

M A T E R I A L S A F E T Y D A T A S H E E T

FMOM No.: 3238-1MM-0.00

DATE: 3/15/04

PRODUCT NAME: Rifampin/Isoniazid Capsules

POTENCY: 300 mg/150 mg

BATCH SIZE: 120,000 Capsules

RIFAMPIN: CAS # 13292-46-1

- Adverse Effects:** Rifampin is usually well-tolerated and adverse effects are more common during intermittent use. Adverse effects may include diarrhea; stomach cramps; reddish-orange to reddish-brown discoloration of urine, feces, saliva, sweat, or tears; chills; difficulty breathing; dizziness; fever; headache; muscle and bone pain; shivering; itching, redness, or rash of the skin; and sore mouth or tongue. Possible allergic reaction to material if inhaled, ingested or in contact with skin.
- Overdose Effects:** Symptoms of overdose may include mental changes, swelling around the eyes or the whole face, itching over the whole body, and red-orange discoloration of the skin, mucous membranes, and whites of the eyes.
- Acute:** Possible eye, skin, gastrointestinal and/or respiratory tract irritation.
- Chronic:** Possible hypersensitization.
- Inhalation:** May cause irritation. Remove to fresh air.
- Eye:** May cause irritation. Flush with copious quantities of tepid water for 15 minutes.
- Skin:** May cause irritation and contact dermatitis. Flush with copious quantities of water.
- Ingestion:** May cause irritation. Flush out mouth with water. This material is well absorbed from the gastrointestinal tract.
- Medical Conditions**
Aggravated by
Exposure: Hypersensitivity to material, history of or active alcoholism, and impaired liver function.
- Cross Sensitivity:** Persons sensitive to any of the rifamycins may be sensitive to the material also.
- Pregnancy Comments:** Adequate and well-controlled pregnancy studies in humans have not been done. Rifampin has rarely caused postnatal hemorrhage in the mother and infant following administration during the last few weeks of pregnancy. Studies in rodents has shown that rifampin given in extremely large doses causes abnormal development of the fetus, primarily cleft palate and spin bifida; similar studies in rabbits caused abnormal bone formation and embryo death.

Pregnancy Category: C

First Aid Measures

General: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Overdose Treatment: Treatment of overdose with rifampin is primarily supportive and may include the following:

1. To decrease absorption, empty the stomach using syrup of ipecac or gastric lavage.
2. Administer an activated charcoal slurry to help absorb residual rifampin in the gastrointestinal tract.
3. Antiemetic medication may be required to control severe nausea and vomiting.
4. Active diuresis (with measured input and output) will help promote excretion of the drug.
5. Hemodialysis may be of value in some patients. [USP DI 20th ed. 2000; PDR 2000]

ISONIAZID POWDER: CAS # 54-85-3

EMERGENCY AND FIRST AID PROCEDURES:

Remove from exposure. Remove contaminated clothing. Person developing serious hypersensitivity reactions must receive immediate attention. If not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Overdose treatment consists of the following:

Establish an airway with adequate respiratory exchange and establish IV access.

Because seizures may occur after ingestion, induced vomiting is not recommended. Gastric lavage may be performed within 2 or 3 hours of ingestion, and activated charcoal and a cathartic may be administered if seizures are controlled and the airway is protected.

Administer intravenous **Pyridoxine** (vitamin B6) in a gram for gram dose, equivalent to the amount of Isoniazid ingested, as a 5-10% solution with water over 30 to 60 minutes. If the amount of overdose is unknown, administer 5 grams of **Pyridoxine Hydrochloride** (50mls of a 10% solution) intravenously over 3 to 5 minutes, even if no seizures have occurred. This may be repeated every 5 to 20 minutes, as needed.

Seizures may also be controlled with **Diazepam**, which acts synergistically with pyridoxine.

Thiopental may be effective in treating refractory seizures.

Administrator **Sodium Bicarbonate** if Pyridoxine and Diazepam do not control seizure activity. Watch for hypokalemia or hyperkalemia.

INHALATION: May cause irritation of respiratory tract. Avoid inhalation. Remove to fresh air.

EYES: May cause irritation. Flush with copious quantities of water

SKIN: Causes irritation. Flush with copious quantities of water.

INGESTION: May cause irritation. Flush with copious quantities of water.

NOTE: Person may show no symptoms for up to 2 hours after an acute overdose. Seizures may occur within 1 to 3 hours after ingestion.

LACTOSE:

Signs and Symptoms
of Overexposure:

NONE – Not a health hazard.

CORN STARCH 21: CAS #

Route(s) of Entry: Eye contact; skin contact; inhalation; ingestion.

1. Eyes: Matriculates may scratch eye surfaces/cause mechanical irritation.

2. Skin: Low order of toxicity.

3. Inhalation: Low order of toxicity.

4. Ingestion: No hazard in normal industrial use.

First Aid Procedures:

1. Eyes: Flush eyes with large amounts of water until irritation subsides. If irritation persists, get medical attention.

2. Skin: Wash with soap and water.

3. Inhalation: Remove to fresh air.

4. Ingestion: Not applicable.

COLLOIDAL SILICON DIOXIDE (CAB-O-SIL): CAS # 112945-52-5

Effects of

Overexposure:

ACUTE: None known other than possible temporary discomfort due to inhalation of dust concentration above the permissible exposure limit.

CHRONIC: None Known.

Emergency and First

Aid Procedures:

Flush eyes with plenty of water. For inhalation discomfort, move victim to fresh air.

STARCH 1500: CAS #9005-25-8

Signs and Symptoms

of Overexposure:

Minimal - Dust may be irritating to nose and eyes.

Primary route(s)

of Entry:

Inhalation.

Emergency and First

Aid Procedures:

Unlikely to be necessary. Flush eyes with water. Remove to fresh air.

MAGNESIUM STEARATE: CAS #557-04-0

Signs and Symptoms

of Overexposure:

1. Inhalation: Symptoms from excessive inhalation of dust may include coughing and difficult breathing.
2. Ingestion: Low level of toxicity by ingestion.
3. Skin Contact: No information found. Not expected to be a hazard.
4. Eye Contact: May cause mechanical irritation.
5. Chronic Exposure: Grossly excessive and chronic inhalation of the dust may cause a progressive chemical pneumonitis.
6. Aggravation of Pre-existing Conditions: Persons with pre-existing skin disorders, impaired respiratory function, or a history of pulmonary disease should not be exposed to dusts.