



Material Safety Data Sheet

Material Name: Ibutilide Fumarate Injection

*** Section 1 - Chemical Product and Company Identification ***

Manufacturer Information

Bioniche Pharma
272 E Deerpath Road
Suite 304
Lake Forest, IL 60045

Phone: 888-258-4199

Emergency # 888-875-1671

*** Section 2 - Hazards Identification ***

Emergency Overview

May cause eye, skin and respiratory tract irritation.

Potential Health Effects: Eyes

May cause eye irritation.

Potential Health Effects: Skin

May cause skin irritation.

Potential Health Effects: Ingestion

Not considered a likely route of exposure under normal product use. No adverse effects known if ingested.

Potential Health Effects: Inhalation

May cause respiratory tract irritation.

HMIS Ratings: Health: 1 Fire: 0 HMIS Reactivity 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard

*** Section 3 - Composition / Information on Ingredients ***

CAS #	Component
7732-18-5	Water
122647-32-9	Ibutilide fumarate
1310-73-2	Sodium hydroxide
7647-01-0	Hydrogen chloride
7647-14-5	Sodium chloride
6131-90-4	Acetate, sodium, trihydrate

*** Section 4 - First Aid Measures ***

First Aid: Eyes

Flush eye(s) immediately with plenty of water. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

First Aid: Skin

Rinse immediately with plenty of water for at least 15 minutes.

First Aid: Ingestion

If swallowed wash mouth with water provided person is conscious. Treat symptomatically and supportively. Get medical advice if adverse symptoms appear.

First Aid: Inhalation

Avoid breathing aerosols and dusts that may be generated by handling of the product. Remove the person from the exposed area to fresh air immediately. Get medical advice if adverse symptoms appear.

*** Section 5 - Fire Fighting Measures ***

General Fire Hazards

See Section 9 for Flammability Properties.

Thermal decomposition or combustion may generate toxic and hazardous fumes (COx, NOx, SOx).

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Hazardous Combustion Products

Thermal decomposition or combustion may generate toxic and hazardous fumes (COx, NOx, SOx) or compounds containing chlorine.

Extinguishing Media

Use dry powder, CO₂, water spray or regular foam.

Fire Fighting Equipment/Instructions

Firefighters should wear full protective gear.

NFPA Ratings: Health: 1 Fire: 0 Reactivity: 0

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

* * * Section 6 - Accidental Release Measures * * *

Containment Procedures

Do not let the product enter drainage system, surface and ground-water and soil.

Clean-Up Procedures

Soak up with inert absorbent material, and clean with plenty of water.

Evacuation Procedures

Isolate area. Keep unnecessary personnel away.

Special Procedures

Wear appropriate personal protective equipment.

* * * Section 7 - Handling and Storage * * *

Handling Procedures

Wear suitable protective clothing, gloves, eye/face protection and dust mask to avoid inhalation, contact and ingestion. Do not eat, drink or smoke in work areas.

Storage Procedures

Store at 20° to 25°C (68° to 77°F). Protect from freezing and light.

* * * Section 8 - Exposure Controls / Personal Protection * * *

A: Component Exposure Limits

Hydrogen chloride (7647-01-0)

ACGIH: 2 ppm Ceiling
OSHA: 5 ppm Ceiling; 7 mg/m³ Ceiling
NIOSH: 5 ppm Ceiling; 7 mg/m³ Ceiling

Sodium hydroxide (1310-73-2)

ACGIH: 2 mg/m³ Ceiling
OSHA: 2 mg/m³ Ceiling
NIOSH: 2 mg/m³ Ceiling

Engineering Controls

Ensure adequate ventilation, especially in confined areas.

PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment: Eyes/Face

Safety glasses with side-shields

Personal Protective Equipment: Skin

Use impervious gloves.

Personal Protective Equipment: Respiratory

Breathing apparatus only if aerosol or dust is formed.

Personal Protective Equipment: General

Eye wash fountain is recommended.

* * * Section 9 - Physical & Chemical Properties * * *

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Appearance:	Clear	Odor:	None
Physical State:	Liquid	pH:	4.6
Vapor Pressure:	ND	Vapor Density:	ND
Boiling Point:	ND	Melting Point:	NA
Solubility (H2O):	Slightly Soluble	Specific Gravity:	ND
Evaporation Rate:	ND	VOC:	ND
Octanol/H2O Coeff.:	ND	Flash Point:	ND
Flash Point Method:	ND	Upper Flammability Limit (UFL):	ND
Lower Flammability Limit (LFL):	ND	Burning Rate:	ND
Auto Ignition:	ND		

*** Section 10 - Chemical Stability & Reactivity Information ***

Chemical Stability

This is a stable material.

Chemical Stability: Conditions to Avoid

Avoid heat and exposure to UV light

Incompatibility

Strong oxidizing agents

Hazardous Decomposition

Thermal decomposition or combustion may include toxic and hazardous fumes of COx, SOx, NOx.

Possibility of Hazardous Reactions

Will not occur.

