Dihydroergotamine Mesylate Injection Safety Data Sheet

1.1. Identification			
Product name	: Dihydroergotamine Mesylate Injectio	n	
1.2. Relevant identified uses of the	substance or mixture and uses advised ag	ainst	
Use of the substance/mixture	: Pharmaceutical	amot	
1.3. Details of the supplier of the sa Apollo Pharmaceuticals USA Inc.	iety data sheet		
4400 PGA Blvd. Suite 102			
Palm Beach Gardens, FL 33410			
1.4. Emergency telephone number			
Emergency number	: 833-727-6556 (833-7APOLLO)		
SECTION 2: Hazard(s) identificat	ion		
2.1. Classification of the substance	or mixture		
GHS US classification			
Repr. 1B H360			
Full text of hazard classes and H-statement	s : see section 16		
2.2. Label elements			
GHS US labeling			
Hazard pictograms (GHS US)	· · · · · · · · · · · · · · · · · · ·		
······································			
	GHS08		
Signal word (GHS US)	: Danger		
Hazard statements (GHS US)	: H360 - May damage fertility or the ur	nborn child	
Precautionary statements (GHS US)	: P201 - Obtain special instructions be		
	P202 - Do not handle until all safety		
	P280 - Wear protective gloves/protective gloves/protective P308+P313 - If exposed or concerned		
	P405 - Store locked up.		
	P501 - Dispose of contents/contained		
	accordance with local, regional, nation	onai ano/or internatio	nai regulation.
2.3. Other hazards			
No additional information available			
2.4. Unknown acute toxicity (GHS U	IS)		
Not applicable			
SECTION 3: Composition/Inform	ation on ingredients		
3.1. Substances			
Not applicable			
3.2. Mixtures			
Name	Product identifier	%	GHS US classification
Dihydroergotamine mesilate	(CAS-No.) 6190-39-2	< 1	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312
			Acute Tox. 4 (Inhalation), H332
			Skin Irrit. 2, H315 Eye Irrit. 2, H319
			Repr. 1B, H360
			STOT SE 3, H335

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Full text of hazard classes and H-statements : see section 16

SECTION 4: First aid measures	
4.1. Description of first aid measures	
First-aid measures after inhalation	 If aerosols of this product are inhaled, remove victim to fresh air. The contaminated individual must seek medical attention if any adverse effects occur.
First-aid measures after skin contact	: If contact with this product results in adverse effect, flush affected area with water. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effects occur after flushing.
First-aid measures after eye contact	: If this product enters the eyes, open contaminated individual's eyes while under gently running water. Use sufficient force to open eyelids. Have contaminated individual "roll" eyes. Minimum flushing is for 20 minutes. Contaminated individual must seek medical attention if adverse effect occurs or continues after flushing.
First-aid measures after ingestion	: Seek immediate medical attention.
4.2. Most important symptoms and effects	s, both acute and delayed
Symptoms/effects after inhalation	: May cause breathing difficulties if inhaled.
Symptoms/effects after skin contact	: May cause skin irritation.
Symptoms/effects after eye contact	May cause eye irritation.
Symptoms/effects after ingestion	: May be harmful if swallowed.
4.3. Indication of any immediate medical a	attention and special treatment needed
No additional information available	
SECTION 5: Firefighting measures	
5.1. Extinguishing media	
	: Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: None.
5.2. Special hazards arising from the subs	stance or mixture
Fire hazard	: None known.
5.3. Advice for firefighters	
Protection during firefighting	: Firefighters should wear full protective gear.
SECTION 6: Accidental release measu	
6.1. Personal precautions, protective equi	pment and emergency procedures
General measures	: No special measures required.
6.1.1. For non-emergency personnel No additional information available	
6.1.2. For emergency responders	
No additional information available	
6.2. Environmental precautions	
Prevent entry to sewers and public waters.	
6.3. Methods and material for containmen	t and cleaning up
For containment	: Stop the flow of material, if this is without risk.
6.4. Reference to other sections	
No additional information available	
SECTION 7: Handling and storage	
7.1. Precautions for safe handling	
Precautions for safe handling	: Do not eat, drink or smoke when using this product.
7.2. Conditions for safe storage, including	any incompatibilities
Storage conditions	: Keep container tightly closed. Store at 20° to 25°C (68° to 77°F). Do not refrigerate or freeze.

