

AMPHOTERICINE-B

GHS Safety Data Sheet

Version No:4

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Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

AMPHOTERICINE -B

OTHER NAMES

C47-H73-N-O17, C47-H73-N-O17, Ampho-moronal, "amphoteracin beta", "amphotericine B", amphotone, fungilin, fungisone, fungizone

PRODUCT USE

A polyene antifungal antibiotic produced by *Streptomyces nodosus* M4575> interferes with the permeability of the cell membrane of sensitive fungi. Active against *Aspergillus fumigatus*, *Blastomyces dermatitis*, *Candida* spp., *Coccidioides immitis*, *Cryptococcus neoformans*, *Histoplasma capsulatum*, *Microsporum audouinii*, *Paracoccidioides brasiliensis*, *Rhizopus* spp., *Sporothrix schenckii* and *Trichophyton* spp. Inactive against bacteria, rickettsias and viruses. Used in the treatment of severe mycotic infection. Applied topically to treat cutaneous and mucocutaneous infections caused by *Candida* spp.; pessaries and creams are used for vaginal candidiasis; given by mouth for suppression of oral or intestinal candidiasis. A colloidal form with sodium deoxycholate (Fungizone) is used for injection.

SUPPLIER

Company: S D FINE- CHEM LIMITED

Address:

315- 317, T.V. INDUSTRIAL ESTATE,

248, WORLI,

MUMBAI- 400030.INDIA.

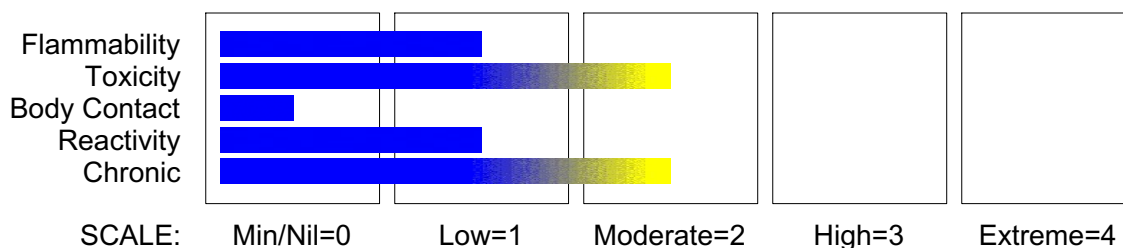
technical@sdfine.com

Telephone: 91- 22- 24959898

Telephone: 91- 22- 24959899

Fax: 91- 22- 24937232

HAZARD RATINGS



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Section 2 - HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

HAZARD

Not hazardous

No hazards determined by using GHS criteria

PRECAUTIONARY STATEMENTS

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
amphotericin B	1397-89-3	>98

Section 4 - FIRST AID MEASURES

SWALLOWED

- 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.

EYE

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.
- If pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

SKIN

If skin or hair contact occurs:

- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

INHALED

- 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.

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Section 4 - FIRST AID MEASURES

NOTES TO PHYSICIAN

Treat symptomatically.

Poorly absorbed from the gastrointestinal tract. The colloidal form is better absorbed but is associated with gastrointestinal upset. Plasma half-life is reported to be about 24 hours although traces may be present for up to 2 months after the treatment. Toxic effects such as nausea, vomiting may be treated with aspirin, antihistamine, or anti-emetics.

Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

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

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.

FIRE/EXPLOSION HAZARD

- Combustible solid which burns but propagates flame with difficulty.
 - Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited.
 - Dry dust can be charged electrostatically by turbulence, pneumatic transport, pouring, in exhaust ducts and during transport.
 - Build-up of electrostatic charge may be prevented by bonding and grounding.
 - Powder handling equipment such as dust collectors, dryers and mills may require additional protection measures such as explosion venting.
 - All movable parts coming in contact with this material should have a speed of less than 1-meter/sec.
- Combustion products include: carbon monoxide (CO), carbon dioxide (CO₂), nitrogen oxides (NO_x), other pyrolysis products typical of burning organic material.
May emit poisonous fumes.

FIRE INCOMPATIBILITY

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

Section 6 - ACCIDENTAL RELEASE MEASURES

EMERGENCY PROCEDURES

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Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- 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

Moderate hazard.

- CAUTION: Advise personnel in area.
- Alert Emergency Services and tell them location and nature of hazard.
- Control personal contact by wearing protective clothing.
- Prevent, by any means available, spillage from entering drains or water courses.
- Recover product wherever possible.
- IF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. IF WET: Vacuum/shovel up and place in labelled containers for disposal.
- ALWAYS: Wash area down with large amounts of water and prevent runoff into drains.
- If contamination of drains or waterways occurs, advise Emergency Services.

