

DIHYDROERGOTAMINE MESYLATE- NASAL SPRAY - 4 MG/ML



SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2020/878)

SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : DIHYDROERGOTAMINE MESYLATE- NASAL SPRAY - 4 MG/ML

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

Pharmaceutical product.

1.3. Details of the supplier of the safety data sheet

Registered company name : SUBSTIPHARM DEVELOPPEMENT.

Address : 24, rue Erlanger.75016.Paris.France.

Telephone : +33 (0)1 43 18 13 00. Fax : +33 (0)1 42 27 09 90.

contact@substipharm.com

http://www.substipharm.com

1.4. Emergency telephone number : +33 (0)1 45 42 59 59.

Association/Organisation : INRS / ORFILA <http://www.centres-antipoison.net>.

Other emergency numbers

National Poisons Information Service of England: <http://npis.org> - NHS 111: dial 111 - National Poisons Information Centre of Ireland: 353 (1) 809 2166 - European Emergency Number Association (EENA): 112

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Reproductive toxicity, Category 1B (Repr. 1B, H360D).

2.2. Label elements

In compliance with EC regulation No. 1272/2008 and its amendments.

Hazard pictograms :



GHS08

Signal Word :

DANGER

Product identifiers :

EC 228-235-6 DIHYDROERGOTAMINE MESILATE

Hazard statements :

H360D May damage the unborn child.

Precautionary statements - General :

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

Precautionary statements - Prevention :

P202 Do not handle until all safety precautions have been read and understood.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statements - Response :

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

Precautionary statements - Disposal :

P501 Dispose of contents/container at a disposal facility in accordance with local regulations.

2.3. Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) \geq 0.1% published by the European Chemicals Agency (ECHA) under article 59 of REACH: <http://echa.europa.eu/fr/candidate-list-table>

The mixture fulfils neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

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The mixture does not contain substances > = 0.1% with endocrine disrupting properties in accordance with the criteria of the Delegated Regulation (EU) 2017/2100 of the Commission or Regulation (EU) 2018/605 of the Commission.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS**3.2. Mixtures****Composition :**

Identification	Classification (EC) 1272/2008	Note	%
INDEX: 613-086-00-5 CAS: 58-08-2 EC: 200-362-1 REACH: 01-2119433305-48 CAFFEINE	GHS07 Wng Acute Tox. 4, H302		0 < x% < 10
CAS: 6190-39-2 EC: 228-235-6 DIHYDROERGOTAMINE MESILATE	GHS08, GHS07 Dgr Acute Tox. 4, H302 Acute Tox. 4, H312 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Acute Tox. 4, H332 STOT SE 3, H335 Repr. 1B, H360Df	[ii]	0.3 <= x% < 3

Specific concentration limits:

Identification	Specific concentration limits	ATE
CAS: 6190-39-2 EC: 228-235-6 DIHYDROERGOTAMINE MESILATE		inhalation: ATE = 1.5 mg/l 4h (dust/mist) dermal: ATE = 1100 mg/kg BW oral: ATE = 500 mg/kg BW

Information on ingredients :

(Full text of H-phrases: see section 16)

[ii] Carcinogenic, mutagenic or reprotoxic (CMR) substance.

SECTION 4 : FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

4.1. description of first aid measures**In the event of splashes or contact with eyes :**

Wash thoroughly with soft, clean water for 15 minutes holding the eyelids open.

If there is any redness, pain or visual impairment, consult an ophthalmologist.

In the event of swallowing :

Seek medical attention, showing the label.

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

No data available.

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

No data available.

SECTION 5 : FIREFIGHTING MEASURES

Non-flammable.

5.1. Extinguishing media

No data available.

5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

In the event of a fire, the following may be formed :

- carbon monoxide (CO)

- carbon dioxide (CO₂)

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5.3. Advice for firefighters

No data available.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

6.2. Environmental precautions

Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal.

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Clean preferably with a detergent, do not use solvents.

6.4. Reference to other sections

No data available.

SECTION 7 : HANDLING AND STORAGE

Requirements relating to storage premises apply to all facilities where the mixture is handled.

Avoid exposure to pregnant women and warn women of child-bearing age of the possible risks

7.1. Precautions for safe handling

Always wash hands after handling.

Remove and wash contaminated clothing before re-using.

Fire prevention :

Prevent access by unauthorised personnel.

