



GLENMARK PHARMACEUTICALS LIMITED

SAFETY DATA SHEET

PRODUCT: FLUCONAZOLE	SDS NO.	: SDSEU.016.00
	EFFECTIVE DATE	:02/05/2015
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Section 1. Chemical Product and Company Identification

1.1 Substance Name: Fluconazole

1.2 Chemical Name: 1H-1,2,4-Triazole-1-ethanol, 1-(2,4-difluorophenyl)-1-(1H-1,2,4-triazol-1-ylmethyl)- 2,4-Difluoro-1',1'-bis(1H-1,2,4-triazol-1-ylmethyl)benzyl alcohol






1.3 Relevant identified uses of the substance or mixture and uses advised against:
Antifungal agent

1.4 Company Identification: Glenmark Pharmaceutical Ltd
Plot No. A- 607, T.T.C Industrial Area, MIDC.
Mahape, Navi Mumbai
MAHARASHTRA, INDIA
Pin- 400 709

1.5 Emergency Contact details: 022-67720000

Section 2. Hazard Identification

2.1 Classification of the substance or mixture:
Chemwatch Hazard Ratings

	Min	Max	
Flammability:	1		
Toxicity:	2		
Body Contact:	0		Min/Nil=0
Reactivity:	1		Low=1
Chronic:	0		Moderate=2
			High=3
			Extreme=4

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2.2 Label elements:



Emergency overview

Risk

Harmful if swallowed.

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Limited evidence of a carcinogenic effect*.

May possibly affect fertility*.

May possibly be harmful to the foetus/embryo*.

* (limited evidence).

2.3 Risk Phrases: Not Known

2.4 Safety advice: Not Known

2.5 Other hazards:

Potential Health Effects

Acute Health Effects

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 characterized 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:

- Skin contact is not thought to produce harmful health effects (as classified under EC Directives using animal models). Systemic harm, however, has been identified following exposure of animals by at least one other route and the material may still produce health damage following entry through wounds, lesions or abrasions. Good hygiene practice



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requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.

- Open cuts, abraded or irritated skin should not be exposed to this material.
- 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.

Ingestion:

- 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.
- Aromatase inhibitors (including triazoles and azoles) produce several side effects including mood swing, depression, weight gain, hot flushes, vaginal dryness, bloating, early onset of menopause. Long-term use may result in bone weakness, increased risk of blood clots, gastrointestinal disturbance, and sweats.
Aromatase inhibitors lower the level of oestrogen in post-menopausal women who have hormone-receptor-positive breast cancers. Prior to menopause oestrogen is mostly produced in the ovaries. Post-menopausal women produce oestrogen from another hormone, androgen. Aromatase inhibitors prevent the enzyme, aromatase from catalysing this reaction. Breast cancer cell growth in post-menopausal women is stimulated by oestrogen.

Inhalation:

- The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
- Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.

Chronic Health Effects:



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There has been some concern that this material can cause cancer or mutations but there is not enough data to make an assessment.

Based on experience with similar materials, there is a possibility that exposure to the material may reduce fertility in humans at levels which do not cause other toxic effects.

Based on experience with animal studies, there is a possibility that 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.

Azole fungicides show broad antifungal activity, and can be used to prevent or cure fungal infections. They are therefore important in agricultural production. They work by blocking the assembly of the cell membrane of fungi. Animal testing has shown inconclusive results regarding the effect of this group of fungicides on the reproductive organs in mammals.

Extensive studies suggest that triazole pesticides may induce liver tumours.

Administration to rats produced an increased incidence of hepatocellular adenomas.


Administration to pregnant rabbits produced reduced maternal weight gain, increases in foetal anatomical variants and delayed foetal ossification. Doses of 20-60 times the recommended human level, produced abortion.

Section 3- Composition/Information on Ingredients

3.1 Substances

CAS#	Chemical Name	Percent	EINECS/ELINCS
86386-73-4	1H-1,2,4-Triazole-1-ethanol, 1-(2,4-difluorophenyl)-1-(1H-1,2,4-triazol-1-ylmethyl)- 2,4-Difluoro-1',1'-bis(1H-1,2,4-triazol-1-ylmethyl)benzyl alcohol	>98.5	-

3.2 Molecular Formula: C₁₃H₁₂F₂N₆O

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Section 4. First aid Measures

4.1 Eyes: If this product comes in contact with the eyes:

- Wash out immediately with fresh running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Seek medical attention without delay; if pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

4.2 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.

