

MATERIAL SAFETY DATA SHEET

FMOM No.: 9101-1MM-0.03

DATE: 5/21/99

PRODUCT NAME: Ethambutol HCl Tablet Cores

POTENCY: 400 mg

BATCH SIZE: 1,000,000 Cores

ETHAMBUTOL HYDROCHLORIDE CAS #74-55-5

Threshold Limit
Value Signs and
Symptoms of
Overexposure:

None established

TDL0: 45 mg/Kg/3D-I oral-man;

TDL0: 46 mg/Kg/3D-I oral-man;

TDL0: 720 mg/Kg/48D unreported-woman

LD₅₀: 6800 mg/Kg oral/rats

LD₅₀: 1200 mg/Kg intraperitoneal-rat;

LD₅₀: 300 mg/Kg intravenous-rat;

LD₅₀: 8890 mg/Kg oral-mouse;

LD₅₀: 1800 mg/Kg subcutaneous-mouse;

LD₅₀: 230 mg/Kg intravenous-mouse;

Mutation data (RTECS)

TDL0: 900 mg/Kg56OD-(oral-woman)

TDL0: 600 mg/Kg oral-man;

TDL0: 1200 mg/Kg- oral-man;

LD₅₀: 8700 mg/Kg oral mouse;

LD₅₀: 1075 mg/Kg intraperitoneal-mouse

LD₅₀: 240 mg/Kg intravenous-mouse;

LD₅₀: 890 mg/Kg subcutaneous-mammal;

LD₅₀: 300 mg/Kg intravenous-mammal;

Possible allergic reaction to dust if inhaled, ingested or in contact with skin.

Adverse effects include blurred vision, eye pain, red7green color blindness, or any loss of vision.

ACUTE: Eye, skin and/or respiratory tract irritation.

CHRONIC: Possible hypersensitization

PRECAUTION TO CONSIDER:

Persons developing hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Material may be irritation to mucous membranes and respiratory tract. As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, fumes, mists, and/or vapors associated with the material. Keep container tightly closed and use with adequate ventilation; wash thoroughly after handling. Individuals working with chemicals should consider all chemicals to be potentially hazardous even if their individual hazards may be uncharacterized or unknown. Ethambutol crosses the placenta, resulting in fetal plasma concentrations approximately 30% of material plasma concentrations. Problems in humans have not been documented. However, studies in mice given high doses have shown that Ethambutol causes low incidence of cleft palate etc. (USP DI, 10th Edition).

Emergency and First Aid Procedures:

Remove from exposure. Remove contaminated clothing. Person developing serious hypersensitivity reactions must receive immediate attention. Upon eye or skin contact, flush affected area with copious quantities of water. Obtain medical attention. If not breathing give artificial respiration. If breathing is difficult, give oxygen.

1. Inhalation: May cause irritation of respiratory tract. Avoid inhalation. Remove to fresh air.
2. Eyes: May cause irritation. Flush with copious quantities of water.
3. Skin: May cause irritation. Flush with copious amounts of water.
4. Ingestion: May cause irritation. Flush out mouth with water.

COMPRESSIBLE SUGAR (DIPAC):

Routes of Entry: Inhalation.

Acute or Chronic Health Hazards: Nuisance dust.

Signs and Symptoms Of Exposure: Overexposure may irritate eyes, nose, throat and/or lungs. Continued overexposure may lead to increased sensitivity, which is reversible.

Medical Conditions Generally Aggravated By Exposure: Any pre-existing upper respiratory ailment or allergic sensitivity.

Emergency and First Aid Procedures: Flush eyes with water; provide adequate ventilation, e.g., fresh air; in case of respiratory difficulty obtain immediate medical attention.

CROSCARMELLOSE SODIUM (AC-DI-SOL): CAS #74811-65-7

Hazards Identification:

Emergency Overview: Accumulation of overhead settled dust may form explosive concentrations in air when disturbed and dispersed.

Potential Health

Effects: Minimally irritating to the eyes and skin.

First Aid Measures:

1. Eyes: Flush with water for at least 15 minutes. If irritation occurs and persists, obtain medical attention.
2. Skin: Wash with plenty of soap and water. Get medical attention if irritation occurs and persists.
3. Inhalation: Remove to fresh air. If breathing difficulty or discomfort occurs and persists, obtain medical attention.
4. Ingestion: Drink plenty of water. Never give anything by mouth to an unconscious person. If any discomfort persists, obtain medical attention.

Notes to Medical

Doctor: AC-DI-Sol Croscarmellose Sodium has a very low toxicity. Treatment is symptomatic and supportive only.

Fire Fighting

Measures:

Extinguishing

Media: Water.

