50	48	Crustacea	>4.8mg/L	2
	EC50	72	Algae or other aquatic plants	>0.9mg/L	2
	NOEC	504	Crustacea	>0.22mg/L	2
vinylpyrrolidone homopolymer	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
	EC50	72	Algae or other aquatic plants	440mg/L	1

Continued...

Pro-Cid™, Probenecid 500mg Tablet

	EC10	72	Algae or other aquatic plants	140mg/L	1
	NOEC	72	Algae or other aquatic plants	60mg/L	1
magnesium stearate	ENDPOINT	TEST DURATION (HR)	SPECIES	VALUE	SOURCE
	Not Available	Not Available	Not Available	Not Available	Not Available
Opadry YS-1-7006	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
probenecid	HIGH	HIGH
cellulose	LOW	LOW
stearic acid	LOW	LOW
vinylpyrrolidone homopolymer	LOW	LOW
silica amorphous	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation
probenecid	LOW (LogKOW = 3.21)
cellulose	LOW (LogKOW = -5.1249)
stearic acid	LOW (LogKOW = 8.23)
vinylpyrrolidone homopolymer	LOW (LogKOW = 0.2484)
silica amorphous	LOW (LogKOW = 0.5294)

Mobility in soil

Ingredient	Mobility
probenecid	LOW (KOC = 296.2)
cellulose	LOW (KOC = 10)
stearic acid	LOW (KOC = 11670)
vinylpyrrolidone homopolymer	LOW (KOC = 40.46)
silica amorphous	LOW (KOC = 23.74)

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

Product / Packaging disposal	<ul style="list-style-type: none"> ▶ Containers may still present a chemical hazard/ danger when empty. ▶ Return to supplier for reuse/ recycling if possible. Otherwise: <ul style="list-style-type: none"> ▶ If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill. ▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product. ▶ DO NOT allow wash water from cleaning or process equipment to enter drains. ▶ It may be necessary to collect all wash water for treatment before disposal. ▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. ▶ Where in doubt contact the responsible authority. ▶ Recycle 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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SECTION 14 TRANSPORT INFORMATION

Labels Required

Marine Pollutant	NO
HAZCHEM	Not Applicable

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

Continued...

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

PROBENECID(57-66-9) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

CELLULOSE(9004-34-6) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Inventory of Chemical Substances (AICS)

SODIUM CARBOXYMETHOXY STARCH(9063-38-1) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

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

Australia Exposure Standards

Australia Inventory of Chemical Substances (AICS)

STEARIC ACID(57-11-4) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Inventory of Chemical Substances (AICS)

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

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

MAGNESIUM STEARATE(557-04-0) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards

Australia Inventory of Chemical Substances (AICS)

OPADRY YS-1-7006(117698-04-1) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Not Applicable

National Inventory	Status
Australia - AICS	N (Opadry YS-1-7006)
Canada - DSL	N (Opadry YS-1-7006; probenecid)
Canada - NDSL	N (sodium carboxymethoxy starch; magnesium stearate; Opadry YS-1-7006; stearic acid; vinylpyrrolidone homopolymer)
China - IECSC	N (Opadry YS-1-7006; probenecid)
Europe - EINEC / ELINCS / NLP	N (sodium carboxymethoxy starch; Opadry YS-1-7006; vinylpyrrolidone homopolymer)
Japan - ENCS	N (Opadry YS-1-7006; cellulose)
Korea - KECI	N (Opadry YS-1-7006; probenecid)
New Zealand - NZIoC	N (Opadry YS-1-7006; probenecid)
Philippines - PICCS	N (Opadry YS-1-7006; probenecid)
USA - TSCA	N (Opadry YS-1-7006)
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

Name	CAS No
cellulose	9004-34-6, 68442-85-3
starch	9005-25-8, 65996-63-6, 68441-21-4, 9005-84-9
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
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

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.

Continued...

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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