



## Material Safety Data Sheet

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

Emergency Telephone Number  
 (888) 875-1671

Telephone Number for Information  
 (888) 258-4199

MSDS Prepared: May 22, 2007

### Section I – IDENTITY

**Common/Trade Name:** Esmolol Injection, 10 mg/mL, 10 mL vial

**Chemical Names:** 4-(2-Hydroxy-3-((1-methylethyl)amino)propoxy) benzenepropanoic acid, methyl ester, hydrochloride

**Synonyms:** Esmolol Hydrochloride, ASL 8052, Brevibloc®\_ Injection

### Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Esmolol Hydrochloride	1	81161-17-3	NONE	NONE	NONE KNOWN
Sodium Acetate Trihydrate	0.28	6131-90-4	NONE	NONE	NONE KNOWN
Glacial Acetic Acid	0.05	64-19-7	10 PPM	10 PPM	NONE KNOWN
Water for Injection	97	7732-18-5	NONE	NONE	NONE KNOWN

Sodium Hydroxide and Hydrochloric Acid are used to adjust the pH of the product

Esmolol Hydrochloride is a sterile parenteral liquid drug provided in a Type I Glass Vial.

### Section III - HEALTH HAZARD DATA

**Routes of Entry:** Esmolol may be absorbed via contact with skin or eyes; inhalation of aerosols or accidentally ingested. Under normal use with supervision of a physician, Esmolol presents little hazard.

**Health Hazard (Acute & Chronic):** Esmolol is a drug generally used as antiarrhythmic agent and/or betablocker. Minimal adverse health effect should occur from routine use under care of a physician with this product. Acute signs and symptoms of exposure include changes in blood pressure, irregular heartbeat, drowsiness and possible loss of consciousness. Esmolol may also cause nausea, vomiting, anorexia, headache, dizziness and constipation. Chronic effects are not determined.

**Medical Conditions Generally Aggravated by Exposure:** Esmolol may aggravate persons with sinus bradycardia, heart block greater than first degree, cardiogenic shock or overt heart failure. Persons with bronchospastic diseases should not receive beta-blockers. See package insert for additional warnings.

**Carcinogenicity: NTP? NO IARC Monographs? NONE OSHA Regulated? NO**

#### **Section IV - FIRST AID MEASURES**

**Eye Exposure:** Flush eyes with large volumes of water for 15 or more minutes. Get medical attention if irritation persist.

**Skin Exposure:** Remove contaminated clothing, wash skin with water and soap for 15 minutes. Get medical attention if irritation persist.

**Ingestion:** If ingestion occurs, flush mouth with water and seek medical attention immediately. Do not induce vomiting. Never give anything by mouth to an unconscious person.

**Injection:** In cases of accidental injection, wash and disinfect area, get medical attention.

**Inhalation:** If difficulty with breathing, remove from exposure and administer oxygen. Seek attention of a physician immediately. When appropriate and trained in CPR, provide artificial respiration.

#### **Section V - FIRE AND EXPLOSION HAZARD DATA**

**Flash Point (Method Used):** Not Determined **LEL:** Not Determined **UEL:** Not Determined  
**Flammable Limits:** Not Determined

**Extinguishing Media:** Use water or an ABC multi-purpose extinguisher.

**Special Fire Fighting Procedures:** As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is aqueous alcohol based keep containers cool with water.

**Unusual Fire/Explosion Hazards:** Heat of the fire could cause vials to burst.

#### **Section VI - ACCIDENTAL RELEASE INFORMATION**

**Release to Land:** Absorb Esmolol with absorbent materials and dispose according to local, state, and federal guidelines.

**Release to Air:** If aerosolized, reduce exposures by ventilating area; clean up spill immediately to prevent evaporation.

**Release to Water:** Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

#### **Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE**

**Steps to be taken in case material is released or spilled:** See Section VI above.

Wear latex or nitrile gloves and safety glasses when cleaning spills. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated.

**Waste Disposal Method:** Incineration in an approved incinerator is recommended. Refer to local, state, and federal rules.

**Precautions to be taken in handling and storing:** Store at approximately 25°C range (15-30 °C). Follow instructions provided in packaging.

**Other Precautions:** None Known

## **Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT**

**Respiratory Protection:** Under normal use, respirators are not required. If aerosols are generated, a disposable dust/mist respirator (N95) may be used. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

**Ventilation:** Handle product in a well-ventilated area.

**Protective Gloves:** Latex or nitrile

**Eye Protection:** Safety glasses

**Other Protective Clothing or Equipment:** Lab Coat

**Work/Hygienic Practices:** Wash hands following use. No eating, drinking, or smoking while handling this product.

## **Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS**

**Physical State:** Liquid

**Appearance and Odor:** Clear to Yellowish

**Boiling Point:** Approx. 100°C

**Vapor Pressure:** Not available

**Vapor Density:** Not available

**Specific Gravity:** Approx. to water

**Melting Point:** Approx. 0°C

**Evaporation Rate:** Approx. to water

**Solubility in Water:** Soluble

**pH:** 4.5 –5.5

## **Section X - STABILITY AND REACTIVITY DATA**

**Stability:** Stable

**Incompatibility (Materials to Avoid):** Bases and oxidizing materials.

**Hazardous Decomposition or Byproducts:** Decomposition products of this compound may include potentially hazardous byproducts such as oxides of carbon, nitrogen and hydrochloric acid.

**Hazardous Polymerization:** Will not occur

**Conditions to Avoid:** Unknown

## **Section XI - TOXICOLOGICAL INFORMATION**

For Esmolol Hydrochloride (active ingredient) RTECS Number DA8346000

LD<sub>50</sub> human, intravenous = 775 ug/kg

LD<sub>50</sub> rat, intravenous = 71 mg/kg

LD<sub>50</sub> mouse, intravenous = 93 mg/kg

LD<sub>50</sub> dog, intravenous = 32 mg/kg

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

## **Section XII - ENVIRONMENTAL IMPACT INFORMATION**

Information is currently not available on the environmental impact of Esmolol. Handle in a manner to prevent spills or releases to the environment.

## **Section XIII - DISPOSAL INFORMATION**

Dispose of by incineration at an approved/permitted incinerator.  
Review local, state, and federal regulations for your regulatory area.

## **Section XIV - TRANSPORTATION INFORMATION**

Esmolol Injection is not a DOT Hazardous material  
Esmolol Injection is not a DOT Marine Pollutant.

## **Section XV - REGULATORY INFORMATION**

SARA 313 listed?: NO  
CERCLA listed?: NO  
RCRA listed?: NO  
TSCA Listed YES

## **Section XVI - OTHER DATA**

1. Use of this product should be through or under the direction of a physician.  
This MSDS does not address therapeutic use of this material.  
2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company management.

### **REFERENCES:**

1. Registry of Toxic Effects of Chemical Substances, 11/2002
2. Physicians Desk Reference, On-Line PDR Electronic Library

The information provided is believed to be complete and accurate. It is the user's responsibility to use the information according to their application. Bioniche Pharma USA assumes no additional liability or responsibility resulting from the use of or reliance on this information.