Material Safety Data Sheet

Miconazole Nitrate

sc-205753

Hazard Alert Code Key:

EXTREME  HIGH  MODERATE  LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
Miconazole Nitrate

STATEMENT OF HAZARDOUS NATURE

NFPA

SUPPLIER
Company: Santa Cruz Biotechnology, Inc.
Address: 2145 Delaware Ave
Santa Cruz, CA 95060
Telephone: 800.457.3801 or 831.457.3800
Emergency Tel: CHEMWATCH: From within the US and Canada: 877-715-9305
Emergency Tel: From outside the US and Canada: +800 2436 2255 (1-800-CHEMCALL) or call +613 9573 3112

PRODUCT USE
Used in medicine as a potent drug against fungi (Candida and dermatophytes); also has antibacterial (Gram-positive) action.

SYNONYMS
C18-H15-Cl4-N3-O4, "1-(2,4-dichloro-beta-(2,4-dichlorobenzyl)phenylethyl)-", imidazolenenitrates, "1-(2,4-dichloro-beta-(2,4-dichlorobenzyl)phenylethyl)-", imidazolenenitrates, Daklarin, Florid, Gyno-Daktarin, Nonistat, Gyno-Monistat, R-14889, R-14889, Micatin, "MCZ Nitrate", Albistate, Andergin, Brentan, Conofite, Daktar, Deralbin, Dermonistat, Epi-Monistat, "antimycotic azole pesticide"

Section 2 - HAZARDS IDENTIFICATION

CANADIAN WHMIS SYMBOLS

EMERGENCY OVERVIEW
RISK
Harmful if swallowed.
Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

POTENTIAL HEALTH EFFECTS
ACUTE HEALTH EFFECTS

SWALLOWED
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.

**EYE**
- Although the material is not thought to be an irritant, 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 using animal models). Nevertheless inhalation of dusts, or fume, 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**
- Exposure to the material may cause concerns for human fertility, on the basis that similar materials provide some evidence of impaired fertility in the absence of toxic effects, or evidence of impaired fertility occurring at around the same dose levels as other toxic effects, but which are not a secondary non-specific consequence of 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 fetus, at levels which do not cause significant toxic effects to the mother.

Azo fungicides show a broad antifungal activity and are used either to prevent fungal infections or to cure an infection. Therefore, they are important tools in integrated agricultural production. According to their chemical structure, azole compounds are classified into triazoles and imidazoles; however, their antifungal activity is due to the same molecular mechanism. The cell membrane assembly of fungi and yeast is disturbed by blocking the synthesis of the essential membrane component ergosterol. This fundamental biochemical mechanism is the basis for the use of azole fungicides in agriculture and in human and veterinary antymycotic therapies. The enzyme involved is sterol 14α-demethylase, which is found in several phyla. In mammals, it converts lanosterol into the meiosis-activating sterols (MAS) which regulate or modify cell division. These precursors of cholesterol have been discovered to moderate the development of male and female germ (sexual) cells. Several metabolites of lanosterol have been regarded only as precursors of cholesterol without any biological function in animals. This view dramatically changed recently with the observation that FF-MAS isolated from human follicle fluid and T-MAS isolated from bull testis as well as the MAS-412 and MAS-414 induced resumption of meiosis in cultivated mouse oocytes (Byskov et al. 1995).

Aromatase is another target enzyme of azole compounds. In steroidogenesis, it converts androgens into the corresponding oestrogens. The importance of androgens and oestrogens for the development of reproductive organs, for fertility, and in certain sex steroid-dependent diseases is well known. Therefore, azole compounds can be directed against aromatase to treat oestrogen-responsive diseases. Based on the inhibitory activity of azoles on key enzymes involved in sex steroid hormone synthesis, it is likely that effects on fertility, sexual behavior, and reproductive organ development will occur depending on dose level and duration of treatment of laboratory animals. Several azole compounds were shown to inhibit the aromatase and to disturb the balance of androgens and estrogens in vivo. In fact, the clinical use of azole compounds in estrogen-dependent diseases is based on this effect. Additionally, azoles with sterol 14α-demethylase of fungi and yeast in agriculture and medicine are also inhibiting aromatase. Therefore, these antifungals may unintentionally disturb the balance of androgens and estrogens. Until now, it is not clear whether this effect is compensated by an increased expression of aromatase or by other unknown mechanisms.

