

# MATERIAL SAFETY DATA SHEET

## **Esmolol HCl Injection, 10 mg/mL, 10mL Vial**

**Paddock Laboratories, Inc.**  
**3940 Quebec Avenue North**  
**Minneapolis, MN 55427**

**Emergency Assistance:**  
**CHEMTREC® (24-hour) 1-800-424-9300**

Tel: (763) 546-4676

Paddock Technical Assistance: 1-800-328-5113

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

PRODUCT NAME: Esmolol Hydrochloride Injection  
COMMON NAME: Esmolol Hydrochloride  
CHEMICAL NAME: 4-[2-Hydroxy-3-[(1-methylethyl)amino]propoxy]benzene propanoic acid, methyl ester, hydrochloride  
SYNONYMS: N/A  
CHEMICAL FAMILY: Beta-Blocker

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

CHEMICAL NAME	CAS#	% w/v	OSHA PEL	ACGIH TLV
Esmolol Hydrochloride	81161-17-3	1	NE	NE
Sodium Acetate Trihydrate	6131-90-4	<1	NE	NE
Glacial Acetic Acid	64-19-7	<1	10 ppm	10 ppm
Water	7732-18-5	>90	NE	NE

NE = Not Established

Sodium Hydroxide and/or Hydrochloric acid may be used to adjust the pH.

Esmolol Hydrochloride is a sterile injectable liquid drug provided in a vial.

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

#### **EMERGENCY OVERVIEW:**

Routes of entry: Esmolol may be absorbed via contact with skin or eyes, inhalation of aerosols or accidental ingestion. Under normal use with supervision of a physician, Esmolol presents little hazard.

Symptoms of Overexposure by Route of Exposure: Minimal adverse health effects should occur from routine use under the care of a physician.

Acute: Changes in blood pressure, irregular heartbeat, drowsiness and possible loss of consciousness. Esmolol may also cause nausea, vomiting, anorexia, headache, dizziness, and constipation.

Chronic: Long-term effects have not been determined for this product.

Pre-Existing Medical Conditions 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.

#### SECTION 4: FIRST AID MEASURES

- Skin Exposure: Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.
- Eye Exposure: Flush eyes with large volumes of clean water. For direct contact, hold eyelids apart and flush the affected eye(s) with clean water for at least 20 minutes. Seek medical attention if irritation persists.
- Inhalation: If respiratory symptoms develop, move victim away from source of exposure and remove to fresh air. Seek medical attention immediately. If victim is not breathing, have CPR performed by trained personnel. If breathing difficulties develop, oxygen should be administered by qualified personnel.
- Ingestion: If swallowed, seek emergency medical attention. Flush mouth with water. DO NOT induce vomiting. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth.
- Injection: If accidental injection occurs, wash and disinfect area, seek medical attention.

Victims of chemical exposure must be taken for medical attention. Take a copy of the MSDS to the physician or health professional with victim. Physicians should refer to Section 11 (Toxicological Information) as well as the Physicians Desk Reference for additional treatment information.

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

Flash Point: NE

Flammable Limits: Lower: NE Upper: NE

Fire Extinguishing Equipment: Use extinguishing agent suitable for type of surrounding fire.

Water Spray: OK Carbon Dioxide: OK Halon: OK  
Foam: OK Dry Chemical: OK Other: Any "ABC" Class

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

Special Fire Fighting Procedures: For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by the DOT *Emergency Response Guidebook*, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8). Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk.

NFPA HAZARD CLASS: Health: 1 (High)  
 Flammability: 0 (Least)  
 Reactivity: 0 (Least)

#### SECTION 6: SPILL AND LEAK PROCEDURES

Spill and Leak Response:

For small releases of this product, wear nitrile or latex gloves and safety glasses. Absorb spilled liquid and rinse area thoroughly with soap and water.

For large or uncontrolled releases, stay upwind and away from spill. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant (see Section 8). Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways. Dike far ahead of spill for later recovery or disposal. Spilled material may be absorbed into an appropriate absorbent material. Notify appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended.

**SECTION 7: HANDLING AND STORAGE**

Work and Hygiene Practices: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Storage and Handling Practices: Employees must be trained to properly use the product. Ensure vials are properly labeled. Store only in approved containers. Keep away from any incompatible materials or conditions (see Section 10). Store in a dark place at controlled room temperature. Follow instructions provided in packaging.