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

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.
- DO NOT enter confined spaces until atmosphere has been checked.
- DO NOT allow material to contact humans, exposed food or food utensils.
- Avoid contact with incompatible materials.
- When handling, DO NOT eat, drink or smoke.
- Keep containers securely sealed when not in use.
- Avoid physical damage to containers.
- Always wash hands with soap and water after handling.
- Work clothes should be laundered separately. Launder contaminated clothing before re-use.
- Use good occupational work practice.
- Observe manufacturer's storing and handling recommendations.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

SUITABLE CONTAINER

- Glass container is suitable for laboratory quantities.
- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

STORAGE INCOMPATIBILITY

- Avoid reaction with oxidising agents.

STORAGE REQUIREMENTS

- Store in original containers.

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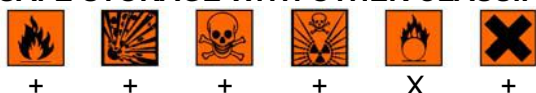
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Section 7 - HANDLING AND STORAGE

- Keep containers securely sealed.
 - Store in a cool, dry, well-ventilated area.
 - Store away from incompatible materials and foodstuff containers.
 - Protect containers against physical damage and check regularly for leaks.
 - Observe manufacturer's storing and handling recommendations.
- Store at temperatures not exceeding 5 deg C. Protect from light.

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS



- +: May be stored together
O: May be stored together with specific precautions
X: Must not be stored together

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- amphotericin B:

CAS:1397- 89- 3

MATERIAL DATA

It is the goal of the ACGIH (and other Agencies) to recommend TLVs (or their equivalent) for all substances for which there is evidence of health effects at airborne concentrations encountered in the workplace. At this time no TLV has been established, even though this material may produce adverse health effects (as evidenced in animal experiments or clinical experience). Airborne concentrations must be maintained as low as is practically possible and occupational exposure must be kept to a minimum. NOTE: The ACGIH occupational exposure standard for Particles Not Otherwise Specified (P.N.O.S) does NOT apply.

Airborne particulate or vapour must be kept to levels as low as is practicably achievable given access to modern engineering controls and monitoring hardware. Biologically active compounds may produce idiosyncratic effects which are entirely unpredictable on the basis of literature searches and prior clinical experience (both recent and past).

PERSONAL PROTECTION



EYE

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

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

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 lens 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].

HANDS/FEET

- Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Protective shoe covers.
- Head covering.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- polychloroprene
- nitrile rubber
- butyl rubber
- fluorocautchouc
- polyvinyl chloride

Gloves should be examined for wear and/ or degradation constantly.

Suitability and durability of glove type is dependent on usage. Factors such as:

- frequency and duration of contact,
- chemical resistance of glove material,
- glove thickness and
- dexterity,

are important in the selection of gloves.

OTHER

- 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.

RESPIRATOR

Protection Factor	Half- Face Respirator	Full- Face Respirator	Powered Air Respirator
10 x ES	P1 Air- line*	- -	PAPR- P1 -
50 x ES	Air- line**	P2	PAPR- P2
100 x ES	-	P3	-
		Air- line*	-
100+ x ES	-	Air- line**	PAPR- P3

* - Negative pressure demand ** - Continuous flow.

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information consult

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

your Occupational Health and Safety Advisor.

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. When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kilogram may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment laboratory using appropriate barrier/ containment technology. Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies. Barrier/ containment technology and direct coupling (totally enclosed processes that create a barrier between the equipment and the room) typically use double or split butterfly valves and hybrid unidirectional airflow/ local exhaust ventilation solutions (e.g. powder containment booths). Glove bags, isolator glove box systems are optional. HEPA filtration of exhaust from dry product handling areas is required. Fume-hoods and other open-face containment devices are acceptable when face velocities of at least 1 m/s (200 feet/minute) are achieved. Partitions, barriers, and other partial containment technologies are required to prevent migration of the material to uncontrolled areas. For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
solvent, vapours, etc. evaporating from tank (in still air)	0.25- 0.5 m/s (50- 100 f/min.)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers (released at low velocity into zone of active generation)	0.5- 1 m/s (100- 200 f/min.)
direct spray, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1- 2.5 m/s (200- 500 f/min.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood- local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2.5 m/s (200-500 f/min.) for extraction of gases discharged 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated: Dependent on levels of contamination, PAPR, full face

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated.

The following protective devices are recommended where exposures exceed the recommended exposure control guidelines by factors of:

10; high efficiency particulate (HEPA) filters or cartridges

10-25; loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator.

25-50; a full face-piece negative pressure respirator with HEPA filters

50-100; tight-fitting, full face-piece HEPA PAPR

100-1000; a hood-shroud HEPA PAPR or full face-piece supplied air respirator operated in pressure demand or other positive pressure mode.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

Deep yellow to orange, odourless, tasteless crystals; do not mix with water. Soluble at pH 2 or pH 11. Soluble in dimethylformamide (1:200), dimethyl sulfoxide (1:20), propylene glycol.

PHYSICAL PROPERTIES

Solid.

Does not mix with water.