The broad use of biologically active compounds in human therapy as well as in nonhuman applications may involve some risks, as exemplified by emerging antibiotic resistance. In agriculture, fungi and yeast are well known to develop resistance to azoles, and some molecular mechanisms of resistance development have been described. The significance of the agricultural azole resistance for human clinical antymycotic therapies has been discussed in Europe, but is not clarified yet. The actual target enzyme of azole antifungals, the fungal sterol 14α-demethylase, is expressed in many species including humans, and it is highly conserved through evolution. Hence, it seems reasonable to assume that most of the azole antifungals used in agriculture and medicine as well as azoles used in management of breast cancer also act as inhibitors on human sterol 14α-demethylase to an unknown extent. The toxicologic profiles of individual azole fungicides provide evidence for endocrine effects. In fact, many of these fungicides have effects on prostate, testis, uterus, and ovaries as well as on fertility, development, and sexual behavior. The current database does not allow us to establish causal relationships of these effects with inhibition of sterol 14α-demethylase and/or aromatase, but the overall view strongly suggests a connection with disturbed steroidogenesis.

Zam et al; Environmental Health Perspectives - 3/1/2003

Some azoles have been associated with prolongation of the QT interval on the electrocardiogram.

Imidazole is structurally related to histamine and has been used as an antagonist to counteract the effects of excess histamine found in certain induced physiological conditions (it therefore acts as an antihistamine).

Imidazoles have been reported to disrupt male fertility through disruption of testicular function. 2-Methylimidazole decreased luteinising hormone secretion and tissue interstitial fluid testosterone concentration two hours after injection into Sprague Dawley rats.

Imidazoles bind to cytochrome P450 haeme, resulting in inhibition of catalysis. However, 2-substituted imidazoles are considered to be poor inhibitors. Imidazole is probably an inducer of cytochrome P4502E1. In general, inducers of this isozyme stabilize the enzyme by preventing phosphorylation of a serine which leads to haem loss. Several drugs containing an imidazole moiety were retained and bound in connective tissue when administered to laboratory animals. The bound material was primarily recovered from elastin (70%) and the collagen. It is postulated that reaction with aldehydes gives an aldol condensation product.

Dust inhalation may cause mucous membrane irritation and respiratory sensitisation in susceptible individuals. Few systemic effects are to be expected as drug is only little absorbed in gastrointestinal tract or after topical administration.
Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

HAZARD RATINGS

<table>
<thead>
<tr>
<th>Property</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Toxicity</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Body Contact</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Reactivity</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Chronic</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

NAME
- miconazole nitrate
- CAS RN: 22832-87-7
- %: 100

Section 4 - FIRST AID MEASURES

SWALLOWED
- IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.
  - Where Medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:
    - For advice, contact a Poisons Information Center or a doctor.
    - Urgent hospital treatment is likely to be needed.
    - If conscious, give water to drink.
    - 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.
    - CARE: Wear a protective glove when inducing vomiting by mechanical means.
  - 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 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.

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.

NOTES TO PHYSICIAN
- 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 edema.
- 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 hypovolemia are present use lactated Ringers solution. Fluid overload might create complications.
• Drug therapy should be considered for pulmonary edema.
• Hypotension with signs of hypovolemia 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.

MEDICATION: - Specific antidote: NONE
- Although only little substance is absorbed after oral intake a gastric lavage with aqueous potassium permanganate (20mg/100ml) may be performed. Then administer a purgative (30g sodium sulfate in 250 ml water).

## Section 5 - FIRE FIGHTING MEASURES

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Vapour Pressure (mmHg)</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Upper Explosive Limit (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Specific Gravity (water=1)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Lower Explosive Limit (%)</td>
<td>30g/m3 (dust)</td>
</tr>
</tbody>
</table>

**EXTINGUISHING MEDIA**

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

**FIRE FIGHTING**

- Alert Emergency Responders and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves for fire only.
- Prevent, by any means available, spillage from entering drains or water course.
- 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.

**GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS**

- Solid which exhibits difficult combustion or is difficult to ignite.
- 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 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.