Recommended equipment and procedures :

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Avoid exposure - obtain special instructions before use.

Prohibited equipment and procedures :

No smoking, eating or drinking in areas where the mixture is used.

7.2. Conditions for safe storage, including any incompatibilities

No data available.

Storage

Keep out of reach of children.

Packaging

Always keep in packaging made of an identical material to the original.

7.3. Specific end use(s)

No data available.

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No data available.

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

Pictogram(s) indicating the obligation of wearing personal protective equipment (PPE) :



Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

DIHYDROERGOTAMINE MESYLATE- NASAL SPRAY - 4 MG/ML**- Eye / face protection**

Avoid contact with eyes.

Use eye protectors designed to protect against liquid splashes

Before handling, wear safety goggles in accordance with standard ISO 16321.

- Hand protection

Wear suitable protective gloves in the event of prolonged or repeated skin contact.

Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN ISO 374-1.

Gloves must be selected according to the application and duration of use at the workstation.

Protective gloves need to be selected according to their suitability for the workstation in question : other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of dexterity required.

Type of gloves recommended :

- Natural latex
- Nitrile rubber (butadiene-acrylonitrile copolymer rubber (NBR))
- PVC (polyvinyl chloride)
- Butyl Rubber (Isobutylene-isoprene copolymer)

- Body protection

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES**9.1. Information on basic physical and chemical properties****Physical state**

Physical state : Fluid liquid.

Colour

Colour: Not stated.

Odour

Odour threshold : Not stated.

Freezing point

Freezing point / Freezing range : Not stated.

Boiling point or initial boiling point and boiling range

Boiling point/boiling range : Not relevant.

Flammability

Flammability (solid, gas) : Not stated.

Lower and upper explosion limit

Explosive properties, lower explosivity limit (%) Not stated.

:

Explosive properties, upper explosivity limit (%) Not stated.

:

Flash point

Flash point interval : Not relevant.

Auto-ignition temperature

Self-ignition temperature : Not relevant.

Decomposition temperature

Decomposition point/decomposition range : Not relevant.

pH

pH (aqueous solution) : Not stated.

pH : Not stated.

Neutral.

Kinematic viscosity

Viscosity : Not stated.

Solubility

Water solubility : Dilutable.

Fat solubility : Not stated.

Partition coefficient n-octanol/water (log value)

Partition coefficient: n-octanol/water : Not stated.

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Vapour pressure

Vapour pressure (50°C) : Not relevant.

Density and/or relative density

Density : Not stated.

Relative vapour density

Vapour density : Not stated.

Particle characteristics

The mixture does not contain nanoforms.

9.2. Other information

No data available.

9.2.1. Information with regard to physical hazard classes

No data available.

9.2.2. Other safety characteristics

No data available.

SECTION 10 : STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Avoid :

- frost

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

The thermal decomposition may release/form :

- carbon monoxide (CO)

- carbon dioxide (CO₂)

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

11.1.1. Substances

a) Acute toxicity :

DIHYDROERGOTAMINE MESILATE (CAS: 6190-39-2)

Oral route : LD50 = 500 mg/kg body weight

Dermal route : LD50 = 1100 mg/kg body weight

Inhalation route (Dusts/mist) : LC50 = 1.5 mg/l
Duration of exposure : 4 h

b) Skin corrosion/skin irritation :

No data available.

c) Serious damage to eyes/eye irritation :

No data available.

d) Respiratory or skin sensitisation :

No data available.

e) Germ cell mutagenicity :

No data available.

f) Carcinogenicity :

No data available.

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g) Reproductive toxicant :

No data available.

h) Specific target organ systemic toxicity - single exposure :

No data available.

i) Specific target organ systemic toxicity - repeated exposure :

No data available.

j) Aspiration hazard :

No data available.

11.1.2. Mixture

11.1.2.1 Information on hazard classes

a) Acute toxicity :

Oral route : No data available.

Dermal route : No data available.

Inhalation route (Dusts/mist) : No data available.

b) Skin corrosion/skin irritation :

No data available.

c) Serious damage to eyes/eye irritation :

No data available.

d) Respiratory or skin sensitisation :

No data available.

e) Germ cell mutagenicity :

No data available.

f) Carcinogenicity :

No data available.

g) Reproductive toxicant :

Presumed human reproductive toxicant.

