Safety Data Sheet

Myambutol®
Ethambutol Hydrochloride Tablets, USP

Section 1: Chemical Product and Company Identification

Product Name: Ethambutol Hydrochloride Tablets, USP
Chemical Name(s): 1-Butanol, 2, 2'-(1, 2-ethanediyldiimino)bis-, dihydrchlrodie, [S-(R*,R*)]-
Synonym: Ethambutol diydrochloride, Myambutol
CAS Number: 1070-11-7
RTECS #: EL3854000
Trade Name: Ethambutol Hydrochloride Tablets, USP
Chemical Formula: $C_{10}H_{24}N_2O_2 \cdot 2HCl$

Contact Information:
X-GEN Pharmaceuticals, Inc.
PO Box 445, Big Flats, NY 14814
Technical Assistance: 607-562-2700
Online Assistance: www.x-gen.us

Emergency phone number:
National Poison Control
1-800-222-1222

**For information regarding recommended uses and restrictions on usage refer to the product package insert.

Section 2: Hazard Identification

Hazard pictograms (GHS-US):

Potential Acute Health Effects: Possible eye, skin, gastrointestinal, and/or respiratory tract irritation.

Potential Chronic Health Effects: Possible hyper-sensitization, possible ocular damage

Carcinogenic Effects: Not available

Mutagenic Effects: Micronucleus chromosome aberration test result: Positive
S. typhimurium Ames assay result: Negative

Teratogenic Effects: This product has been used in humans throughout pregnancy and no adverse fetal effects have been reported.

Developmental Toxicity: Studies in animals given high doses have shown that this product can cause a low incidence of minor developmental abnormalities.

Adverse effects: Adverse effects may include chills; painful or swollen joints, especially big toe, ankle, or knee, with tense, hot skin over affected joints; confusion; disorientation; headache; abdominal pain; nausea; vomiting; and loss of appetite. Blurred vision, eye pain, red-green color blindness, or any loss of vision may indicate serious ocular damage. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Section 3: Composition and Information on Ingredients

Principle Components:

Name	CAS #	% by Weight
Gelatin	9000-70-8	1.5%
Ethambutol	74-55-5	66.8%
Magnesium Stearate	557-04-0	0.9%
Sorbitol	50-70-4	4.2%
Stearic Acid	57-11-4	0.9%
Sucrose	57-50-1	22.2%
OPA Dry White	Not assigned	2.6%
Mineral Oil	8042-47-5	0.9%

Section 4: First Aid Measures

General: Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposure. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Obtain medical attention.

Inhalation: Move to fresh air. Material may be absorbed into the lungs. Seek medical attention immediately.

Skin contact: Flush with copious amounts of water. After using and removing gloves, wash hands and other exposed skin thoroughly. Seek medical attention immediately.

Eye contact: Avoid eye contact. Flush with copious quantities of water. Seek medical attention immediately.

Ingestion: Flush out mouth with water. If ingestion of large amount does occur, call a poison control center immediately. Seek medical attention immediately.

Notes to physician: Seek product package insert for complete information.

Overdose Treatment: Treatment should be symptomatic and supportive. Ethambutol hydrochloride is removed by hemodialysis and peritoneal dialysis.

Section 5: Fire Fighting Measures

Flammability of the product: This product is assumed to be combustible at high temperatures

Combustion Products: Emits toxic fumes of nitric oxides and hydrochloride.

Unusual Fire and Explosion Hazards: Product is not expected to present a fire hazard.

Extinguishing Media and Instruction:
Small fire: Use DRY chemical powder. **Large fire:** Use water spray, fog or foam. May use type ABC multi-purpose extinguisher. DO NOT use water jet.

Protective equipment & precautions for firefighters: As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus and protective clothing.

Special remarks on fire hazard: Not available

Special remarks on explosion hazard: Not available

Section 6: Accidental Release Measures

Release to land:
Small Spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Clean equipment and work surfaces with suitable detergent or solvent after use. Finish cleaning by spreading water on the contaminated surface and dispose of according to local, state, and federal regulations.
Large Spill: Use a shovel to put the material into a convenient waste disposal container. Sweep up or vacuum with caution to avoid generation of dust during clean-up. Finish cleaning by spreading water on the contaminated surface and clean surface thoroughly to remove residual contamination. Avoid generation of dust during clean-up. Collect in suitable container for disposal. For proper waste disposal, see section 13 of the SDS.

Release to air: If dust is generated, wear a disposable dust respirator (N95), and reduce exposures by ventilating area. Clean up spill immediately.

Release to water: Refer to local water authority; drain disposal is not recommended.

Protective equipment: Keep unnecessary personnel away. Wear approved respiratory protection, chemically compatible gloves and protective clothing.

Section 7: Handling and Storage

Handling: As a general rule, when handling Ethambutol Hydrochloride Tablets USP, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Use only in accordance with directions.