4.3 Inhalation:

- If dust is inhaled, remove from contaminated area.
- Encourage patient to blow nose to ensure clear passage of breathing.
- If irritation or discomfort persists seek medical attention.

4.4 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 meantime, 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 MSDS 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 MSDS.

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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.

4.5 Indication of any immediate medical attention and special treatment needed

Notes to Physician:

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.



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- 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.

Fluconazole is largely excreted in the urine; forced volume diuresis would probably increase the elimination rate. A three-hour haemodialysis session decreases plasma levels by approximately 50%

Section 5. Fire-fighting Measures

5.1 General Information:

- 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.

When any large container (including road and rail tankers) is involved in a fire, consider evacuation by 100 meters in all directions.

5.2 Extinguishing Media:

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



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5.3 Fire Incompatibility:

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

5.4 Fire/Explosion Hazard:

- Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.
- Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions).
- 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 - particles exceeding this limit will generally not form flammable dust clouds; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.
- In the same way as gases and vapors, dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL) are applicable to dust clouds but only the LEL is of practical use; - this is because of the inherent difficulty of achieving homogeneous dust clouds at high temperatures (for dusts the LEL is often called the "Minimum Explosible Concentration", MEC).
- When processed with flammable liquids/vapors/mists, ignitable (hybrid) mixtures may be formed with combustible dusts. Ignitable mixtures will increase the rate of explosion pressure rise and the Minimum Ignition Energy (the minimum amount of energy required to ignite dust clouds - MIE) will be lower than the pure dust in air mixture. The Lower Explosive Limit (LEL) of the vapor/dust mixture will be lower than the individual LELs for the vapors/mists or dusts.
- A dust explosion may release of large quantities of gaseous products; this in turn creates a subsequent pressure rise of explosive force capable of damaging plant and buildings and injuring people.
- Usually the initial or primary explosion takes place in a confined space such as plant or machinery, and can be of sufficient force to damage or rupture the plant. If the shock



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wave from the primary explosion enters the surrounding area, it will disturb any settled dust layers, forming a second dust cloud, and often initiate a much larger secondary explosion. All large scale explosions have resulted from chain reactions of this type.

- 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.
- A sudden release of statically charged materials from storage or process equipment, particularly at elevated temperatures and/ or pressure, may result in ignition especially in the absence of an apparent ignition source.
- One important effect of the particulate nature of powders is that the surface area and surface structure (and often moisture content) can vary widely from sample to sample, depending of how the powder was manufactured and handled; this means that it is virtually impossible to use flammability data published in the literature for dusts (in contrast to that published for gases and vapors).
- Autoignition temperatures are often quoted for dust clouds (minimum ignition temperature (MIT)) and dust layers (layer ignition temperature (LIT)); LIT generally falls as the thickness of the layer increases.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO₂), hydrogen fluoride, nitrogen oxides (NO_x), other pyrolysis products typical of burning organic material.

5.5 NFPA Rating: Not Known

Section 6. Accidental Release Measures

6.1 General Information: Use proper personal protective equipment as indicated in

Section 8

6.2 Minor Spills:

- Remove all ignition sources.
- Clean up all spills immediately.
- Avoid contact with skin and eyes.

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- Control personal contact with the substance, by using protective equipment.
- Use dry clean up procedures and avoid generating dust.
- Place in a suitable, labeled container for waste disposal.

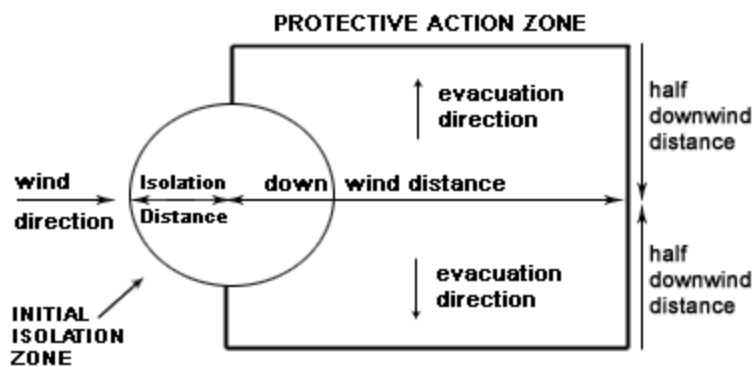
Environmental hazard - contain spillage.