Unusual Fire and
Explosion Hazard:

Accumulation of overhead settled dust may form explosive concentrations in air when disturbed and dispersed. The propagation of flame through air-floated dusts takes place usually following a small explosion which shakes down accumulated dust.

Special Fire Fighting
Procedures:

For fires involving this material, do not enter any enclosed or confined fire space without wearing full protective clothing and self-contained breathing apparatus (SCBA) approved for firefighting. This is necessary to protect against the hazards of heat, products of combustion and oxygen deficiency. Do not breathe smoke, gases or vapors generated.

Hazardous
Decomposition

Products: None known.

Exposure Controls/
Personal Protection:

1. Respiratory: Whenever dust in the worker's breathing zone cannot be controlled with ventilation, workers should wear respirators which are approved by NIOSH/MSHA (or equivalent agency) for protection against airborne dust.
2. Eyes: Whenever airborne dust concentrations are high, appropriate protective eyewear, such as monogoggles, should be worn to prevent eye contact.
3. Gloves: Not required.
4. Special Clothing & Equipment: Not required.
5. Exposure Limits: None known.

TECHNOLOGICAL INFORMATION

- Eye Contact: Minimally irritating (Rabbit). FMC study number I82-603.
- Skin Contact: Minimally irritating. Primary Irritation Index (Rabbit) = 0.1/8.0 FMC Study Number I82-602. Non-sensitizing (Guinea Pig). FMC Study Number I91-1186.
- Skin Absorption: Dermal LD50 (Rabbit) > 2 g/kg. FMC Study Number I82-601.
- Inhalation: No mortality in rats at maximum a concentration. 4 hour LC50 > 0.13 mg/l. FMC Study Number I82-604.
- Ingestion: Oral LD50 (Rat) > 5050 mg/kg. FMC Study Number I80-433.
- Acute Effects for Overexposure: No significant hazard in animal toxicity tests.
- Chronic Effects from Overexposure: AC-DI-SOL SD-711 was negative (nonmutagenic) in the Ames test (FMC Study Number I87-960) and did not induce chromosome aberrations in rats (FMC Study Number I87-979), A 90 day animal study showed no adverse effects when administered in the diet (FMC Study Number I80-434). No adverse human effects known.

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.

STEARIC ACID: CAS # 57-11-4

Signs and Symptoms of Over Exposure

1. Inhalation Nuisance dust may cause coughing, sneezing or labored breathing if large amount are inhaled.
2. Ingestion No adverse effects expected.
3. Skin Mild irritant, possibly causing surface inflammation, especially on prolonged contact with oily skin.
4. Eyes May cause mechanical irritation.

Emergency and First Aid Procedures

1. Inhalation Remove to fresh air. Get medical attention for any breathing difficulty.
2. Ingestion If large amounts were swallowed, give water to drink and get medical advise.
3. Skin Not expected to require first aid measures.
4. Eyes Wash thoroughly with running water. Get medical advise if irritation develops.

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.

MATERIAL SAFETY DATA SHEET

FMOM No.: 90-0006-2.22

DATE: 1/14/00

PRODUCT NAME: Ethambutol HCl Pre-mix

POTENCY: N/A

BATCH SIZE: 183.6 kg

ETHAMBUTOL HYDROCHLORIDE CAS #74-55-5

Threshold Limit

Value Signs and

Symptoms of
Overexposure:

None established

TDL0: 45 mg/Kg/3D-I oral-man;

TDL0: 46 mg/Kg/3D-I oral-man;

TDL0: 720 mg/Kg/48D unreported-woman

LD50: 6800 mg/Kg oral/rats

LD50: 1200 mg/Kg intraperitoneal-rat;

LD50: 300 mg/Kg intravenous-rat;

LD50: 8890 mg/Kg oral-mouse;

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LD50: 240 mg/Kg intravenous-mouse;

LD50: 890 mg/Kg subcutaneous-mammal;

LD50: 300 mg/Kg intravenous-mammal;

Possible allergic reaction to dust if inhaled, ingested or in contact with skin.

Adverse effects include blurred vision, eye pain, red7green color blindness, or any loss of vision.

ACUTE: Eye, skin and/or respiratory tract irritation.

CHRONIC: Possible hypersensitization

**PRECAUTION TO
CONSIDER:**

Persons developing hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Material may be irritation to mucous membranes and respiratory tract. As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, fumes, mists, and/or vapors associated with the material. Keep container tightly closed and use with adequate ventilation; wash thoroughly after handling. Individuals working with chemicals should consider all chemicals to be potentially hazardous even if their individual hazards may be uncharacterized or unknown. Ethambutol crosses the placenta, resulting in fetal plasma concentrations approximately 30% of material plasma concentrations. Problems in humans have not been documented. However, studies in mice given high doses have shown that Ethambutol causes low incidence of cleft palate etc. (USP DI, 10th Edition).