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

**FIRE INCOMPATIBILITY**

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

**PERSONAL PROTECTION**

Glasses:
Chemical goggles.
Gloves:
Respirator:
Particulate

## Section 6 - ACCIDENTAL RELEASE MEASURES

**MINOR SPILLS**

- Remove all ignition sources.
- Clean up all spills immediately.
- Avoid contact with skin and eyes.
- Control personal contact by using protective equipment.
- Use dry clean up procedures and avoid generating dust.
- Place in a suitable, labelled container for waste disposal.

Environmental hazard - contain spillage.

**MAJOR SPILLS**

- Environmental hazard - contain spillage.
- Moderate hazard.
**CAUTION:** Advise personnel in area. 
Alert Emergency Responders 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.

**PROTECTIVE ACTIONS FOR SPILL**

**PROTECTIVE ACTION ZONE**

![Diagram of protective action zone]

**Isolation Distance**

**Evacuation Direction**

**Downwind Protection Distance**

**Half Downwind Distance**

From IERG (Canada/Australia)

**Isolation Distance**

**Downwind Protection Distance 10 meters**

**PROTECTIVE ACTIONS FOR SPILL**

From IERG (Canada/Australia)

**Isolation Distance**

**Downwind Protection Distance**

**Evacuation Direction**

**Half Downwind Distance**

**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 vapour 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 vapour 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 localised 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 litres (55 US gallons) or less, such as a drum (jerrican or box with inner containers). Larger packages leaking less than 200 litres 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.


6 IERG information is derived from CANUTEC - Transport Canada.

**ACUTE EXPOSURE GUIDELINE LEVELS (AEGL) (in ppm)**

**AEGL 1:** The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.

**AEGL 2:** The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.

**AEGL 3:** The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening health effects or death.

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**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.

**RECOMMENDED STORAGE METHODS**
Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

<table>
<thead>
<tr>
<th>Source</th>
<th>Material</th>
<th>TWA ppm</th>
<th>TWA mg/m³</th>
<th>STEL ppm</th>
<th>STEL mg/m³</th>
<th>Peak ppm</th>
<th>Peak mg/m³</th>
<th>TWA F/CC</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>US - Oregon Permissible Exposure Limits (Z3)</td>
<td>miconazole nitrate (Inert or Nuisance Dust: (d) Total dust)</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*</td>
</tr>
<tr>
<td>US OSHA Permissible Exposure Levels (PELs) - Table Z3</td>
<td>miconazole nitrate (Inert or Nuisance Dust: (d) Respirable fraction)</td>
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<td></td>
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<tr>
<td>US OSHA Permissible Exposure Levels (PELs) - Table Z3</td>
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</tr>
<tr>
<td>US - Hawaii Air Contaminant Limits</td>
<td>miconazole nitrate (Particulates not otherwise regulated - Total dust)</td>
<td>10</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>US - Hawaii Air Contaminant Limits</td>
<td>miconazole nitrate (Particulates not otherwise regulated - Respirable fraction)</td>
<td>5</td>
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<tr>
<td>US - Oregon Permissible Exposure Limits (Z3)</td>
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<td>US - Tennessee Occupational Exposure Limits - Limits For Air Contaminants</td>
<td>miconazole nitrate (Particulates not otherwise regulated Respirable fraction)</td>
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<tr>
<td>US - Wyoming Toxic and Hazardous Substances Table Z1 Limits for Air Contaminants</td>
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<td>US - Michigan Exposure Limits for Air Contaminants</td>
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</table>

MATERIAL DATA
MICONAZOLE NITRATE:
- 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.

PERSONAL PROTECTION

Consult your EHS staff for recommendations

EYE

- Safety glasses with side shields
- Chemical goggles.
Contact lenses pose a special hazard; soft lenses may absorb irritants and all lenses concentrate them.

HANDS/FEET
- Wear chemical protective gloves, eg. PVC.
- Wear safety footwear or safety gumboots, eg. Rubber.
Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:
  - 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).
- 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) is recommended.
- 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) 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 moisturiser is recommended.

