

MATERIAL SAFETY DATA SHEET

HONEYWELL CHEMICALS{PRIVAT } VALE ROAD ARKLOW CO WICKLOW IRELAND. TEL: 353 (402) 20300 FAX: 353 (402) 31147	SPECIALTY	MSDS NO: MS-070-0 SUPERSEDES: MS-000-0 VALID FROM: _____ APPROVED BY: _____ Health & Safety Manager
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COMMERCIAL PRODUCT NAME: BUTOCONAZOLE NITRATE

SECTION 1: IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND OF THE COMPANY UNDERTAKING

Product Name	: Butoconazole Nitrate
Product Type	: Active Pharmaceutical ingredient (antifungal azole)
Manufacturer/Supplier	: Honeywell Research & Life Science Solutions
Address	: Vale Road, Arklow, Co. Wicklow, Ireland.
Phone Number	: 353-402-20300
Fax Number	: 353-402-31147
Emergency Phone Number	: 353-402-20300

SECTION 2: COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	: 1-[4-(p-chlorophenyl)-2-[2,6-dichlorophenyl)Thio]butyl]imidazole mononitrate
CAS No.	: 64872-77-1
Einecs No.	: Not listed.
Weight %	: 100%
Symbols	: Harmful (Xn)
R. Phrases	: R22 harmful if swallowed.

SECTION 3: HAZARDS IDENTIFICATION

Main Hazards	: May be irritating to the eyes, Chronic overexposure may cause liver and kidney effects. Avoid ingestion, inhalation, skin contact and eye contact. Material intended for pharmaceutical manufacturing use only.
Health Effects - Eye	: Butoconazole nitrate may cause eye irritation.
Health Effects - Skin	: The effect of butoconazole nitrate active ingredient on the skin is unknown. No signs of skin irritation were observed in rabbits after a single dermal exposure to a formulated product containing 2.3% butoconazole nitrate. A formulated product containing up to 2.3% butoconazole nitrate did not cause an allergic skin reaction.
Health effects - Ingestion	: Harmful if swallowed.
Health Effects - Inhalation	: Not known.
Systemic	: Acute. Butoconazole nitrate has low to moderate acute oral toxicity. The LD ₅₀ in rats is greater than 1,720 mg/kg. This is roughly equivalent to 1-1/2 to 2 ounces to a 150 lb person. Chronic. Repeated oral doses in laboratory animals produced slight increases in liver enzyme activities and kidney (cellular changes) toxicity.
Reproductive and Developmental Toxicity	: Reproduction studies in rats indicated a dose-related increase in gestation period, difficult or prolonged labor and decreased survival of offspring. However, no teratologic (birth defects) changes were observed. Limited clinical (human) studies have shown that butoconazole nitrate was administered as a vaginal cream during pregnancy.
Carcinogenicity and Mutagenicity	: This chemical has not been tested for its carcinogenic potential and is not listed by NTP, IARC, or OSHA as a carcinogen. Butoconazole nitrate was not mutagenic in a battery of genotoxicity studies.
Medical Conditions Aggravated by Exposure	: None known or reported.
Occupational Exposure Limit	: No level has been established by OSHA, NIOSH or ACGIH.

SECTION 4: FIRST AID MEASURES

- Symptoms and Effects** : Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity reactions must receive immediate medical attention. Upon eye or skin contact, flush afflicted area with copious quantities of water. Obtain medical attention. If large amounts are ingested, induce vomiting, if unconscious, do not induce vomiting or give anything by mouth. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. The accidental ingestion of small quantities should not result in damages.
- First Aid - Inhalation** : Immediately move to fresh air. If symptoms develop, get medical attention and notify supervisor.
- First Aid - Skin** : Immediately wash thoroughly with water for at least 15 minutes. If symptoms develop, get medical attention and notify supervisor. Remove and discard or decontaminate affected clothing, shoes and personal protective equipment.
- First Aid - Eyes** : Immediately flush thoroughly with water for at least 15 minutes. If symptoms develop, get medical attention and notify supervisor.
- First Aid - Ingestion** : Drink one to two (8-16 oz or 250-500 mL) of water. Immediately notify medical personnel and supervisor.

