

MATERIAL SAFETY DATA SHEET

Boehringer Ingelheim Pharmaceuticals, Inc.

Albuterol Sulfate[®]

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DATE ISSUED 11/10/05

EMERGENCY TELEPHONE NUMBER
CHEMTREC - 24 hours
1-800-424-9300

1. SUBSTANCE IDENTIFICATION

CHEMICAL NAME:

Albuterol sulfate: (1,3-benzenedimethanol, α' -[[[(1,1-dimethyl-ethyl)amino] methyl]-4-hydroxy, sulfate (2:1)(salt),(±)

CAS TYPE: 1

GENERIC NAME: Albuterol sulfate

MOLECULAR FORMULA: $(C_{13}H_{21}NO_3)_2 \cdot H_2SO_4$

TRADEMARK:

MOLECULAR WEIGHT: 576.7

CHEMICAL FAMILY: Bronchodilator

CAS NUMBER: 51022-70-9

SYNONYMS: Salbumol, Salbutamol, Salbulin, Albuterol hemisulfate, salbumol hemisulfate, Salbutamol hemisulfate, and Salbulin hemisulfate

2. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW

White crystalline powder.

Warning! Dusts may be harmful if inhaled. May cause eye and skin irritation, nervousness, tremor, headache, tachycardia and palpitations. May cause hypersensitization.

Danger! Dusts may form explosive clouds. Use extinguishing media suitable for surrounding fire.

ROUTES OF ENTRY: Inhalation, Ingestion, Skin and Eye contact.

Acute Exposure: Eye, skin and/or respiratory irritation.

Signs and Symptoms of Overexposure: Nervousness, tremor, headache, tachycardia and palpitations muscle cramps, insomnia, nausea, weakness, dizziness and irritability. Can cause paradoxical bronchospasms.

Chronic Effects: May cause effects described above and possible hypersensitization.

Medical Conditions Aggravated by Exposure: hyperthyroidism, myocardial insufficiency, arrhythmia, susceptibility to QT-interval prolongation, hypertension, and diabetes mellitus.

Carcinogenicity: In a 2 year rat study there was a significant dose-related increase in the incidence of benign tumors. The relevance of these findings to humans is not known. An 18 month study in mice and a lifelong study in hamsters revealed no evidence of tumorigenicity. There was no evidence of mutagenesis. Reproduction studies in rats revealed no evidence of impaired fertility. It was found to be teratogenic in mice. It is listed as a Pregnancy Category C.

3. COMPONENTS PER UNIT DOSE

MATERIAL	EXPOSURE LIMITS
Active Ingredient: Albuterol Sulfate	8 ug/m3**

**BIEL is the BI Exposure Control Level. When lower governmentally imposed occupational exposure limits exist, such limits should take precedence.

4. EMERGENCY FIRST AID PROCEDURES

INHALATION: Remove from area to fresh air. Seek medical attention if respiratory irritation develops or if breathing becomes difficult.

INGESTION: Rinse out mouth then give 3-4 glasses of water, but **DO NOT** induce vomiting. If vomiting occurs, give fluids again. Get medical attention to determine whether vomiting or evacuation of stomach is necessary. Do not give anything by mouth to an unconscious or convulsing person.

SKIN CONTACT: Remove contaminated clothing. Wash affected areas with plenty of water, and soap if available, for several minutes. Seek medical attention if irritation or rash develops and persists.

INJECTION: In case of accidental injection, wash and thoroughly disinfect, get medical attention.

EYE CONTACT: Flush eyes with large amounts of running water for 15 minutes. Get immediate medical attention.

EYE CONTACT: Flush eyes with large amounts of running water for at least 15 minutes. Get immediate medical attention.

5. FIRE AND EXPLOSION HAZARD DATA

Flash Point	Flammable Limits	
	Upper	Lower
N/A	N/A	N/A

FIRE EXTINGUISHING MEDIA: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

SPECIAL FIRE FIGHTING PROCEDURES: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use water spray to keep fire-exposed containers cool and protect against all exposures.

UNUSUAL FIRE AND EXPLOSION HAZARDS: As with all organic powders, this material presents a dust explosion hazard. It can burn in a fire, producing acrid flammable fumes including acid gases, oxides of carbon, nitrogen and sulfur.

6. SPILL AND ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN THE EVENT OF A SPILL: Wear approved respirator and chemically compatible gloves if containers have been compromised. Vacuum or sweep up spillage. Avoid creating dust. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before reuse. Ventilate area; wash down spill site and control wash water. Do not allow product to reach sewage system or waterway.

7. PRECAUTIONS FOR SAFE HANDLING AND USE

HANDLING AND STORAGE PRECAUTIONS: Avoid contact with eyes, skin or clothing. Avoid generating or breathing dust. Store in tight, light-resistant containers away from foodstuffs.

OTHER PRECAUTIONS: Wash thoroughly after handling material. Wear fresh clothing daily. Wash contaminated clothing before reuse.

8. CONTROL MEASURES

ENGINEERING CONTROLS: Minimize dust generation. Use closed equipment where possible. Use spot ventilation to remove dust from the work area. If operations generate dusts, use explosion-proof ventilation equipment to control airborne levels. Use appropriate respiratory protection based on an industrial hygiene survey.)

RESPIRATORY PROTECTION: The need for respiratory protection should be determined by an industrial hygiene survey. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection: Safety glasses with side shields or goggles	Hand Protection: Chemical protective gloves
Protective Clothing: Laboratory coats or protective work clothing	Other: Eye wash & safety shower

WORK/HYGIENIC PRACTICES: Do not permit eating, drinking or smoking near this material. Wash thoroughly after handling material, before eating and at the end of work.