*** Section 11 - Toxicological Information ***

Acute Dose Effects

A: General Product Information

No information available for the product.

B: Component Analysis - LD50/LC50

Water (7732-18-5)

Oral LD50 Rat >90 mL/kg

Hydrogen chloride (7647-01-0)

Inhalation LC50 Rat 3124 ppm 1 h; Oral LD50 Rat 700 mg/kg; Dermal LD50 Rabbit >5010 mg/kg

Sodium chloride (7647-14-5)

Inhalation LC50 Rat >42 g/m³ 1 h; Oral LD50 Rat 3 g/kg; Dermal LD50 Rabbit >10 g/kg

Sodium hydroxide (1310-73-2)

Dermal LD50 Rabbit 1350 mg/kg

Carcinogenicity

A: General Product Information

No information available for the product.

B: Component Carcinogenicity

Hydrogen chloride (7647-01-0)

ACGIH: A4 - Not Classifiable as a Human Carcinogen

IARC: Monograph 54 [1992] (Group 3 (not classifiable))

*** Section 12 - Ecological Information ***

Ecotoxicity

A: General Product Information

No information available for the product.

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B: Component Analysis - Ecotoxicity - Aquatic Toxicity

Hydrogen chloride (7647-01-0)

Test & Species

	Conditions
96 Hr LC50 Gambusia affinis	282 mg/L [static]

Sodium chloride (7647-14-5)

Test & Species

	Conditions
96 Hr LC50 Lepomis macrochirus	5560-6080 mg/L [flow-through]
96 Hr LC50 Lepomis macrochirus	12946 mg/L [static]
96 Hr LC50 Pimephales promelas	6020-7070 mg/L [static]
96 Hr LC50 Pimephales promelas	7050 mg/L [semi- static]
96 Hr LC50 Pimephales promelas	6420-6700 mg/L [static]
96 Hr LC50 Oncorhynchus mykiss	4747-7824 mg/L [flow-through]
48 Hr EC50 Daphnia magna	1000 mg/L
48 Hr EC50 Daphnia magna	340.7 - 469.2 mg/L [Static]

Sodium hydroxide (1310-73-2)

Test & Species

	Conditions
96 Hr LC50 Oncorhynchus mykiss	45.4 mg/L [static]

*** Section 13 - Disposal Considerations ***

US EPA Waste Number & Descriptions

Component Waste Numbers

No EPA Waste Numbers are applicable for this product's components.

Disposal Instructions

All wastes must be handled in accordance with local, state and federal regulations.

See Section 7 for Handling Procedures. See Section 8 for Personal Protective Equipment recommendations.

*** Section 14 - Transportation Information ***

US DOT Information

Shipping Name: Not Regulated

*** Section 15 - Regulatory Information ***

US Federal Regulations

Component Analysis

This material contains one or more of the following chemicals required to be identified under SARA Section 302 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65) and/or CERCLA (40 CFR 302.4).

Hydrogen chloride (7647-01-0)

SARA 302: 500 lb TPQ (gas only)

SARA 313: 1.0 % de minimis concentration (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

CERCLA: 5000 lb final RQ; 2270 kg final RQ

Sodium hydroxide (1310-73-2)

CERCLA: 1000 lb final RQ; 454 kg final RQ

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State Regulations

Component Analysis - State

The following components appear on one or more of the following state hazardous substances lists:

Component	CAS	CA	MA	MN	NJ	PA	RI
Hydrogen chloride	7647-01-0	Yes	Yes	Yes	Yes	Yes	Yes
Sodium hydroxide	1310-73-2	Yes	Yes	Yes	Yes	Yes	Yes

Component Analysis - WHMIS IDL

The following components are identified under the Canadian Hazardous Products Act Ingredient Disclosure List:

Component	CAS #	Minimum Concentration
Hydrogen chloride	7647-01-0	1 %
Sodium hydroxide	1310-73-2	1 %

Additional Regulatory Information

Component Analysis - Inventory

Component	CAS #	TSCA	CAN	EEC
Water	7732-18-5	Yes	DSL	EINECS
Ibutilide fumarate	122647-32-9	No	No	No
Acetate, sodium, trihydrate	6131-90-4	No	No	No
Hydrogen chloride	7647-01-0	Yes	DSL	EINECS
Sodium chloride	7647-14-5	Yes	DSL	EINECS
Sodium hydroxide	1310-73-2	Yes	DSL	EINECS

*** Section 16 - Other Information ***

Other Information

The information herein is presented in good faith and believed to be accurate as of the effective date given. However, no warranty, expressed or implied, is given. It is the buyer's responsibility to ensure that its activities comply with Federal, State or provincial, and local laws.

Key/Legend

EPA = Environmental Protection Agency; TSCA = Toxic Substance Control Act; ACGIH = American Conference of Governmental Industrial Hygienists; IARC = International Agency for Research on Cancer; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration., NJTSR = New Jersey Trade Secret Registry.

End of Sheet