**Emergency and First
Aid Procedures:**

Remove from exposure. Remove contaminated clothing. Person developing serious hypersensitivity reactions must receive immediate attention. Upon eye or skin contact, flush affected area with copious quantities of water. Obtain medical attention. If not breathing give artificial respiration. If breathing is difficult, give oxygen.

1. Inhalation: May cause irritation of respiratory tract. Avoid inhalation. Remove to fresh air.
2. Eyes: May cause irritation. Flush with copious quantities of water.
3. Skin: May cause irritation. Flush with copious amounts of water.
4. Ingestion: May cause irritation. Flush out mouth with water.

LACTOSE MONOHYDRATE: CAS 163-42-3

**Signs and Symptoms
of Overexposure:**

None - Not a Health Hazard.

CORN STARCH (Purity 21): CAS #9005-25-8

Effects of
Overexposure

Acute Overexposure: NONE

Chronic
Overexposure: NONE

Emergency and First
Aid Procedures

Eyes: Flush with water.

Skin: N/A

Inhalation: N/A

Ingestion: N/A

CROSCARMELLOSE SODIUM (AC-DI-SOL): CAS #74811-65-7

Hazards Identification:

Emergency Overview: Accumulation of overhead settled dust may form explosive concentrations in air when disturbed and dispersed.

Potential Health

Effects: Minimally irritating to the eyes and skin.

First Aid Measures:

1. Eyes: Flush with water for at least 15 minutes. If irritation occurs and persists, obtain medical attention.
2. Skin: Wash with plenty of soap and water. Get medical attention if irritation occurs and persists.
3. Inhalation: Remove to fresh air. If breathing difficulty or discomfort occurs and persists, obtain medical attention.
4. Ingestion: Drink plenty of water. Never give anything by mouth to an unconscious person. If any discomfort persists, obtain medical attention.

Notes to Medical
Doctor:

AC-DI-Sol Croscarmellose Sodium has a very low toxicity. Treatment is symptomatic and supportive only.

Fire Fighting
Measures:

Extinguishing
Media:

Water.

Unusual Fire and
Explosion Hazard:

Accumulation of overhead settled dust may form explosive concentrations in air when disturbed and dispersed. The propagation of flame through air-floated dusts takes place usually following a small explosion which shakes down accumulated dust.

Special Fire Fighting
Procedures:

For fires involving this material, do not enter any enclosed or confined fire space without wearing full protective clothing and self-contained breathing apparatus (SCBA) approved for firefighting. This is necessary to protect against the hazards of heat, products of combustion and oxygen deficiency. Do not breathe smoke, gases or vapors generated.

Hazardous
Decomposition
Products:

None known.

Exposure Controls/
Personal Protection:

1. Respiratory: Whenever dust in the worker's breathing zone cannot be controlled with ventilation, workers should wear respirators which are approved by NIOSH/MSHA (or equivalent agency) for protection against airborne dust.
2. Eyes: Whenever airborne dust concentrations are high, appropriate protective eyewear, such as monogoggles, should be worn to prevent eye contact.
3. Gloves: Not required.
4. Special Clothing & Equipment: Not required.
5. Exposure Limits: None known.

TECHNOLOGICAL INFORMATION

Eye Contact:

Minimally irritating (Rabbit). FMC study number I82-603.

Skin Contact:

Minimally irritating. Primary Irritation Index (Rabbit) = 0.1/8.0 FMC Study Number I82-602. Non-sensitizing (Guinea Pig). F'MC Study Number I91-1186.

Skin Absorption:

Dermal LD50 (Rabbit) > 2 g/kg. FMC Study Number I82-601.

Inhalation: No mortality in rats at maximum a concentration. 4 hour LC50 > 0.13 mg/l. FMC Study Number I82-604.

Ingestion: Oral LD50 (Rat) > 5050 mg/kg. FMC Study Number I80-433.

Acute Effects for Overexposure: No significant hazard in animal toxicity tests.

Chronic Effects from Overexposure: AC-DI-SOL SD-711 was negative (nonmutagenic) in the Ames test (FMC Study Number I87-960) and did not induce chromosome aberrations in rats (FMC Study Number I87-979), A 90 day animal study showed no adverse effects when administered in the diet (FMC Study Number I80-434). No adverse human effects known.

POVIDONE: CAS # 9003-35-8

Signs and Symptoms of Exposure

Symptoms of Ingestion: No effects of exposure expected.

Symptoms of Inhalation: If misted, no effects of exposure expected.

Symptoms of Skin Contact: No effects of exposure expected due to absorption or contact. May possibly cause irritation or dermatitis in some individuals upon prolonged contact.

