

SAFETY DATA SHEETS

This SDS packet was issued with item:

078443532

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078600706

MATERIAL SAFETY DATA SHEET

FMOM No.: 1268-4.250MM-0.04

DATE: 9/16/08

PRODUCT NAME: Lisinopril Tablets

POTENCY: 20mg

BATCH SIZE: 4,250,000 Tablets

RED IRON OXIDE: CAS #1309-37-1

Health Hazard: Routes of entry for solids and liquids include eye and skin contact, ingestion and inhalation. Routes of entry for gases include inhalation and eye contact. Skin contact may be a route of entry for liquefied gases.

Toxicology Test Date:

Rabbit, Eye Irritation (unrinsed) –

Nonirritating

Rabbit, Primary Skin Irritation –

Nonirritating

Rat, Oral LD₅₀ - > 2 G/KG

Moderately Toxic

Acute Overexposure: Prolonged or repeated eye or skin contact may result in irritation. Acute overexposure to iron may result in stupor, shock, acidosis, bloody, diarrhea and shock.

Chronic Overexposure: Chronic overexposure to iron oxide fume or dust has been associated with x-ray changes of the lungs; however, it dose not result in illness. Changes are due to a benign lung condition called siderosis, or iron pigmentation. Animal studies indicate that chronic overexposure to iron oxide dust does not cause lung impairment or fibrosis

First Aid Procedures:

Skin: Wash affected areas with soap and water. Remove and launder contaminated clothing before reuse. If irritation develops, get medical attention.

Eye: Immediately rinse eyes with running water for 15 minutes. If irritation develops, get medical attention.

Ingestion: If swallowed, dilute with water and immediately induce vomiting. Never give fluids or induce vomiting if the victim is unconscious or having convulsions. Get medical attention.

Inhalation: Move to fresh air. Aid in breathing, if necessary, and get immediate medical attention.

CORN STARCH 21: CAS # 9005-25-8

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

Toxicity

Primary Route(s) of Entry:

Inhalation. Non-toxic LD₅₀ = Greater than 5000 mg/kg (oral) Cab-o-sil is not considered a potential carcinogen by IARC, NTP, or OSHA.

Signs and Symptoms of Overexposure

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

Emergency and First Aid Procedures

1. Eyes: Flush Eyes with plenty of water.
2. Inhalation: Move victim to fresh air.

LISINOPRIL: CAS #83195-83-7; 76547-98-3 (anhydrous)

Health Hazard:

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 water.

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

Ingestion: May cause irritation. Flush out mouth with water.

Medical Conditions

Aggravated by

Exposure: Hypersensitivity to the material, history of angioedema, hereditary or idiopathic angioedema, hyperkalemia, active alcoholism, kidney transplant, function impairment or artery stenosis and severe dietary sodium restriction or dialysis.

Cross Sensitivity: Persons sensitive to any of the ACE inhibitors may be sensitive to this material also.

Pregnancy

Comments:

Pregnancy studies with lisinopril have shown it not to be teratogenic in mice given doses up to 625 times the maximum recommended human dose. However, when used during the second and third trimesters, lisinopril can cause injury and even death to the developing fetus.

Pregnancy

Category:

C/D

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.

MANNITOL: CAS #69-65-8

Health Hazard:

- Ingestion:** The acute oral LD₅₀ in rat is 17,300 mg/kg. Relative to other materials, this material is classified as "relatively harmless" by ingestion.
- Eyes:** This material is non-irritating in rabbit eye irritation studies; no irritation is likely to occur after human eye contact.
- Skin:** This material is non-irritating in rabbit dermal irritation studies. No irritation is likely to develop following contact with human skin.
- Inhalation:** No toxic effects are known to be associated with inhalation of dust from this material.
- Other Effects of Overexposure:** No other adverse clinical effects have been associated with exposures to this material. However, excessive consumption has been associated with a laxative effect.

First Aid Procedures:

- Skin:** Wash material off of the skin with plenty of soap and water. If redness, itching, or a burning sensation develops, get medical attention.
- Eyes:** Immediately flush with plenty of water for at least 15 minutes. If redness, itching, or a burning sensation develops, have eyes examined and treated by medical personnel.
- Ingestion:** Give 1 or 2 glasses of water to drink. If gastrointestinal symptoms develop, consult medical personnel. (Never give anything by mouth to an unconscious person.)
- Inhalation:** Remove victim to fresh air. If a cough or other respiratory symptoms develop, consult medical personnel.

DIBASIC CALCIUM PHOSPHATE: CAS #7757-93-9

Exposure/Health Effects

1. **Inhalation:** Hazard is that of a nuisance dust. Coughing sneezing and labored breathing may occur in case of acute inhalation.
 2. **Ingestion:** No adverse health effects expected.
 3. **Skin Contact:** No adverse health effects expected.
 4. **Eye Contact:** May cause mechanical irritation.
 5. **Chronic Exposure:** No adverse health effects expected.
- Aggravation of Pre-existing Conditions:** No adverse health effects expected.

FIRST AID

1. Inhalation: Remove to fresh air. Get medical attention for any breathing difficulty.
2. Ingestion: Give several glasses of water to drink to dilute. If large amounts were swallowed, get medical advice.
3. Skin Exposure: Wash exposed area with soap and water. Get medical advice if irritation develops.
4. Eye Exposure: Wash thoroughly with running water. Get medical advice if irritation develops.

SODIUM STARCH GLYCOLATE (PRIMOJEL): CAS # 9063-38-1

Signs and Symptoms
of Overexposure: Not a Health Hazard.

SPECIAL FIRE FIGHTING

PROCEDURES: Use health protection because poisonous gas will be formed when burning.

MAGNESIUM STEARATE: CAS # 557-04-0

Exposure/Health Effects:

Inhalation: Symptoms from excessive inhalation of dust may include coughing and difficult breathing.

Ingestion: Low level of toxicity by ingestion.

Skin Contact: No information found. Not expected to be a hazard.

Eye Contact: May cause mechanical irritation.

Chronic
Exposure: Grossly excessive and chronic inhalation of the dust may cause a progressive chemical pneumonitis.

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.