

Section 1: IDENTIFICATION OF SUBSTANCE AND SOCIETY

1.1. Identification of the substance

Product form: Solution for injection.

Product name: Dihydroergotamine mesylate injection.

Chemical name: (5'.alpha.,10.alpha.)-9,10-dihydro-12'-hydroxy-2'-methyl-5'-(phenylmethyl)-ergotaman-3',6',18-trione.

Synonym: Dihydroergotamine mesylate, 9,10-Dihydroergotamine mesylate, Dihydroergotamine methanesulfonate, monomethanesulfonate.

National Drug Code (NDC): 81284-411-00.

Trade name: Not applicable.

Molecular formula: C₃₃H₃₇N₅O₅-CH₄O₃S.

CAS No.: 6190-39-2.

EC No.: Not applicable.

REACH No.: Not applicable.

1.2. Uses

Pharmaceutical. Treatment of migraine headaches.

1.3. Information about the security data sheet provider

Company	Supplier	Distributor
Provepharm SAS 22 Rue Marc Donadille 13013 Marseille, France Phones: 04 91 08 69 30 Website: www.provepharm.com Email: hse@provepharm.com	Cenexi 52 rue Marcel et Jacques Gaucher BP 41 94120 Fontenay sous-bois, France	Provepharm Inc. 100 Springhouse drive, Suite 105, Collegeville, PA 19426, USA Phone: +1 610 601 8600

1.4. Emergency telephone number:

CHEMTREC: 1-800-424-9300 (within USA and Canada), +1 703-527-3887 (outside USA and Canada).

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or the mixture

Repr. 1B H360.

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

2.2. Label elements

Warning mention: Danger

Hazard statements:

H360 - May damage fertility or the unborn child.

Precautionary statements:

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

Not available.

2.4. Unknown acute toxicity

Not applicable.

Section 3: COMPOSITION/INFORMATIONS ON THE SUBSTANCE

3.1. Substances

Name	Product identifier	%	Classification
Dihydroergotamine mesilate	CAS-No.: 6190-39-2 Molecular weight: 679.78 g/mol	< 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

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

3.2. Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1. Description of 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.

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.

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.

After ingestion: Seek immediate medical attention.

4.2. Most important symptoms and effects, both acute and delayed

After inhalation: May cause breathing difficulties if inhaled.

After skin contact: May cause skin irritation.

After eye contact: May cause eye irritation.

After ingestion: May be harmful if swallowed.

4.3. Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1. 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 or explosion hazard: A pressure increase will occur and the container may burst.

Combustion Products: Decomposition products may include carbon oxides (CO, CO2).



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5.3. Advice for firefighters

Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Wear appropriate protecting clothing and equipment as described in section 8. Ventilate the area. Eliminate all ignition sources.

6.2. Environmental precautions

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3. Methods and material for containment and cleaning up

Small spill: Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth.

Large spill: Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble.

Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. For proper waste disposal, see section 13 of the SDS.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Do not eat, drink or smoke when using this product. Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

7.2. Conditions for safe storage, including any incompatibilities

Storage: Keep container tightly closed. Store at 20° to 25°C (68° to 77°F). Excursions permitted between 15° to 30°C (59° to 86°F). Do not refrigerate or freeze.

Incompatibilities: None.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure limit: Not available.

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 (EN 374).

Eye protection: In case of dust production: wear protective goggles (EN 166).

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
pH:	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

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Not available.

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Under normal conditions of storage and use, hazardous reactions will not occur.

10.4. Conditions to avoid

None.

10.5. Incompatible materials

None.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity:

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



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ATE US (dust, mist):

1.5 mg/l/4h

Routes of exposure: Dermal contact, eye contact, inhalation, ingestion.

Carcinogenic/mutagenic/toxic effects for reproduction: Not available.

Specific target organ toxicity – single exposure: Not available.

Specific target organ toxicity – repeated exposure: Not available.

Aspiration hazard: Not available.

Symptoms short term: Not available.

Symptoms long term: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Not available.

12.2. Persistence and degradability

Not available.

12.3. Bioaccumulative potential

Not available.

12.4. Mobility in soil

Not available.

12.5. Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste classification: Not available.

Advice on disposal: Dispose of waste in accordance with all applicable federal, state and local laws.

Waste disposal number of waste from residues/unused products: Dispose of waste in accordance with federal, state and local environment control regulations.

Contaminated packaging: Empty containers should be taken for local recycling, recovery or waste disposal. Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse. Packaging that cannot be cleaned should be disposed of like the product.

SECTION 14: TRANSPORT INFORMATION

The listed CAS ingredient(s) in this final formula for finished goods are not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Department of Transportation (DOT) Classification:

UN Number: Not regulated.

UN Shipping name: Not available.

Transport hazard class: Not available.

Packing Group: Not available.

Environmental hazard: None.

Transport in bulk: Not available.

Special precautions needed with transport: Always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

SECTION 15: REGULATORY INFORMATION

15.1. US Federal regulations

Not available.

15.2. US State regulations

U.S. - California - Proposition 65 - Carcinogens List: No

U.S. - California - Proposition 65 - Developmental Toxicity: Yes

U.S. - California - Proposition 65 - Reproductive Toxicity – Female: No

U.S. - California - Proposition 65 - Reproductive Toxicity – Male: 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