Symptoms of Eye Contact: No effects of exposure expected with the exception of possible irritation.

Emergency and First Aid Procedure

First Aid for Ingestion: General precautionary measures suggest inducing vomiting immediately by giving two glasses of water and sticking finger down throat. Never give anything by mouth to an unconscious person. Call a physician.

First Aid for Inhalation: None required.

First Aid for Skin Contact: For all foreign materials, wash after exposure.

First Aid for Eye Contact: For all foreign materials, immediately flush eyes with plenty of water.

Medical Conditions
Aggravated by
Exposure: No Data Found.

DOCUSATE SODIUM (DIOCTYL SODIUM SULFOSUCCINATE): CAS #577-11-7

HEALTH HAZARD DATA

ACUTE EFFECTS: Harmful if swallowed. May be harmful if inhaled. May be harmful if absorbed through the skin. Causes eye and skin irritation. Material is irritating to mucous membranes and upper respiratory tract. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

FIRST AID: In case of contact, immediately flush eyes with copious amounts of water for at least 15 minutes.

In case of contact, immediately wash skin with soap and copious amounts of water.

If inhaled, remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. call a physician.

Wash contaminated clothing before reuse.

FIRE AND EXPLOSION HAZARD DATA

Extinguishing
Media: Water spray.
Carbon Dioxide, Dry Chemical Powder, Alcohol or Polymer Foam.

Fire Fighting
Procedures: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Unusual Fire and
Explosion Hazard: Emits toxic fumes under fire conditions.

MATERIAL SAFETY DATA SHEET

FMOM No.: 9101C-1MM-0.13

DATE: 7/8/99

PRODUCT NAME: Ethambutol HCl F/C Tablet Cores

POTENCY: 400 mg

BATCH SIZE: 1,000,000 Tablets

ETHAMBUTOL HYDROCHLORIDE: CAS #74-55-5

Threshold Limit Value

Signs and Symptoms

of Overexposure: None established

TDL_o: 45 mg/Kg/3D-I oral-man;
TDL_o: 46 mg/Kg/3D-(oral-man;
TDL_o: 720 mg/Kg/48D unreported-woman
LD₅₀: 6800 mg/Kg oral/rats
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LD₅₀: 1800 mg/Kg subcutaneous-mouse;
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TDL_o: 1200 mg/Kg- oral-man;
LD₅₀: 8700 mg/Kg oral mouse;
LD₅₀: 1075 mg/Kg intraperitoneal-mouse
LD₅₀: 240 mg/Kg intravenous-mouse;
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Possible allergic reaction to dust if inhaled, ingested or in contact with skin. Adverse effects include blurred vision, eye pain, red 7green color blindness, or any loss of vision.

ACUTE: Eye, skin and/or respiratory tract irritation.

CHRONIC: Possible hypersensitization

PRECAUTION TO
CONSIDER:

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Emergency And First

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1. Inhalation: May cause irritation of respiratory tract. Avoid inhalation. Remove to fresh air.
2. Eyes: May cause irritation. Flush with copious quantities of water.
3. Skin: May cause irritation. Flush with copious amounts of water.
4. Ingestion: May cause irritation. Flush out mouth with water.

F/C SOLUTION CONTAINS:

OPADRY WHITE YS 1-7003: CAS # N/A

Unusual Fire and
Explosion Hazards: None

Effects of
Overexposure: None

Primary Route(s)
of Entry: Inhalation

Emergency and First
Aid Procedures: In case of accidental eye contact, flush eyes with water. If irritation exists, obtain medical attention.

Ventilation: Sufficient to prevent inhalation of dust.

Respiratory
Protection: An approved dust respirator should be worn.

Protective Clothing: Gloves and coveralls recommended to protect from dust.

Eye Protection: Safety goggles.

POLISHING SOLUTION CONTAINS:

POLYETHYLENE GLYCOL 400: CAS #25322-68-3

Signs and Symptoms of Overexposure:

1. Ingestion No evidence of adverse effects from available information.
2. Skin Absorption No evidence of adverse effects from available information.
3. Inhalation No evidence of adverse effects from available information.
4. Skin Contact No evidence of adverse effects from available information.
5. Eye Contact No evidence of adverse effects from available information.

Effects of Repeated
Over Exposure No evidence of adverse effects from available information.

Other Effects of
Over Exposure: This material may contribute to nuisance dusts and possibly to respirable dusts; avoid breathing dusts. overexposure to vapors generated at high temperatures may result in eye and respiratory tract irritation and the inhalation of harmful amounts of material.

Emergency and First Aid Procedures

1. Ingestion No harmful effects expected.
2. Skin Wash with soap and water.
3. Inhalation No emergency care anticipated.
4. Eyes Flush with water.