6.3 Major Spills: Environmental hazard - contain spillage.

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 labeled 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.

Protective Actions for Spill





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From IERG (Canada/Australia)

Isolation Distance -

Downwind Protection Distance 10 meters

Footnotes

1 PROTECTIVE ACTION ZONE is defined as the area in which people are at risk of harmful exposure. This zone assumes that random changes in wind direction confines the vapor plume to an area within 30 degrees on either side of the predominant wind direction, resulting in a crosswind protective action distance equal to the downwind protective action distance.

2 PROTECTIVE ACTIONS should be initiated to the extent possible, beginning with those closest to the spill and working away from the site in the downwind direction. Within the protective action zone a level of vapor concentration may exist resulting in nearly all unprotected persons becoming incapacitated and unable to take protective action and/or incurring serious or irreversible health effects.

3 INITIAL ISOLATION ZONE is determined as an area, including upwind of the incident, within which a high probability of localized wind reversal may expose nearly all persons without appropriate protection to life-threatening concentrations of the material.

4 SMALL SPILLS involve a leaking package of 200 liters (55 US gallons) or less, such as a drum (Jerry can or box with inner containers). Larger packages leaking less than 200 liters and compressed gas leaking from a small cylinder are also considered "small spills". LARGE SPILLS involve many small leaking packages or a leaking package of greater than 200 litres, such as a cargo tank, portable tank or a "one-tonne" compressed gas cylinder.

5 Guide 171 is taken from the US DOT emergency response guide book.

6 IERG information is derived from CANUTEC - Transport Canada.

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- 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 storage and handling recommendations contained within this MSDS.
- Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.
- Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions)
- Minimize airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame.
- Establish good housekeeping practices.
- Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.
- Use continuous suction at points of dust generation to capture and minimize the accumulation of dusts. Particular attention should be given to overhead and hidden horizontal surfaces to minimize the probability of a "secondary" explosion. According to NFPA Standard 654, dust layers 1/32 in.(0.8 mm) thick can be sufficient to warrant immediate cleaning of the area.
- Do not use air hoses for cleaning.



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- Minimize dry sweeping to avoid generation of dust clouds. Vacuum dust-accumulating surfaces and remove to a chemical disposal area. Vacuums with explosion-proof motors should be used.
- Control sources of static electricity. Dusts or their packages may accumulate static charges, and static discharge can be a source of ignition.
- Solids handling systems must be designed in accordance with applicable standards (e.g. NFPA including 654 and 77) and other national guidance.
- Do not empty directly into flammable solvents or in the presence of flammable vapors.
- The operator, the packaging container and all equipment must be grounded with electrical bonding and grounding systems. Plastic bags and plastics cannot be grounded, and antistatic bags do not completely protect against development of static charges.

Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.

- Do NOT cut, drill, grind or weld such containers.
- In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorization or permit

7.2 Storage:

Preserve in tight containers, and store below 30°C

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry area protected from environmental extremes.
- Store away from incompatible materials and foodstuff containers.
- Protect containers against physical damage and check regularly for leaks.
- Observe manufacturer's storage and handling recommendations contained within this MSDS.

For major quantities:

- Consider storage in banded areas - ensure storage areas are isolated from sources of community water (including storm water, ground water, lakes and streams).
- Ensure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities

SAFE STORAGE WITH OTHER CLASSIFIED CHEMICALS



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+ X + X X +

X: Must not be stored together

O: May be stored together with specific preventions

+: May be stored together

7.3 Suitable container:

- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

7.4 Storage incompatibility:

Avoid reaction with oxidizing agents

Section 8. Exposure Controls/Personal Protection


8.1 Occupational Exposure Limits (OEL):

Chemical Name	ACGIH	NIOSH	OSHA - Final PELs
FLUCONAZOLE	-	-	-

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

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(P.N.O.S) does NOT apply.
CEL TWA: 0.5 mg/m³

8.2 Exposure controls:

Engineering Controls:

■ 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:

Process controls which involve changing the way a job activity or process is done to reduce the risk.