SECTION 5: FIRE FIGHTING MEASURES

- Extinguishing Media** : Use water, foam, vaporizing liquid or multipurpose dry chemical. Avoid application of high pressure water streams that may create dust clouds.
- Unsuitable Extinguishing Media** : High pressure water streams.
- Special Hazards of Product** : Data not available.
- Hazardous Combustion Products** : May produce toxic bi products on heating.
- Protective equipment for Fire Fighting** : Keep personnel removed from and upwind of fire. Wear full fire-fighting turn-out gear (full Bunker Gear) and NIOSH/MSHA-approved self-contained breathing apparatus (SCBA). Avoid creating dust clouds. Prevent run-offs to sanitary or storm sewers or surface bodies of water, e.g., stream. Decontaminate and inspect protective and fire-fighting equipment thoroughly after use.
- Flammability/Explosivity** : As a solid, not considered flammable. No explosivity data available. High airborne concentrations of finely divided organic powder can explode if ignited.

SECTION 6: ACCIDENTAL RELEASE MEASURES

- Personal Precautions** : If material is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment.
- Environmental Precautions** : Cordon off spill area. Prevent or minimize material from reaching surface waters, sanitary drains or storm drains. Before collecting material, wet down with appropriate wetting agent, e.g., water, to minimize airborne particulate generation. Alternatively, use vacuum cleaner equipment with high efficiency particulate air (HEPA) filter. Discard collected material in containers suitable for proper disposal. Rinse/decontaminate spill area. Release may need to be reported to regulatory authorities. Dispose of waste in accordance with all applicable federal, state and local laws.

SECTION 7: HANDLING AND STORAGE

- Handling** : Avoid contact with skin, eyes or clothing. Use adequate ventilation and/or appropriate personal protective equipment. Wash thoroughly after handling.
- Storage** : Store in a cool, well-ventilated area or according to material specifications.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

- Occupational Exposure Standards** : Not known.
- Engineering Control Measures** : Not known.
- Respiratory Protection** : Wear respirator that affords protection against airborne particulates or aerosols. Base choice of protection on the job activity, potential for inhalation exposure or air monitoring results.
- Hand Protection** : Wear gloves.
- Eye Protection** : Wear safety glasses with side shields or chemical splash goggles if eye/face contact is likely. Base the choice of protection on the job activity and potential for eye or face contact.
- Skin Protection** : Wear gloves and lab coat or other protective overgarment. Base the choice of skin protection, e.g., choice of glove material, on the job activity and potential for skin contact.

- Ventilation** : When practical, handle material in contained processes with adequate local exhaust ventilation. Minimize operations that result in uncontrolled airborne particulate or aerosol generation.
- Other** : Wash hands, face and other potentially exposed areas immediately after handling material, especially before eating, drinking or smoking. Assure that all personal protective equipment is clean and all personal protective equipment and engineering controls are operational at all times.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

- Physical State** : White, crystalline powder, no data on odour.
- Colour** : White.
- Odour** : No data on odour.
- Boiling Point (°C)** : As a solid, not applicable.
- Flash Point (°C)** : Not applicable.
- Water Solubility** : 0.26 mg/ml water; soluble in methanol, acetone, chloroform and ethanol.
- Melting Point** : 159°C to 161°C.
- Vapour Density (Air=1)** : Nil.
- Vapour Pressure** : Nil.
- Octanol/Water Partition Coefficient** : No data available.
- Percent Volatile** : Nil.
- Specific Gravity** : No data available.
- Molecular Weight** : 475.
- Evaporation** : Nil.