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

RESPIRATOR
- Protection Factor
  - Half-Face Respirator
  - Full-Face Respirator
  - Powered Air Respirator

<table>
<thead>
<tr>
<th>Protection Factor</th>
<th>Half-Face Respirator</th>
<th>Full-Face Respirator</th>
<th>Powered Air Respirator</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 x PEL</td>
<td>P1</td>
<td>-</td>
<td>PAPR-P1</td>
</tr>
<tr>
<td></td>
<td>Air-line*</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>50 x PEL</td>
<td>Air-line**</td>
<td>P2</td>
<td>PAPR-P2</td>
</tr>
<tr>
<td>100 x PEL</td>
<td>-</td>
<td>P3</td>
<td>-</td>
</tr>
<tr>
<td>100+ x PEL</td>
<td>-</td>
<td>Air-line*</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Air-line**</td>
<td>-</td>
<td>PAPR-P3</td>
</tr>
</tbody>
</table>

* - Negative pressure demand  ** - Continuous flow

Explanation of Respirator Codes:
- Class 1 low to medium absorption capacity filters.
- Class 2 medium absorption capacity filters.
- Class 3 high absorption capacity filters.
- PAPR Powered Air Purifying Respirator (positive pressure) cartridge.
- Type A for use against certain organic gases and vapors.
- Type AX for use against low boiling point organic compounds (less than 65°C).
- Type B for use against certain inorganic gases and other acid gases and vapors.
- Type E for use against sulfur dioxide and other acid gases and vapors.
- Type K for use against ammonia and organic ammonia derivatives.

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

Use appropriate NIOSH-certified respirator based on informed professional judgement. In conditions where no reasonable estimate of exposure can be made, assume the exposure is in a concentration IDLH and use NIOSH-certified full face pressured demand SCBA with a minimum service life of 30 minutes, or a combination full facepiece pressure demand SAR with auxiliary self-contained air supply. Respirators provided only for escape from IDLH atmospheres shall be NIOSH-certified for escape from the atmosphere in which they will be used.

ENGINEERING CONTROLS
- Local exhaust ventilation usually required. If risk of overexposure exists, wear an approved respirator. Correct fit is essential to obtain adequate protection an approved self contained breathing apparatus (SCBA) may be required in some situations.
- Provide adequate ventilation in warehouse or closed storage area.
- 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.

<table>
<thead>
<tr>
<th>Type of Contaminant:</th>
<th>Air Speed:</th>
</tr>
</thead>
<tbody>
<tr>
<td>solvent, vapors, degreasing etc., evaporating from tank (in still air)</td>
<td>0.25-0.5 m/s (50-100 ft/min.)</td>
</tr>
<tr>
<td>aerosols, fumes from pouring operations, intermittent container filling, low speed conveyor transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)</td>
<td>0.5-1 m/s (100-200 ft/min.)</td>
</tr>
<tr>
<td>direct spray, spray painting in shallow booths, drum filling, conveyor loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)</td>
<td>1-2.5 m/s (200-500 ft/min.)</td>
</tr>
<tr>
<td>grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion)</td>
<td>2.5-10 m/s (500-2000 ft/min.)</td>
</tr>
</tbody>
</table>

Within each range the appropriate value depends on:
- Lower end of the range
- Upper end of the range

1: Room air currents minimal or favorable to capture 1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only. 2: Contaminants of high toxicity
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 m/s (200-400 f/min) for extraction of solvents generated in a tank 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.

**Section 9 - PHYSICAL AND CHEMICAL PROPERTIES**

**PHYSICAL PROPERTIES**

<table>
<thead>
<tr>
<th>State</th>
<th>Divided solid</th>
<th>Molecular Weight</th>
<th>479.16 (416.13+6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting Range (°F)</td>
<td>338.5-365 (dec)</td>
<td>Viscosity</td>
<td>Not available</td>
</tr>
<tr>
<td>Boiling Range (°F)</td>
<td>Not available</td>
<td>Solubility in water (g/L)</td>
<td>Immiscible</td>
</tr>
<tr>
<td>Flash Point (°F)</td>
<td>Not applicable</td>
<td>pH (1% solution)</td>
<td>4.0 (Sat. Soln.)</td>
</tr>
<tr>
<td>Decomposition Temp (°F)</td>
<td>Not available</td>
<td>pH (as supplied)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition Temp (°F)</td>
<td>950</td>
<td>Vapour Pressure (mmHG)</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

**APPEARANCE**

White to light beige crystals or powder, almost insoluble in water. Slightly soluble in alcohols, chloroform and acetone. Solubility in water 160 mg/litre.

**Section 10 - CHEMICAL STABILITY**

**CONDITIONS CONTRIBUTING TO INSTABILITY**

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

**STORAGE INCOMPATIBILITY**

- Avoid reaction with oxidizing agents.