Molecular Weight: 924.11

Melting Range (°C): Not applicable

Solubility in water (g/L): Immiscible

pH (1% solution): 6- 8 (3% suspen)

Volatile Component (%vol): Negligible

Relative Vapour Density (air=1): Not available

Lower Explosive Limit (%): Not available

Autoignition Temp (°C): Not available

State: Divided solid

Boiling Range (°C): Not applicable

Specific Gravity (water=1): Not available

pH (as supplied): Not applicable

Vapour Pressure (kPa): Negligible

Evaporation Rate: Not available

Flash Point (°C): Not available

Upper Explosive Limit (%): Not available

Decomposition Temp (°C): Not Available

Viscosity: Not Applicable

Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

Accidental ingestion of the material may be damaging to the health of the individual.

At sufficiently high doses the material may be nephrotoxic(i.e. poisonous to the kidney).

At sufficiently high doses the material may be hepatotoxic (i.e. poisonous to the liver).

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Section 11 - TOXICOLOGICAL INFORMATION

EYE

Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.

SKIN

The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting. Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds 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.

INHALED

Inhalation may produce health damage*.

The material is not thought to produce respiratory irritation (as classified by EC Directives using animal models). Nevertheless inhalation of dusts, or fumes, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress. Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual.

CHRONIC HEALTH EFFECTS

Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

Long term exposure to high dust concentrations may cause changes in lung function (i.e. pneumoconiosis) caused by particles less than 0.5 micron penetrating and remaining in the lung. A prime symptom is breathlessness. Lung shadows show on X-ray.

Exposure to small quantities may induce hypersensitivity reactions characterised by acute bronchospasm, hives (urticaria), deep dermal wheals (angioneurotic oedema), running nose (rhinitis) and blurred vision. Anaphylactic shock and skin rash (non-thrombocytopenic purpura) may occur. An individual may be predisposed to such antibody mediated reaction if other chemical agents have caused prior sensitisation (cross-sensitivity).

TOXICITY AND IRRITATION

unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY

Intravenous (man) LDLo: 0.164 mg/kg/5h - I

Oral (rat) LD50: >5000 mg/kg

Intraperitoneal (rat) LD50: >5000 mg/kg

Intravenous (rat) LD50: 11.3 mg/kg

Intramuscular (rat) LD50: >5000 mg/kg

Oral (mouse) LD50: >8000 mg/kg

Intraperitoneal (mouse) LD50: 27.74 mg/kg

Intravenous (mouse) LD50: 1.2 mg/kg

Intramuscular (mouse) LD50: >5000 mg/kg

Intravenous (dog) LD50: 6 mg/kg

Intravenous (woman) LDLo: 22 mg/kg/4d - I

Tremor, convulsions, cardiac changes, respiratory tract changes, leukopenia, paternal effects recorded.

IRRITATION

Skin : Mild

Nil Reported

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Section 12 - ECOLOGICAL INFORMATION

No data

Section 13 - DISPOSAL CONSIDERATIONS

- Recycle wherever possible.
- Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.
- Dispose of by: Burial in a licenced land-fill or Incineration in a licenced apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

Section 14 - TRANSPORTATION INFORMATION

HAZCHEM: None

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: UN, IATA, IMDG

Section 15 - REGULATORY INFORMATION

REGULATIONS

No regulations applicable

No data available for amphotericin B as CAS: 1397-89-3.

Section 16 - OTHER INFORMATION

MSDS SECTION CHANGES

The following table displays the version number of and date on which each section was last changed.

Section Name	Version	Date	Section Name	Version	Date	Section Name	Version	Date
Advice to Doctor	4	4- Jun- 2007	Handling Procedure	4	4- Jun- 2007	Acute Health (skin)	4	4- Jun- 2007
First Aid (inhaled)	4	4- Jun- 2007	Storage (storage incompatibility)	4	4- Jun- 2007	Acute Health (swallowed)	4	4- Jun- 2007
First Aid (skin)	4	4- Jun- 2007	Storage (suitable container)	4	4- Jun- 2007	Chronic Health	4	4- Jun- 2007
First Aid (swallowed)	4	4- Jun- 2007	Exposure Standard	4	4- Jun- 2007	Toxicity and Irritation (Irritation)	4	4- Jun- 2007
Fire Fighter (fire fighting)	4	4- Jun- 2007	Physical Properties	4	4- Jun- 2007	Environmental	4	4- Jun- 2007
Fire Fighter (fire/explosion hazard)	4	4- Jun- 2007	Acute Health (eye)	4	4- Jun- 2007	Disposal	4	4- Jun- 2007
Spills (major)	4	4- Jun- 2007	Acute Health (inhaled)	4	4- Jun- 2007	Transport	4	4- Jun- 2007
Spills (minor)	4	4- Jun- 2007						

The above information is believed to be accurate and represent the best information currently available to us, but does not represent any warranty expressed or implied of the properties of the product. User should make their own investigation to determine the suitability of the information for their particular purpose.

Issue date: 10-07-2018