May damage the unborn child.

h) Specific target organ systemic toxicity - single exposure :

No data available.

i) Specific target organ systemic toxicity - repeated exposure :

No data available.

j) Aspiration hazard :

No data available.

11.1.2.2 Other information

Monograph(s) from the IARC (International Agency for Research on Cancer) :

CAS 58-08-2 : IARC Group 3 : The agent is not classifiable as to its carcinogenicity to humans.

11.2. Information on other hazards

Endocrine disrupting properties

The mixture does not contain any substance evaluated as an endocrine disruptor with effects on human health.

SECTION 12 : ECOLOGICAL INFORMATION

12.1. Toxicity

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

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12.6. Endocrine disrupting properties

The mixture does not contain any substance evaluated as an endocrine disruptor with environmental effects.

12.7. Other adverse effects

No data available.

German regulations concerning the classification of hazards for water (WGK, AwSV Annex I, KBws) :

Nicht wassergefährdend : Not hazardous for water.

SECTION 13 : DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1. Waste treatment methods

Do not pour into drains or waterways.

Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging :

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

SECTION 14 : TRANSPORT INFORMATION

Exempt from transport classification and labelling.

14.1. UN number or ID number

-

14.2. UN proper shipping name

-

14.3. Transport hazard class(es)

-

14.4. Packing group

-

14.5. Environmental hazards

-

14.6. Special precautions for user

-

14.7. Maritime transport in bulk according to IMO instruments

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SECTION 15 : REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Classification and labelling information included in section 2:

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 2023/707.

- EU Regulation No. 1272/2008 amended by EU Regulation No. 2024/2564. (ATP 22)

Container information:

No data available.

Particular provisions :

No data available.

Restrictions applied under Title VIII of Regulation (EC) No. 1907/2006 (REACH):

The mixture contains at least one restricted substance under Annex XVII of Regulation (EC) No. 1907/2006 (REACH): <https://echa.europa.eu/substances-restricted-under-reach>. Please refer to Section 3 to identify the substance involved.

Banned from sale to the general public (EC Regulation No. 1907/2006) - For professional users only.

Authorisations agreed under Title VII of Regulation (EC) No.1907/2006 (REACH):

The mixture does not contain any substance subject to authorisation according to Annex XIV of REACH Regulation (EC) No 1907/2006: <https://echa.europa.eu/fr/authorisation-list>.

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Substances that deplete the ozone layer (EC Regulation No. 1005/2009, Montreal Protocol) :

The mixture does not contain any substance posing a risk to the ozone layer.

Persistent organic pollutants (POP) (Regulation (EU) 2019/1021):

The mixture does not contain a persistent organic pollutant.

PIC Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals (Rotterdam Convention):

The mixture is not subject to the Prior Informed Consent (PIC) procedure.

Explosives precursors :

The mixture does not contain any substance subject to Regulation (EU) 2019/1148 on the marketing and use of explosives precursors.

German regulations concerning the classification of hazards for water (WGK, AwSV Annex I, KBws) :

Nicht wassergefährdend : Not hazardous for water.

15.2. Chemical safety assessment

No data available.

SECTION 16 : OTHER INFORMATION

Wording of the phrases mentioned in section 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.
H360Df	May damage the unborn child. Suspected of damaging fertility.

Abbreviations and acronyms :

LD50 : The dose of a test substance resulting in 50% lethality in a given time period.
LC50 : The concentration of a test substance resulting in 50% lethality in a given period.
REACH : Registration, Evaluation, Authorization and Restriction of Chemical Substances.
ATE : Acute Toxicity Estimate
BW : Body Weight
CMR: Carcinogenic, mutagenic or reprotoxic.
ADR : Agreement concerning the international carriage of dangerous goods by road.
GHS08 : Health hazard
IATA : International Air Transport Association.
IMDG : International Maritime Dangerous Goods.
ICAO : International Civil Aviation Organisation
PBT: Persistent, bioaccumulable and toxic.
PIC: Prior Informed Consent.
POP: Persistent Organic Pollutant.
RID : Regulations concerning the International carriage of Dangerous goods by rail.
SVHC : Substances of very high concern.
WGK : Water Hazard Class.

The information contained in this safety data sheet is based on our current knowledge at the time of publication and is provided in good faith. It does not constitute any guarantee of specific product properties nor establish any contractual relationship. The user remains solely responsible for safe and compliant use of the product in accordance with current regulations.
