Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Dihydroergotamine Mesylate Injection

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

Apollo Pharmaceuticals USA Inc. 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) identification

2.1. Classification of the substance or mixture

GHS US classification

Repr. 1B H360

Full text of hazard classes and H-statements: 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 unborn child Precautionary statements (GHS US) : P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood. P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P308+P313 - If exposed or concerned: Get medical advice/attention.

P405 - Store locked up.

P501 - Dispose of contents/container to hazardous or special waste collection point, in

accordance with local, regional, national and/or international regulation.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information 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

01/15/2020 EN (English US) Page 1

Safety Data Sheet

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.

Most important symptoms and effects, both acute and delayed

: May cause breathing difficulties if inhaled. Symptoms/effects after inhalation

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.

Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media None.

5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

Advice for firefighters

Protection during firefighting : Firefighters should wear full protective gear.

SECTION 6: Accidental release measures

Personal precautions, protective equipment 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

Environmental precautions

Prevent entry to sewers and public waters.

Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.

Reference to other sections 6.4.

No additional information available

SECTION 7: Handling and storage

Precautions for safe handling

Precautions for safe handling : Do not eat, drink or smoke when using this product.

Conditions for safe storage, including any incompatibilities

: Keep container tightly closed. Store at 20° to 25°C (68° to 77°F). Do not refrigerate or freeze. Storage conditions

01/15/2020 EN (English US) 2/5

Safety Data Sheet

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 рΗ No data available Melting point : No data available : No data available Freezing point Boiling point No data available : No data available Flash point Relative evaporation rate (butyl acetate=1) No data available Flammability (solid, gas) : No data available : No data available Vapor pressure 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 : No data available **Explosion limits** 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. Chemical stability

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.

01/15/2020 EN (English US) 3/5

Safety Data Sheet

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 : Not classified

exposure

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 considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not applicable

01/15/2020 EN (English US) 4/5

Dihydroergotamine Mesylate Injection Safety Data Sheet

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:

xt of n-prirases.		
Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4	
Acute Tox. 4 (Inhalation)	Acute toxicity (inhalation) Category 4	
Acute Tox. 4 (Oral)	I) 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.

01/15/2020 EN (English US) 5/5