Storage: Keep container tightly closed. Keep container in a cool, dry, well ventilated area (see USP CRT storage conditions). Protect from light and store at controlled room temperature 20° - 25°C (68° - 77°F). Refer to label instructions to ensure product integrity.

Incompatibilities: Not available

Section 8: Exposure Controls / Personal Protection

Engineering controls: Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing or other dust-generating procedures.

Personal protection: 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 is preferred. Maintain eyewash facilities in the work area. Chemically compatible gloves. Use handling practices that minimize direct hand or skin contact.

Respiratory protection: Under normal use, respirators are not required. If dusts are generated, use a disposable mask (N95). Persons wearing respirators should be fit tested and approved for respirator use, under OSHA Respiratory Protection Standard 29 CFR 1910.134.

Exposure limit: Not available

Section 9: Physical and Chemical Properties

Physical appearance: Crystalline powder
Color: White
Molecular Weight: 277.23 g/mole
Taste: Not available
Odor: Odorless
Odor Threshold: Not available
pH: 3.7 – 4.0 (2% solution in water)
Melting Point: Not available
Freezing Point: Not available
Boiling Point: Not available
Flash Point: Not available
Evaporation rate: Not available
Flammability: Not available
Upper Flammable Limit: Not available
Lower Flammable Limit: Not available
Vapor Pressure: 0.0000002 kPa at 25°C

Vapor Density: Not available
Relative density: Not available
Partition Coefficient: Not available
Auto-Ignition Temperature: Not available
Decomposition Temperature: Not available
Viscosity: Not available

Dispersion Properties: Partially dispersed in methanol
Solubility: Freely soluble in water. Soluble in ethanol and in methanol; slightly soluble in ether and in chloroform.

Section 10: Stability and Reactivity

Reactivity: Stable. No reactivity hazards known

Chemical stability: The product is stable under normal conditions of use.

Possibility of hazardous reaction: No dangerous reaction known under conditions of normal use

Conditions to avoid: Not available

Incompatible materials: Not available

Hazardous decomposition products: Chloride and nitrogen oxides. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

Corrosivity: Non-corrosive in presence of glass.

Polymerization: Not available

Section 11: Toxicological Information

Routes of exposure: Ingestion, inhalation, skin and eye contact.

Symptoms:
Short term: Blurred vision, eye pain, vision loss, chills, joint pain, confusion, disorientation, headache, abdominal pain, nausea, vomiting, loss of appetite, dizziness, hallucinations, fever and itching. **Long term:** Optic neuritis.

Reproductive toxicity: Not available

FDA Pregnancy Category: C

Toxicity to animals:
Oral Rat: LD50: 6800 mg/kg **Oral Mouse:** LD50: 8900 mg/kg

Measures of toxicity: Not available

Additional reproductive health and toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) and/or Registry of Toxic Effects of Chemical Substance (RTECS).

Section 12: Ecological Information

Ecotoxicity: Not available

Bioaccumulation potential: Not available

Products of biodegradation: Not available

Toxicity of the products of biodegradation: Not available

Section 13: Disposal Information

Waste classification: Not available

Waste from residues/unused products: Empty containers or liners may retain some product residue. Dispose of waste in accordance with all applicable federal, state and local laws.

Waste Disposal: Dispose of waste in accordance with all applicable federal, state and local laws.

Section 14: Transport Information

DOT Classification: Not a DOT controlled Material (United States).
UN Number: Not available
UN Shipping name: Not available
Transport hazard class: Not available
Packing Group: Not available
Environmental hazard: Not available
Transport in bulk: Not available
Special precautions needed with transport: Not available

Section 15: Regulatory Information

Federal and State Regulations: Not available

Other Regulations: Not available

Other Classifications:
WHMIS (Canada): Not available

DSCL (EEC): Not available

HMIS (U.S.A.):
Health Hazard: 2
Fire Hazard: 1
Reactivity: 0
Personal Protection: E

National Fire Protection Association (U.S.A.):
Health: 2
Flammability: 1
Reactivity: 0

Protective Equipment: Gloves. Lab coat. Safety glasses. Dust Respirator. Be sure to use an approved/certified respirator or equivalent.

Section 16: Other Information

References: Not available
Created: 1/30/2015
Last Updated: 3/27/2015
Prepared & Approved by: X-GEN Pharmaceuticals, Inc., Safety Committee

The above information is believed to be accurate and represents the best information currently available to us. The use of this product should be through or under the direction of a physician. This SDS does not address therapeutic use of this material. X-GEN Pharmaceuticals, Inc. makes no warranties, express or implied with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information. In no event should X-GEN Pharmaceuticals be liable for any claim, loss, or damage of any third party, even if X-GEN Pharmaceuticals has been advised of the possibility of such damages to occur.