

# MATERIAL SAFETY DATA SHEET

## Dihydroergotamine Mesylate Injection 1 mg/mL

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### SECTION 1: PRODUCT IDENTIFICATION

PRODUCT: Dihydroergotamine Mesylate Injectables 1 mg/mL (DHE)  
COMMON NAME: Dihydroergotamine Mesylate  
CHEMICAL NAME: Ergotaman-3, 6, 18-trione,9,10-dihydro-12-hydroxy-2-methyl-5-(phenylmethyl)-,(5a)-monomethanesulfonate  
SYNONYMS: DHE Mesylate, Ergotamine, 9,10-dihydro-Mesylate  
CHEMICAL FORMULA:  $C_{33}H_{37}N_5O_5 \cdot CH_4O_3S$   
CHEMICAL FAMILY: Ergot Alkaloids

### SECTION 2: COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#	% w/w	OSHA PEL	ACGIH TLV	IDLH
Dihydroergotamine Mesylate	6910-39-2	<10	NE	NE	NE
Alcohol, USP	64-17-5	<10 by volume	1000 PPM	1000 PPM	1000 PPM
Glycerin	56-81-4	<50	NE	10mg/cum (vapor)	NE
Water	7732-18-5	>50	NE	NE	NE
Methane Sulfonic Acid	75-75-2	For pH adj.			
Sodium Hydroxide	1310-73-2	For pH adj.			

NE = Not Established

### SECTION 3: HAZARDS IDENTIFICATION

**EMERGENCY OVERVIEW:** Material is a clear, colorless solution. Avoid breathing vapor. Avoid contact with eyes, skin and clothing. Do not taste or swallow. Wash thoroughly after handling. Pregnancy category X.

Symptoms of Overexposure by Route of Exposure: This material is intended for the acute treatment of migraine headaches or the acute treatment of cluster headache episodes. Signs of overexposure include numbness and tingling of fingers and toes, extremity muscle pains, nausea, vomiting, localized edema and itching.

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.

Inhalation: Inhalation of significant amounts of the product is not anticipated to occur because of the small size of individual containers.

Contact With Eyes: Under normal use, D H E presents little hazard.

Contact with Skin: Remove contaminated clothing. Wash skin with soap and water for 15 minutes. Get medical attention if signs of exposure are noted.

Ingestion: Ingestion is not an anticipated route of occupational exposure. If this occurs, flush mouth with water and seek medical attention.

Injection: If accidental injection occurs in an occupational setting, seek medical attention. Medical personnel are not anticipated to experience over-exposures to the therapeutic doses of this product. See package insert for adverse reactions associated with therapeutic doses of this product.

#### **Health Effects or Risks From Exposure :**

Health Hazards (Acute and Chronic): D H E is an alpha adrenergic blocking agent with a stimulating effect on smooth muscle peripheral and cranial blood vessels and produces depression of central vasomotor centers. Adverse acute effects are irritation to mucous membranes and respiratory tract, nausea, vomiting, headache, diarrhea, thirst, coldness of skin, weak pulse numbness.

Pregnancy: D H E is listed as pregnancy category X. If you are pregnant and exposed to D H E, seek medical attention immediately.

Target Organs: This product has not been identified as producing permanent adverse effects on organ systems.

Pre-Existing Medical Conditions: Conditions aggravated by exposure may include peripheral vascular disease, coronary heart disease, hypertension, impaired hepatic/renal function, sepsis, pregnancy.

### **SECTION 4: FIRST AID MEASURES**

<u>Skin Exposure</u> :	Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water for 15 minutes. If irritation or redness develops and persists, seek medical attention.
<u>Eye Exposure</u> :	Immediately flush eyes with clean water. For direct contact, hold eyelids apart and flush the affected eye(s) with clean water for at least 20 minutes. Seek immediate medical attention.
<u>Inhalation</u> :	If symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.
<u>Ingestion</u> :	If swallowed, wash mouth and seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing.

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.



Protective Practices During Maintenance of Contaminated Equipment: When cleaning non-disposable equipment, wear nitrile or other suitable 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: Use with adequate ventilation. 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 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 a face shield and/or chemical goggles to safeguard against potential eye contact, irritation, or injury is recommended.

