



**SDS: Ethambutol Hydrochloride Tablets USP,  
100 mg and 400 mg**

**SAFETY DATA SHEET**

**1. Identification**

**Product Identifier:** Ethambutol Hydrochloride Tablets USP,  
100 mg and 400 mg

**Synonyms:** Ethambutol dihydrochloride

**National Drug Code (NDC):** 61748-011-01  
61748-014-01

**Recommended Use:** Pharmaceutical.

**Company:** Akorn, Inc.  
1925 West Field Court, Suite 300  
Lake Forest, Illinois 60045

**Contact Telephone:** 1-800-932-5676

**E mail:** customer.service@akorn.com

**Emergency Phone Number:** CHEMTREC 1-800-424-9300 (U.S. and Canada)

**2. Hazard(s) Identification**

**Physical Hazards:** Not classifiable.  
**Health Hazards:** Not classifiable.  
**Symbol(s):** None.  
**Signal Word:** None.  
**Hazard Statement(s):** None.  
**Precautionary Statement(s):** None.  
**Hazards Not Otherwise Classified:** Not classifiable.

**Supplementary Information:** While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

**3. Composition/Information on Ingredients**

<b>Chemical Name</b>	<b>CAS Number</b>	<b>Synonyms</b>	<b>Chemical Formula</b>	<b>Molecular Weight</b>	<b>Percentage</b>
1-Butanol, 2,2'-(1,2-ethanediylidimino)bis-, dihydrochloride, [S-(R*,R*)]-	1070-11-7	Ethambutol dihydrochloride	C <sub>10</sub> H <sub>24</sub> N <sub>2</sub> O <sub>2</sub> •2ClH	277.23	10% and 40%

\*The formula also contains Colloidal Silicon Dioxide, Corn Starch, Croscarmellose Sodium, Docusate Sodium, Lactose Monohydrate, Magnesium Stearate, Polyvinylpyrrolidone, Stearic Acid, and Sugar. Film coating and polishing contains: Hydroxypropyl Methylcellulose, Polyethylene Glycol, Polysorbate 80, and Titanium Dioxide.

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**4. First Aid Measures**

**Ingestion:** If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

**Eye Contact:** Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Skin Contact:** Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Inhalation:** Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

**Protection of First-Aiders:** Use personal protective equipment (see section 8).

**WARNINGS:** Ethambutol Hydrochloride may produce decreases in visual acuity which appear to be due to optic neuritis. This effect may be related to dose and duration of treatment. This effect is generally reversible when administration of the drug is discontinued promptly. However, irreversible blindness has been reported.

**Signs and Symptoms:** Ethambutol Hydrochloride is contraindicated in patients who are known to be hypersensitive to this drug. It is also contraindicated in patients with known optic neuritis unless clinical judgment determines that it may be used. Ethambutol Hydrochloride is contraindicated in patients who are unable to appreciate and report visual side effects or changes in vision (e.g., young children, unconscious patients).

**Medical Conditions Aggravated  
by Exposure:** Not determined.



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**Notes to Physician:** Treat supportively and symptomatically.

**5. Firefighting Measures**

**Suitable Extinguishing Media:** Use extinguishing media for type of surrounding fire.

**Unsuitable Extinguishing Media:** Not determined.

**Specific Hazards Arising from the Chemical:**

**Hazardous Combustion Products:** Hazardous combustion or decomposition products are expected when the product is exposed to fire.

**Other Specific Hazards:** Closed containers may explode from the heat of fire.

**Special Protective Equipment/  
Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

**6. Accidental Release Measures**

**Personal Precautions:** Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

**Personal Protective Equipment:** For personal protection see section 8.

**Methods for Cleaning Up:** Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

**Environmental Precautions:** Contain material and prevent release to basements, confined spaces, waterways or soil.

**Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

**7. Handling and Storage**

**Precautions for Safe Handling:** Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage,  
Including Any Incompatibilities:** Store according to label and/or product insert information. Protect from light and moisture. Store away from oxidizers, acids, and bases.