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SECTION 8: Exposure controls/personal protection

8.1. **Control parameters**

Dihydroergotamine mesilate (6190-39-2)

Not applicable

8.2. Exposure controls		
Appropriate engineering controls	: Local exhaust and general ventilation must be adequate to meet exposure standards.	
Hand protection	: Use neoprene or rubber gloves.	
Eye protection	: In case of dust production: protective goggles.	
Skin and body protection	: Wear suitable working clothes.	
Respiratory protection	: If airborne concentrations are above the applicable exposure limits, use NIOSH approved respiratory protection.	

SECTION 9: Physical and chemical	properties
9.1. Information on basic physical and	chemical properties
Physical state	: Liquid
Appearance	: Clear.
Color	: Colorless
Odor	: Odorless
Odor threshold	: No data available
рН	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: No data available
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Soluble.
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. **Other information**

No additional information available

SECTION 10: Stability and reactivity				
10.1.	Reactivity			
No additional information available				
10.2.	2. Chemical stability			
The pro	The product is stable at normal handling and storage conditions.			
10.3.	Possibility of hazardous reactions			
Will not occur.				
10.4.	Conditions to avoid			
None.				

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10.5. Incompatible materials None known. 10.6. Hazardous decomposition products None known. SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

: Not classified

Dihydroergotamine mesilate (6190-39-2)		
LD50 oral rat	> 2 g/kg	
ATE US (oral)	500 mg/kg body weight	
ATE US (dermal)	1100 mg/kg body weight	
ATE US (gases)	4500 ppmV/4h	
ATE US (vapors)	11 mg/l/4h	
ATE US (dust, mist)	1.5 mg/l/4h	
Skin corrosion/irritation	: Not classified	
Serious eye damage/irritation	: Not classified	
Respiratory or skin sensitization	: Not classified	
Germ cell mutagenicity	: Not classified	
Carcinogenicity	: Not classified	
Reproductive toxicity	: May damage fertility or the unborn child.	
Specific target organ toxicity - single exposure	: Not classified	
Specific target organ toxicity – repeated exposure	: Not classified	
Aspiration hazard	: Not classified	

SECTION 12: Ecological information			
12.1. Toxicity			
No additional information available			
12.2. Persistence and degradability			
No additional information available			
12.3. Bioaccumulative potential			
No additional information available			
12.4. Mobility in soil			
No additional information available			
12.5. Other adverse effects			
No additional information available			

SECTION 13: Disposal considerati	ons
13.1. Waste treatment methods	
Product/Packaging disposal recommendation	 Dispose of contents/container in accordance with local/regional/national/international regulations.
SECTION 14: Transport informatic	n

Department of Transportation (DOT)

In accordance with DOT Not applicable

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SECTION 15: Regulatory information

15.1. US Federal regulations

No additional information available

15.2. US State regulations

Dihydroergotamine mesilate (6190-39-2)				
U.S California - Proposition 65 - Carcinogens List	U.S California - Proposition 65 - Developmental Toxicity	U.S California - Proposition 65 - Reproductive Toxicity - Female	U.S California - Proposition 65 - Reproductive Toxicity - Male	No significant risk level (NSRL)
No	Yes	No	No	

SECTION 16: Other information

Full text of H-phrases:	
Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhalation) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Repr. 1B	Reproductive toxicity Category 1B
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H302	Harmful if swallowed
H312	Harmful in contact with skin
H315	Causes skin irritation
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H360	May damage fertility or the unborn child

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.