Hand Protection: Use nitrile, rubber, or other suitable gloves. 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:	Not Available	Vapor Pressure:	Not Available
Melting/Freezing Point:	Not Available	pH:	3.4 – 4.9
Water Solubility:	Slight	Water Reactive:	No
Specific Gravity (Water =1):	Not Available	Evaporation Rate (Butyl acetate = 1):	Not Available
Appearance/Odor:	Clear, colorless solution / odorless		

ND = No Data

## SECTION 10: STABILITY AND REACTIVITY

Stability:	Stable under labeled storage conditions.
Incompatible Materials:	ND.
Hazardous Polymerization:	Will not occur.
Conditions to Avoid:	Protect from light and excessive heat.

## SECTION 11: TOXICOLOGICAL INFORMATION

Toxicity Data: Not Available

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

Irritancy of Product: This product may be irritating to eyes and other tissues.

Sensitization to the Product: This material may produce hypersensitization, irritating to mucous membranes and respiratory tract. May be hypersensitive to other Ergot derivatives.

Reproductive Toxicity Information: Listed below is information concerning the effects of Dihydroergotamine Mesylate on human and animal reproductive systems. This material is classified as a Pregnancy Category X (May cause fetal harm).

Mutagenicity: Negative in the Ames test and the in vitro Chinese hamster V79/HGPRT assay.

Embryotoxicity/Teratogenicity/Reproductive Toxicity: DHE may cause fetal harm if taken while pregnant.

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

## SECTION 12: ECOLOGICAL INFORMATION

All work practices must be aimed at eliminating environmental contamination.

Environmental Stability: This product will be relatively stable under ambient environmental conditions.

Effect of Materials on Plants or Animals: No specific information is available on the effect of DHE on plants or animals in the environment.

Effect of Chemicals on Aquatic Life: No specific information is available on the effect of DHE on aquatic life.

## SECTION 13: WASTE DISPOSAL

Preparing Wastes for Disposal: This material, if discarded as produced, is not a RCRA "listed" or "characteristic" hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

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: DHE is a “drug” as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): This product does NOT contain a chemical known to the State of California to cause developmental and reproductive effects.

Other U.S. Federal Regulations: Based on this product’s use, the requirements of the OSHA Bloodborne pathogen Standard (29 CFR 1910.1030) are applicable.

ANSI Labeling (Based on 129.1. Provided to Summarize Occupational Exposure Hazards):

**WARNING!** Serious AND/OR LIFE-THREATENING PERIPHERAL ISCHEMIA HAS BEEN ASSOCIATED WITH THE COADMINISTRATION OF DHE WITH POTENT CYP3A4 INHIBITORS INCLUDING PROTEASE INHIBITORS AND MACROLIDE ANTIBIOTICS. BECAUSE CYP3A4 INHIBITION ELEVATES THE SERUM LEVELS OF DHE, THE RISK FOR VASOSPASM LEADING TO CEREBRAL ISCHEMIA AND/OR ISCHEMIA OF THE EXTREMITIES IS INCREASED. HENCE, CONCOMITANT USE OF THESE MEDICATIONS IS CONTRAINDICATED. DHE should be administered under the supervision of a qualified physician. Avoid over-exposure. Avoid breathing vapor. Avoid contact with eyes, skin and clothing. Do not eat, drink or smoke when handling DHE. Do not taste or swallow. Wash thoroughly after handling. Clean up spills promptly.

**CANADIAN REGULATIONS:**

Canadian DSL/NDSL Status: DHE is regulated by the Food and Drug Administration of Health Canada and is therefore exempt from the requirements of CEPA.

**SECTION 16: OTHER INFORMATION**

## DEFINITIONS OF ABBREVIATIONS USED:

ACGIH:	American Conference of Governmental Industrial Hygienists
CAS:	Chemical Abstract Service
IARC:	Internal Agency for Research on Cancer
IDLH:	Immediately Dangerous to Life or Health Level
LC <sub>50</sub> :	Median Lethal Concentration
LD <sub>50</sub> :	Median Lethal Dose
MSHA:	Mine Safety and Health Administration
N/A:	Not Available
NIOSH:	National Institute for Occupational Safety and Health
NTP:	National Toxicology Program
OSHA:	Occupational Safety and Health Administration
PEL:	Permissible Exposure Limit
STEL:	Short Term Exposure Limit
TLV:	Threshold Limit Value
TWA:	Time Weighted Average