SECTION 10: STABILITY AND REACTIVITY

- Stability** : Stable.
- Conditions to Avoid Instability** : Bases, high temperatures.
- Materials to Avoid Incompatibility** : Strong oxidizing agents (e.g., peroxides, permanganates, perchlorates, nitric acid, etc.)
- Hazardous Decomposition Products** : May produce toxic by-products upon heating.
- Hazardous Polymerization** : Not determined.

SECTION 11: TOXICOLOGICAL INFORMATION

- Acute Toxicity-Oral** : See Section 3. Health Hazards.
- Acute Toxicity-Dermal** : See Section 3. Health Hazards.
- Acute Toxicity-Inhalation** : See Section 3. Health Hazards.

Eye Irritation	: See Section 3. Health Hazards.
Skin Irritation	: See Section 3. Health Hazards.
Skin Sensitisation	: See Section 3. Health Hazards.
Health Warnings	: See Section 3. Health Hazards.
Medical Symptoms	: See Section 3. Health Hazards.
Acute and Chronic Health Hazards	: See Section 3. Health Hazards.

SECTION 12: ECOLOGICAL INFORMATION

Mobility	:
Persistence / Degradability	: No data available.
Bioaccumulation	: No data available.
Ecotoxicity	: No data available.
Aquatic Toxicity	: No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

Precautions	: All wastes containing the compound should be specially contained, properly labeled and stored separately from other facility waste discharges. Dispose of any waste residues according to prescribed Federal, State and Local guidelines, e.g., appropriately permitted chemical landfill or appropriately permitted municipal or on-site wastewater incinerator. Rinsewaters resulting spill cleanups should be discharged to appropriately permitted municipal or on-site wastewater treatment facilities.
Product/Waste Disposal	: Disposal methods should be used which prevent human exposure to the waste residues. For example, if liquid wastes are sewerred, ensure that there will not be any chance for humans to be exposed to the undiluted/active waste residues. Water may be used to dilute the waste residues.
Container Disposal	:

SECTION 14: TRANSPORT REGULATIONS

UN Number	: None assigned per U. S. DOT or IATA.
UN Class/Packing Group	: Not applicable.
UN Number (Road Transport)	: Not applicable.
ADR/RID Symbol	: Not applicable.
ADR/RID Kemler Number	: Not applicable.
ADR/RID Proper Shipping Name	: Not applicable.
UN Number Sea Transport (IMDG)	: Not applicable.

IMDG Class / Packing Group	: Not applicable.
IMDG Symbol	: Not applicable.
IMDG Marine Pollutant	: Not applicable.
IMDG Proper Shipping Name	: Not applicable.
UN Number Air Transport (ICAO)	: Not applicable.
IATA/ICAO Class/Packing Group	: Not applicable.
IATA/ICAO Symbol	: Not applicable.
IATA/ICAO Proper Shipping Name	: Not applicable.
Hazard Class	: Not classified under U.S. DOT or IATA criteria

SECTION 15: REGULATORY INFORMATION

EC Label Name	: In addition to the material identity, bulk containers of butoconazole nitrate and butoconazole nitrate containing formulations should have affixed the following warning label (in addition to the product identity label):
EC Classification	: Harmful (Xn).
EC Symbols	: Xn
EC Risk Phrases	: R22
EC Safety Phrases	: S22 S 20/21-24/25-36/37-22.
EINECS (EC)	: No listed.
Caution	: May be irritating to the eyes. Chronic overexposure may cause liver and kidney effects. Avoid ingestion, inhalation, skin contact and eye contact. Material intended for pharmaceutical manufacturing use only. Read and understand the Material Safety Data Sheet for additional information before working with this product.

SECTION 16: OTHER INFORMATION

Training	: Train all personnel handling product in safe handling procedures as per this Material Safety Data Sheet.
Revision Date	: N/A
Notice	: The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions.

No representation, warranty or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose) is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is biologically active.