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.

Employers may need to use multiple types of controls to prevent employee overexposure.


- Local exhaust ventilation is required where solids are handled as powders or crystals; even when particulates are relatively large, a certain proportion will be powered by mutual friction.
- Exhaust ventilation should be designed to prevent accumulation and recirculation of particulates in the workplace.
- If in spite of local exhaust an adverse concentration of the substance in air could occur, respiratory protection should be considered. Such protection might consist of:

(a): particle dust respirators, if necessary, combined with an absorption cartridge;

(b): filter respirators with absorption cartridge or canister of the right type;

(c): fresh-air hoods or masks

- Build-up of electrostatic charge on the dust particle 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

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Eyes:

- 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:

The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and

has to be observed when making a final choice.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

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

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).

- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.



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- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- Contaminated gloves should be replaced.

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturizer is recommended.

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.

Clothing:

- Overalls.
- P.V.C. apron.
- Barrier cream.
- Skin cleansing cream.
- Eye wash unit

Respirators:

Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

- 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.



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- 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.

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

For further information consult site specific CHEMWATCH data (if available), or your Occupational Health and Safety Advisor.

Section 9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	:	Solid
Appearance	:	White or almost white crystalline powder
Colour	:	White
pH Value	:	Not Known
Vapor Pressure	:	Negligible
Vapor Density	:	>1
Evaporation Rate	:	Not Known
<i>Other information</i>		Not Known
Flash point	:	Not Known
Molecular Weight	:	Not Known
Melting point/range	:	138-140 °C
Boiling point/boiling range	:	Not Known
Density	:	Not Known
Viscosity	:	Not Known



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Water solubility	:	slightly soluble
Solubility in other solvents	:	Freely soluble in methanol; soluble in alcohol and in acetone, sparingly soluble in isopropanol and in chloroform; very slightly soluble in toluene
Minimum ignition energy (MIE)	:	Not Known
Minimum ignition temperature (MIT)	:	Not Known
Layer ignition temperature (LIT)	:	Not Known
Flammability/explosivity	:	Not Known
Reactivity/exotherms	:	Not Known
Electrostatic nature	:	Not Known
Highly dusty material	:	Not Known
Any other properties which cause handling or processing difficulties	:	Not Known
Average PSD (particle size distribution (micron))	:	Not Known

9.2 Other Information

Section 10. Stability and Reactivity

10.1 Chemical stability: Product is considered stable

10.2 Conditions to Avoid: Strong oxidizing agents

10.3 Incompatibilities with Other Materials: Avoid reaction with oxidizing

10.4 Hazardous Decomposition Products: carbon monoxide (CO), carbon dioxide (CO₂), nitrogen oxides (NO_x), other pyrolysis products typical of burning organic material. May emit poisonous fumes.

10.5 Hazardous Polymerization: Will not occur



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Section 11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

TOXICITY AND IRRITATION

FLUCONAZOLE:

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

TOXICITY

IRRITATION

Oral (rat) LD50:1271 mg/kg

Intraperitoneal (rat) LD50:>941 mg/kg

Intravenous (rat) LD50:>200 mg/kg

Oral (mouse) LD50:1408 mg/kg

Intraperitoneal (mouse) LD50:1273 mg/kg

Intravenous (mouse) LD50:>200 mg/kg

Oral (dog) LD50:>300 mg/kg

Intravenous (dog) LD50:>100 mg/kg

Oral (woman) TDLo:1456 mg/kg/26w - I Nil Reported

Oral (man) TDLo:1040 mg/kg/26w - I

Oral (man) TDLo:60 mg/kg/3w - I



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Section 12. Ecological Information

12.1 Toxicity:

Marine Pollutant	Yes
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Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters.

Wastes resulting from use of the product must be disposed of on site or at approved waste sites. For Azole Containing Substances


Topical azole fungicides and systemically used antifungal drugs act as potent inhibitors of steroid producing enzymes and are known to cause endocrine disruption.