Protective Practices During Maintenance of Contaminated Equipment: When cleaning non-disposable equipment, wear nitrile gloves, goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials and other disposable items contaminated with this product should be disposed of properly.

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

Ventilation and Engineering Controls: Handle product in a well-ventilated area. Follow standard medical product handling procedures.

Respiratory Protection: Not normally required for routine medical administration of this product. A NIOSH certified air-purifying respirator with a type 95 filter may be used under conditions where airborne concentrations are expected to be excessive. Protection provided by air purifying respirators is limited (see manufacturer's respirator selection guide). Use a positive pressure air supplied respirator if there is potential for uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions warrant a respirator's use.

Eye Protection: The use of safety glasses or goggles to safeguard against potential eye contact, irritation, or injury is recommended.

Hand Protection: Use latex or nitrile. Check gloves for leaks. Wash hands before and after using gloves.

Body Protection: No special body protection required for routine medical administration of this product. Wear lab coat, gown, or smock, as appropriate for procedure.

Product Preparation Instructions for Medical Personnel: Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

**SECTION 9: PHYSICAL / CHEMICAL PROPERTIES**

Boiling Point:

Approx. 100°C

Vapor Pressure:

ND

Melting/Freezing Point:	Approx. 0°C	pH:	4.5-5.5
Water Solubility:	Miscible	Water Reactive:	No
Specific Gravity (Water =1):	Approx. to water	Evaporation Rate:	Approx. to water
Appearance and odor:	Clear, colorless to yellowish, odorless solution		

ND = No Data

#### SECTION 10: STABILITY AND REACTIVITY

Stability:	Stable under labeled storage conditions.
Incompatible Materials:	Bases and oxidizing materials.
Hazardous Polymerization:	Will not occur.
Conditions to Avoid:	Unknown
Hazardous Decomposition:	Decomposition products of this compound may include potentially hazardous byproducts such as oxides of carbon, nitrogen, and hydrochloric acid.

#### SECTION 11: TOXICOLOGICAL INFORMATION

Toxicity Data: The following information is for Esmolol Hydrochloride

LD<sub>10</sub> (human, intravenous) = 775 µg/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

LD<sub>50</sub> (rabbit, intravenous) = 40 mg/kg

Target Organs: Cardiovascular system

Suspected Cancer Agent: This product has **NOT** been identified as a carcinogen by NTP, IARC or OSHA.

ACGIH Biological Exposure Indices: Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.

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 12: ECOLOGICAL 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 13: WASTE DISPOSAL

Preparing Wastes for Disposal: Waste is not considered hazardous under EPA definitions. Dispose of in accordance with federal, state and local regulations. Following procedures for disposal of other active drugs is suggested.

U.S. EPA Waste Number: None

#### SECTION 14: TRANSPORTATION INFORMATION

This Material is not Hazardous as Defined by 49 CFR 172.101 by the U. S. Department of Transportation

Proper Shipping Name: Not applicable

Hazard Class Number and Description: Not applicable

UN Identification Number: Not applicable

Packing Group: Not applicable

DOT Label(s) Required: Not applicable

North American Emergency Response Guidebook Number (1996): Not applicable.

MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B)

Transport Canada Transportation of Dangerous Goods Regulations: Not applicable

#### SECTION 15: REGULATORY INFORMATION

##### U.S. REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304 and 313 of Title II of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity: Not applicable

U.S. CERCLA Reportable Quantities (RQ): Not applicable

U.S. TSCA Inventory Status: Esmolol Hydrochloride is a "drug" as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.

#### SECTION 16: OTHER INFORMATION

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.

TO THE BEST OF OUR KNOWLEDGE THE INFORMATION CONTAINED HEREIN IS ACCURATE AS OF THE DATE HEREOF. ANY DETERMINATION AS TO THE SUITABILITY OF THE PRODUCT FOR ANY PARTICULAR PURPOSE, ITS SAFE USE OR DISPOSAL SHALL BE THE RESPONSIBILITY OF THE USER. THE INFORMATION CONTAINED HEREIN IS IN NO WAY INTENDED TO SUPPLEMENT, MODIFY OR SUPERSEDE THE INFORMATION PROVIDED IN THE PRODUCT PACKAGE INSERT WITH RESPECT TO THE USE OF THE PRODUCT FOR MEDICAL PURPOSES.