

# MATERIAL SAFETY DATA SHEET

## **Ibutilide Fumarate Injection**

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### **SECTION 1: PRODUCT IDENTIFICATION**

PRODUCT NAME: Ibutilide Fumarate Injection  
COMMON NAME: N/A  
CHEMICAL NAME: N-[4-[4-(Ethylheptylamino)-1-hydroxybutyl]phenyl]methane-sulfonamide Hemifumarate  
SYNONYMS: (±)-4'-(4-(Ethylheptylamino)-1-hydroxybutyl)methane-sulfoanilide (E)-2-butenedioate (2:1)  
(±)-4'-(4-(Ethylheptylamino)-1-hydroxybutyl)methane-sulfoanilide fumarate (2:1) (salt)  
CHEMICAL FORMULA:  $(C_{20}H_{36}N_2O_3S)_2C_4H_4O_4$   
CHEMICAL FAMILY: Sulfonamide

### **SECTION 2: COMPOSITION AND INGREDIENTS**

CHEMICAL NAME	CAS#	OSHA PEL	ACGIH TLV
Ibutilide Fumarate	122647-32-9	NE	NE
Sodium Acetate	127-09-3	NE	NE
Sodium Chloride	7647-14-5	NE	NE
Hydrochloric Acid	7647-01-0	5 ppm	2 ppm
Water for Injection	N/A	NE	NE

NE = Not Established, Specific amounts are considered proprietary information.  
Other ingredients are not listed as they are less than 1%.

### **SECTION 3: HAZARDS IDENTIFICATION**

Emergency Overview: Physical appearance and odor: Clear liquid.

Potential Health Effects: Adverse cardiovascular effects associated with therapeutic ibutilide include heart block, hypotension, hypertension and bradycardia. Like other antiarrhythmics, it can cause arrhythmias, including torsade de pointes. Other adverse effects include nausea and vomiting. Acute overdose in animals results in CNS toxicity, notable CNS depression, rapid gasping breathing and convulsions.

Acute Eye: No information available

Acute Skin: Not a known irritant.

Acute Inhalation: No information available

Acute Ingestion: No information available

Reproductive Hazard: Pregnancy category C. Was shown to be teratogenic and embryocidal in reproductive studies performed on rats.

#### SECTION 4: FIRST AID MEASURES

Skin Exposure: Avoid direct contact. Immediately flush with lukewarm, gently flowing water for at least 5 minutes or until the chemical is removed. Remove any contaminated clothing and shoes while flushing. Obtain medical advice immediately. Completely decontaminate clothing, shoes, and leather goods before reuse or discard.

Eye Exposure: Avoid direct contact. Immediately flush the contaminated eye with lukewarm, gently flowing water for 5 minutes, or until clear, while holding the eyelid open. Obtain medical advice immediately.

Inhalation: Not likely to occur.

Ingestion: If ingested, wash out the mouth with water. Do not induce vomiting. Have person drink 1-2 cups of water to dilute material in the stomach. If vomiting occurs naturally, rinse mouth and repeat administration of water. Do not give anything by mouth to an unconscious person. Seek immediate medical attention.

#### SECTION 5: FIRE / EXPLOSION HAZARDS & FIRE-FIGHTING MEASURES

Flash Point: NE                      Autoignition Temperature: NE

Flammable Limits (in air by volume, %):    Lower: NE    Upper: NE

Fire Extinguishing Equipment: Extinguishing media appropriate for surrounding fire and materials.

Unusual Fire and Explosion Hazards: No information available.

Special Fire Fighting Procedures: In the event of a fire, wear full protective clothing and breathing apparatus.

#### SECTION 6: ACCIDENTAL RELEASE MEASURES

Spill and Leak Response: Prevent unauthorized access to the spillage area. Wear appropriate protective gear. Contain the spill and dispose of appropriately. Wash spill site thoroughly.

Dispose of materials according to the applicable Federal, State, or local regulations.

#### SECTION 7: HANDLING AND STORAGE

Handling: Wear appropriate protective gear.

Storage: Keep in a tightly closed container.

#### SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: Ensure adequate ventilation.

Respiratory Protection:

Wear appropriate breathing apparatus as needed.

Eye / Face Protection:

Use chemical safety goggles and/or safety glasses where contact is possible. Maintain eye wash fountain and quick-drench facilities in work area.

Skin Protection:

Wear impervious protective clothing, including gloves, apron or coveralls, as appropriate, to prevent skin contact.

### SECTION 9: PHYSICAL / CHEMICAL PROPERTIES

Boiling Point:	ND	Vapor Pressure:	ND
Melting/Freezing Point:	ND	pH:	ND
Water Solubility:	Soluble	Water Reactive:	No
Specific Gravity (Water =1):	ND	Vapor Density:	ND
Appearance/Odor:	Clear liquid		

ND = No Data

### SECTION 10: STABILITY AND REACTIVITY

Stability:	Stable under labeled storage conditions.
Incompatible Materials:	No information available.
Hazardous Polymerization:	Unlikely to occur.
Conditions to Avoid:	High temperatures.

### SECTION 11: TOXICOLOGICAL INFORMATION

LD: >500mg/kg oral Rodent-rat  
 LD50: 94.20 mg/kg Intravenous Rodent-rat  
Chronic Toxicity: No information available.

### SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicological Information:

Degradation: No information available.  
 Accumulation: No information available.  
 Fish-Toxicity: No information available.

**SECTION 13: WASTE DISPOSAL**Waste Disposal Method:

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

Container Handling and Disposal:

Dispose of container and unused contents in accordance with federal, state, and local regulations.

**SECTION 14: TRANSPORTATION INFORMATION**

Not classified as hazardous for all modes of transport, no special transport requirements.

**SECTION 15: REGULATORY INFORMATION**

EEC Hazard Classification: Xn. Harmful

Risk Phrases: R22 Harmful if swallowed

Safety Phrases: S20/21 When using, do not eat, drink, or smoke

S36/37 Wear suitable protective clothing and gloves

S44 If you feel unwell, seek medical advice and show the label where possible

**SECTION 16: OTHER INFORMATION****DEFINITIONS OF ABBREVIATIONS USED:**

Pregnancy Category C: Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans. However, potential benefits may warrant the use of the agent in pregnant women despite the potential risks.

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