**Specific End Use:** Pharmaceuticals.

**8. Exposure Controls/Personal Protection**

**Occupational Exposure Guidelines:**

<b>Common or Chemical Name</b>	<b>Employee Exposure Limits</b>
Ethambutol Hydrochloride	No data available.

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<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures.
<b>Respiratory Protection:</b>	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
<b>Eyes Protection:</b>	Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
<b>Hand Protection:</b>	Chemically compatible gloves are recommended. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
<b>Skin Protection:</b>	Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

### 9. Physical and Chemical Properties

<b>Physical State/Color:</b>	White to off-white round tablet.
<b>Odor:</b>	No data available.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	No data available.
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	No data available.
<b>Boiling Point:</b>	No data available.
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	No data available.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	No data available.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

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**10. Stability and Reactivity**

**Reactivity:** No data available.

**Chemical Stability:** Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** No data available.

**Conditions to Avoid (e.g., static discharge, shock, or vibration):** No data available.

**Incompatible Materials:** Oxidizers, acids, bases.

**Hazardous Decomposition Products:** No data available.

**11. Toxicological Information**

**Information on the Likely Routes of Exposure:**

**Inhalation:** May be harmful if inhaled. May cause respiratory tract irritation.

**Ingestion:** May be harmful if swallowed.

**Skin Contact:** May be harmful if absorbed through the skin. May cause irritation.

**Eye Contact:** May cause eye irritation.

**Symptoms Related to the Physical, Chemical and Toxicological Characteristics:** See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

**Delayed and Immediate Effects of Exposure:** No data available.

**Acute Toxicity:**

Compound	Species	Route	Test Type	Dose
Ethambutol Hydrochloride	Rat	Oral	LD <sub>50</sub>	6,800 mg/kg
Ethambutol Hydrochloride	Mouse	Oral	LD <sub>50</sub>	8,900 mg/kg

**Acute Toxicity – Dermal:** No data available.

**Acute Toxicity – Inhalation:** No data available.

**Corrosivity:** No data available.

**Dermal Irritation:** No data available.

**Eye Irritation:** No data available.

**Sensitization:** No data available.

**Toxicokinetics/Metabolism:** No data available.

**Target Organ Effects:** No data available.

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**Reproductive Effects:** The effects of combinations of Ethambutol Hydrochloride with other antituberculous drugs on the fetus is not known. While administration of this drug to pregnant human patients has produced no detectable effect upon the fetus, the possible teratogenic potential in women capable of bearing children should be weighed carefully against the benefits of therapy. There are published reports of five women who received the drug during pregnancy without apparent adverse effect upon the fetus.

Ethambutol is not recommended for use in children under thirteen years of age since safe conditions for use have not been established.

**Carcinogenicity:** No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

**Mutagenicity:** No data available.

**Aspiration Hazard:** No data available.

### 12. Ecological Information

#### Ecotoxicity

**Aquatic:** No data available.

**Terrestrial:** No data available.

**Persistence and Degradability:** No data available.

**Bioaccumulative Potential:** No data available.

**Mobility in Soil:** No data available.

**Mobility in Environment:** No data available.

**Other Adverse Effects:** No data available.

### 13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

### 14. Transport Information

**UN Number:** Not applicable.

**UN Proper Shipping Name:** Not applicable.

**Transport Hazard Class(es):** Not applicable.

**Packing Group:** Not applicable.

**Department of Transportation:** Not regulated as a hazardous material.

**International Air Transport Association (IATA):** Not regulated as a dangerous good.



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**International Maritime Dangerous Good (IMDG):** Not regulated as a dangerous good.

### 15. Regulatory Information

#### US Federal Regulations:

**Toxic Substance Control Act (TSCA):** This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.

**CERCLA Hazardous Substance and Reportable Quantity:** Not listed.

**SARA 313:** Not listed.  
**SARA 302:** Not listed.

#### State Regulations

**Massachusetts:** Not listed.  
**New Jersey:** Not listed.  
**Pennsylvania:** Not listed.  
**California Proposition 65:** Not listed.

### 16. Other Information

**Revision Date:** 08/24/2015

**Revision Number:** 0

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