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

**Section 11 - TOXICOLOGICAL INFORMATION**

**miconazole nitrate**

**TOXICITY AND IRRITATION**

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

<table>
<thead>
<tr>
<th>TOXICITY</th>
<th>IRRITATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral (rat) LD50: 920 mg/kg</td>
<td>Nil Reported</td>
</tr>
<tr>
<td>Reproductive effector in rat</td>
<td></td>
</tr>
</tbody>
</table>

**Section 12 - ECOLOGICAL INFORMATION**

Refer to data for ingredients, which follows:

**MICONAZOLE NITRATE:**

- 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.

Azole fungicides and systemically used antifungal drugs directly interfere with steroidogenesis by acting as potent inhibitors of steroidogenic enzymes and are known to cause endocrine disruption mainly via this mechanism. An important P450 enzyme involved in the steroidogenesis is aromatase. Aromatase demethylates C10 and specifically converts androstenedione and testosterone. On the protein level, the amino acid sequence homology between aromatase from fish and humans is about 50% and between rats and humans is about 78%. In mammals, aromatase is mainly expressed in the brain and the gonads, but it is also found in placental, adipose, and bone tissue. The physiologic balance between different sex steroid hormones is crucial for the development, maintenance, and function of the reproductive system as well as for the differentiation of the sexual phenotype during ontogeny. Oestrogens (estrone and estradiol) are products of the androgens (androstenedione and testosterone), and the reaction is catalysed by aromatase. In mammals, differentiation of the male
phenotype depends not only on testosterone but also on estradiol generated from testosterone by neuronal aromatase in central nervous system. Therefore, disturbances in aromatase expression and/or changes in its catalytic activity are expected to exhibit negative effects on reproduction parameters.

Azole-containing compounds produce profound effects in the environment. In part this is due to inhibition of several enzyme systems including those involving sterol 14[alpha]-demethylase. Sterol 14[alpha]-demethylase is a member of the superfamily of haeme-containing cytochrome P450 enzymes involved in metabolism of endogenous and xenobiotic substances. The antifungal effect of azoles is due to inhibition of sterol 14[alpha]-demethylase in fungi and yeast, thereby blocking the biosynthesis of ergosterol. The subsequent lack of ergosterol is detrimental because ergosterol is an essential sterol component in the membranes of 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. In plants, the sterol 14[alpha]-demethylase reaction metabolises obtusifoliol and provides precursors for biosynthesis of phytoestrogens. In animals, the sterol 14[alpha]-demethylase reaction is part of the metabolic pathway leading to biosynthesis of cholesterol. Cholesterol in turn is the substrate for the production of many other steroids (e.g., the sex steroid hormones).

The DNA sequences encoding sterol 14[alpha]-demethylase of many fungi and yeast are known, as well as the sequences of mice, rats, pigs, and humans. On the protein level, the amino acid sequences are highly conserved along the phylogenetic tree. This fact is considered by many authors as an indication of the pivotal role of sterol 14[alpha]-demethylase in all organisms. The homology of the amino acid sequence level between rats and humans is 93% and 40% between fungi and humans. In humans, the sterol 14[alpha]-demethylase is expressed in many different tissues.

DO NOT discharge into sewer or waterways.

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions
All waste must be handled in accordance with local, state and federal regulations.

- Puncture containers to prevent re-use and bury at an authorized landfill.

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 reuse may not always be appropriate.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

- Recycle wherever possible.
- Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.
- Dispose of by: Burial in a licensed land-fill 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 - TRANSPORTATION INFORMATION

Air Transport IATA:

ICAO/IATA Class: 9
UN/ID Number: 3077
Packing Group: III
Special provisions: A97

Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. *(CONTAINS MICONAZOLE NITRATE)

Maritime Transport IMDG:

IMDG Class: 9
UN Number: 3077
Packing Group: III
Section 15 - REGULATORY INFORMATION

Miconazole nitrate (CAS: 22832-87-7) is found on the following regulatory lists:
*Canada Domestic Substances List (DSL)*, *OSPAR List of Substances of Possible Concern*, *US - Maine Chemicals of High Concern List*

Section 16 - OTHER INFORMATION

LIMITED EVIDENCE

- Inhalation may produce health damage*.
- May possibly affect fertility*.
- May possibly be harmful to the fetus/embryo*.

* (limited evidence).

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- Classification of the mixture 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.
- The (M)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.

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