

PYRAZINAMIDE TABLETS

Prepared: 05-15-97

Supersedes: 09-16-93

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I. IDENTIFICATION: PYRAZINAMIDE TABLETS

Contains; colloidal silicon dioxide NF,  
croscarmellose sodium NF, dibasic calcium  
phosphate USP, microcrystalline cellulose  
NF, pyrazinamide USP, stearic acid NF

II. DISTRIBUTOR

Name: VersaPharm, Incorporated  
200 North Cobb Parkway  
Suite 210  
Marietta, GA 30065-1509  
Emergency:(770)499-8100  
Information:(770)499-8100

III. MANUFACTURER

Name: Mikart, Incorporated  
2090 Marietta Boulevard, NW  
Atlanta, GA 30318  
Emergency: (404)351-1125  
Information: (404)351-1125

IV. FIRE EXPLOSION AND REACTIVITY DATA

None known

V. HEALTH HAZARD INFORMATION

This product is a "mixture" for which no health hazard data exists. The Hazard Communication Standard requires that such mixtures be assumed to present the same health hazards as do components that constitute at least 1% of the mixture, although OSHA has noted that the hazards of individual components may be altered by including them in a mixture.

ONLY INGREDIENTS PRESENT AT A CONCENTRATION OF  $\delta$ 1%  
ARE LISTED.

COLLOIDAL SILICON DIOXIDE NF

## EXPOSURE

### Inhalation:

Temporary discomfort due to inhalation of dust  
concentration above the permissible exposure  
limit.

### Ingestion:

No information available.

### Skin Contact:

No information available.

### Eye Contact:

Safety goggles recommended.

### Chronic Exposure:

No information available.

### Carcinogenicity:

Not considered a potential carcinogen by IARC,  
NTP, or OSHA.

Toxicity Data:

Non-Toxic LD50 = Greater than 5000 mg/kg(oral)

Systemic Effects:

No information available.

CROSCARMELLOSE SODIUM NF

EXPOSURE

Inhalation:

No significant hazard. No mortality in rats at maximum attainable concentration. 4 hour LC50 > 0.13 mg/L.

Ingestion:

No significant hazard. Oral LD50(Rat) > 5050 mg/kg.

Skin Contact:

Minimally irritating. Primary Irritation Index (Rabbit) = 0.1/8.0.

Eye Contact:

Minimally irritating (Rabbit).

Chronic Exposure:

No significant hazard in animal toxicity tests. No adverse human effects known.

Carcinogenicity:  
No information available.

Toxicity Data:  
No information available.

Systemic Effects:  
No information available.

## DIBASIC CALCIUM PHOSPHATE USP

### EXPOSURE

Inhalation:  
Persons subjected to large amounts of this dust will be forced to leave area because of nuisance conditions; coughing, sneezing and nasal irritations.

Ingestion:  
No information available.

Skin Contact:  
No information available.

Eye Contact:

May cause particulate irritation.

Chronic Exposure:

Occupational exposure is not expected to produce significant adverse human health effects following normal work place exposure.

Carcinogenicity:

No information available.

Toxicity Data:

No information available.

Systemic Effects:

No information available.

MICROCRYSTALLINE CELLULOSE NF

EXPOSURE

Inhalation:

No significant hazard. No mortality in rats at maximum attainable concentration. 4 hour LC50 > 5.05 - 5.49 mg/mL.

Ingestion:

No significant hazard. Oral LD50 (Rat) > 5g/kg.

Skin Contact:

Nonirritant. Primary Irritation Index  
(Rabbit)= 0/8.0.

Eye Contact:

Minimally irritating (Rabbit).

Chronic Exposure:

No significant hazard in animal toxicity  
tests. No adverse human effects known.

Carcinogenicity:

No information available.

Toxicity Data

No information available.

Systemic Effects:

No information available.

PYRAZINAMIDE USP

EXPOSURE

Inhalation:

No information available.

Ingestion:

No information available.

Skin Contact:

No information available.

Eye Contact:

No information available.

Chronic Exposure:

No information available.

Carcinogenicity:

No information available.

Toxicity Data:

Acute toxicity (Rat): 2350 mg/kg; 3800 mg/kg

Systemic Effects:

No information available.

STEARIC ACID NF

EXPOSURE

Inhalation:

Nuisance dust. May cause coughing, sneezing

or labored breathing if large amounts are inhaled.

Ingestion:

No adverse effects expected.

Skin Contact:

Mild irritant, possibly causing surface inflammation, especially on prolonged contact with oily skin.

Eye Contact:

May cause mechanical irritation.

Chronic Exposure:

No adverse health effects expected.

Carcinogenicity:

No information available.

Toxicity Data:

No LD50/LC50 information found relating to normal routes of occupational exposure.

Irritation skin (Rabbit) 500 mg/2411  
moderate

Systemic Effects:

No information available.

## VI. PHYSICAL DATA

Appearance: White, round, standard scored tablet.  
Deboss: "VP" score "012"

## VII. STORAGE INFORMATION

Protect from light and moisture. Store at controlled room temperature, 15 - 30°C (59 - 86°F) in tight, light-resistant container with child-resistant closure. The product is best stored in its original container. Keep container tightly closed.

## VIII. SPILL, LEAK AND DISPOSAL PROCEDURES

Gather spilled material and place in a glass or plastic container. Assess and document the amount of material collected. Ensure compliance with local, state and federal regulations.

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