9. PHYSICAL/CHEMICAL CHARACTERISTICS

APPEARANCE AND ODOR: White to off-white crystalline powders.

Boiling Point: N/A

Vapor Pressure (mmHg): N/A

Vapor Density: N/A

Water Solubility: Soluble

Specific Gravity: N/A

Melting Point: 446-455 oF (230-235 oC)

Evaporation Rate: N/A

pH: N/A

10. REACTIVITY DATA

STABILITY: Stable.

CONDITIONS TO AVOID: Heat, flames, sparks, or other sources of ignition. Avoid contact with oxidizing materials.

INCOMPATIBLE MATERIALS: Oxidizing materials.

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: When heated to decomposition, material emits oxides of carbon, nitrogen and sulfur.

HAZARDOUS POLYMERIZATION: Will not occur.

11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

Rat LD50 - ROUTE: Intraperitoneal; DOSE: 295 mg/kg TOXIC EFFECTS: *Sense Organs and Special Senses (Nose, Eye, Ear, and Taste)* – Lacrimation. *Lung, Thorax, or Respiration* - Respiratory depression

LD50 - ROUTE: Intravenous; DOSE: 59100 ug/kg TOXIC EFFECTS: *Behavioral* - Altered sleep time (including change in righting reflex). *Lung, Thorax, or Respiration* - Respiratory depression

LD50 - ROUTE: Oral; DOSE: >2500 mg/kg

LD50 - ROUTE: Subcutaneous; DOSE: >2500 mg/kg TOXIC EFFECTS: *Lung, Thorax, or Respiration* - Other changes. *Skin and Appendages* - Hair

Mouse LD50 - ROUTE: Intraperitoneal; DOSE: 200 mg/kg

LD50 - ROUTE: Intravenous; DOSE: 48700 ug/kg TOXIC EFFECTS: *Behavioral* - Altered sleep time (including change in righting reflex). *Lung, Thorax, or Respiration* - Respiratory depression

LD50 - ROUTE: Oral; DOSE: 1950 mg/kg

LD50 - ROUTE: Subcutaneous; DOSE: 737 mg/kg TOXIC EFFECTS: *Sense Organs and Special Senses (Nose, Eye, Ear, and Taste)* – Lacrimation. *Behavioral* - Convulsions or effect on seizure threshold

REPRODUCTIVE EFFECTS

Rat TDLo - ROUTE: Oral; DOSE: 1 gm/kg; DURATION: female 1D prior to mating TOXIC EFFECTS: *Maternal Effects* - Uterus, cervix, vagina

TUMORIGENIC EFFECTS

Rat TDLo - ROUTE: Oral; DOSE: 13300 mg/kg/95W continuous TOXIC EFFECTS: *Tumorigenic* - Equivocal tumorigenic agent by RTECS criteria. *Tumorigenic Effects* - Ovarian tumors. *Tumorigenic* - Tumor types after systemic administration not seen spontaneously

OTHER MULTIPLE DOSE TOXICITY DATA

Rat TDLo - ROUTE: Oral; DOSE: 4650 mg/kg/31D intermittent TOXIC EFFECTS: *Cardiac* - Changes in heart weight. *Lung, Thorax, or Respiration* - Changes in Lung Weight. *Others* - Death

TERATOGENICITY: - **PREGNANCY CATEGORY C: Risk to human fetuses cannot be ruled out.** Human studies are lacking, however, animal studies are positive for fetal damage. Consult physician before using if you suspect you are pregnant or nursing.

Albuterol has been shown to be teratogenic in mice when given subcutaneously in doses corresponding to 0.4 times the maximum human oral dose. There are no adequate and well-controlled studies in pregnant women.

A reproduction study in CD-1 mice given albuterol subcutaneously showed cleft palate formation in 5 of 111 (4.5%) fetuses at 0.25 mg/kg (equivalent to the maximum recommended human daily inhalation dose on a mg/m² basis) and in 10 of 108 (9.3%) fetuses at 2.5 mg/kg (approximately 10 times the recommended human daily inhalation dose on mg/m² basis). None was observed at 0.025 mg/kg (approximately one-tenth the maximum recommended human daily inhalation dose). Cleft palate also occurred in 22 of 72 (30.5%) fetuses treated with 2.5 mg/kg isoproterenol (positive control). A reproduction study with oral albuterol in Stride Dutch rabbits revealed cranioschisis in 7 of 19 (37%) fetuses t 50 mg/kg (approximately 1000 times the maximum recommended human daily inhalation does on a mg/m² basis).

12. ECOLOGICAL INFORMATION

None Available

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL CONSIDERATIONS: Dispose of in accordance with local, state and federal regulations. Recommended method is incineration.

14. TRANSPORT INFORMATION

DOT Proper Shipping Name:	N/A	Packing Group:	N/A
Hazard Class:	N/A	Identification Number:	N/A

15. REGULATORY INFORMATION

This material is **not** listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

16. OTHER INFORMATION

ABBREVIATIONS:

BIPI - Boehringer Ingelheim Pharmaceuticals, Inc.
N/A - Not Applicable
N/E - None established
N/D – Not determined

PREPARATION INFORMATION

Prepared by: Environmental Affairs & Safety.

Date Revised: 11/10/05
Replaces: 10/00

REVISION INFORMATION: Updated and reformatted Sections 2 & 3.

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REFERENCES

1. Physicians Desk Reference, 1974-2000 Edition
2. Martindale – The Complete Drug Reference, 1982-2000 Edition
3. Drugdex – Drug Evaluations