Environmental Fate Azole containing compounds produce profound effects in the environment in part due to inhibition of several enzyme systems. Azoles block the biosynthesis of ergosterol in fungi and yeast. The antifungal effect of azoles is due to inhibition of sterol 14[alpha]-demethylase in fungi and yeast. Sterol 14[alpha]-demethylase is not only expressed in fungi and yeast but is also found in many other species ranging from bacteria to mammals. Azoles can also have detrimental effects on plants and mammals from inhibition of Sterol 14[alpha]-demethylase.

DO NOT discharge into sewer or waterways.

Ecotoxicity:

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
FLUCONAZOLE	High	No Data	Low	Low

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Available

Environmental: Not known

12.2 Persistence and degradability: Not known

12.3 Bioaccumulative potential: Not known

12.4 Mobility in soil: Not known

Section 13. Disposal Considerations

13.1 Waste treatment methods:

- Containers may still present a chemical hazard/ danger when empty.
- Return to supplier for reuse/ recycling if possible.

Otherwise:


- If container cannot 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 authorized landfill.
- Where possible retain label warnings and MSDS and observe all notices pertaining to the product.

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or

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reuse may not always be appropriate. In most instances the supplier of the material should be consulted.

- 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.
- 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 land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or Incineration in a licensed apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

Section 14. Transport Information

14.1 Special precautions for user:



Labels Required: MISCELLANEOUS
Land Transport UNDG:

Class or division:	9	Subsidiary risk:	None
UN No.:	3077	UN packing group:	III

Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(contains fluconazole)

Air Transport IATA:



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ICAO/IATA Class:	9	ICAO/IATA Subrisk:	None
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UN/ID Number:	3077	Packing Group:	III
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Special provisions:	A97A158A179
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Cargo Only

Packing Instructions:	956	Maximum Qty/Pack:	400 kg
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Passenger and Cargo	Passenger and Cargo
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Packing Instructions:	956	Maximum Qty/Pack:	400 kg
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Passenger and Cargo	Passenger and Cargo
Limited Quantity	Limited Quantity

Packing Instructions:	Y956	Maximum Qty/Pack:	30 kg G
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Shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.(contains fluconazole)

Maritime Transport IMDG:


IMDG Class:	9	IMDG Subrisk:	None
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UN Number:	3077	Packing Group:	III
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EMS Number:	F-A,S-F	Special provisions:	274 335
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Limited Quantities:	5 kg	Marine Pollutant:	Yes
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Shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.(contains fluconazole)

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Section 15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:



RISK

Risk Codes	Risk Phrases
R22	■ Harmful if swallowed.
R51/53	■ Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R40(3)?	■ Limited evidence of a carcinogenic effect*.
R62?	■ May possibly affect fertility*.
R63?	■ May possibly be harmful to the foetus/ embryo*.

SAFETY

Safety Codes	Safety Phrases
S22	Do not breathe dust.
S24	Avoid contact with skin.
S36	Wear suitable protective clothing.



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- S37 Wear suitable gloves.
- S53 Avoid exposure - obtain special instructions before use.
- S29 Do not empty into drains.
- S401 To clean the floor and all objects contaminated by this material, use water and detergent.
- S35 This material and its container must be disposed of in a safe way.
- S13 Keep away from food, drink and animal feeding stuffs.
- S46 If swallowed, IMMEDIATELY contact Doctor or Poisons Information Centre (show this container or label).
- S57 Use appropriate container to avoid environment contamination.
- S60 This material and its container must be disposed of as hazardous waste.
- S61 Avoid release to the environment. Refer to special instructions/safety data sheets.

REGULATIONS

fluconazole (CAS: 86386-73-4) is found on the following regulatory lists;

"Sigma-AldrichTransport Information"

Section 16. Additional Information

LIMITED EVIDENCE

- Limited evidence of a carcinogenic effect*.
- May possibly affect fertility*.



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- May possibly be harmful to the foetus/ embryo*.
- * (limited evidence).

RISK

Explanation of risk codes used on this MSDS

Risk Codes	Risk Phrases
R22	■ Harmful if swallowed.
R51/53	■ Toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment.

ANNEX 2: Indications of Danger


N	Dangerous for the environment
Xn	Harmful

- 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.



A list of reference resources used to assist the committee may be found at:
www.chemwatch.net/references.

Product Name:

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the

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specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Compiled By (R & D)	Approved by (EHS Head)
 08/04/2015	 09/04/2015
Signature /Date	Signature /Date