

**Phentolamine Mesylate for Injection, USP (5 mg/vial)****MATERIAL SAFETY DATA SHEET**

according to EC 1907/2006

Printed 2/7/2018

Creation Date 6/2/2018  
Revision 01 date 6/2/2018

Trade name: Not available

**SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING****1.1 Product identifiers**

Product name: **Phentolamine Mesylate for Injection, USP (5 mg/vial)**  
 Trade name: 4,5-Dihydro-2-[N-(m-hydroxyphenyl)-N-(p-methyl-phenyl)aminomethyl]-1H-imidazole 1:1methanesulfonate  
 Chemical Name: Not available  
 Synonyms: Not available  
 CAS number: -

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

Identified uses : Pharmaceutical

**1.3 Details of the supplier of the safety data sheet**

Supplier: NerParMa srl  
 Viale Pasteur,10 - 20014 Nerviano (Milan) - Italy  
 Email: MDSD@nmsgroup.it

**1.4 Emergency telephone number**

NerParMa srl  
 Tel. +39 331 581111 - working hours (GTM +1)

**SECTION 2. HAZARDS IDENTIFICATION****2.1 Classification of the substance or mixture**

Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]  
 Exempt from requirements – regulated as medicinal product

**2.2 Label elements**

Labelling according Regulation (EC) No 1272/2008



Pictogram:

Signal word **Warning**

Hazard statement(s):

H302: Harmful if swallowed  
 H315: Causes serious irritation  
 H319: Causes skin irritation

Precautionary statement(s)

P280: Wear protective gloves/protective clothing/eye protection/face protection  
 P264: Wash hands thoroughly after handling

Response

P302 + P352 + P362 + P364 - IF ON SKIN: Wash with plenty of soap and water. Take off contaminated clothing and wash it before reuse.

P332 + P313 - If skin irritation occurs: Get medical attention.

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes.  
 Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 - If eye irritation persists: Get medical attention.

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Supplemental Hazard Statements

None

2.3 Other hazards

None

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

3.1 Substances

N.A.

3.2 Mixtures

Hazardous ingredients according to Regulation (EC) No 1272/2008

Chemical Name	EC No.	Reach Reg. No.	CAS No	Weight %	CLP/GHS classification
Phentolamine Mesylate	EEC No. 200-604-6	Not Available	65-28-1	10-30	Acute Tox.(O) 4: H302 Acute Tox.(D) 4: H312 Skin Corr. 2: H315 Eye Damage 2: H319 Acute Tox.(I) 4: H332 TOST (SE) 3: H335 H336
D-Mannitol	EEC No. 200-711-8	Not Available	69-65-8	60-100	No data available

Full text phrases reported in section 16

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section. Occupational exposure limits, if available, are listed in Section 8

**SECTION 4. FIRST AID MEASURES**

4.1 Description of first aid measures

General advice Consult a physician. Show this safety data sheet to the doctor in attendance.

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects

Eye contact Causes serious eye irritation.  
 Inhalation No known significant effects or critical hazards.  
 Skin contact Causes skin irritation.  
 Ingestion No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact Adverse symptoms may include the following: pain or irritation  
 watering  
 redness

Inhalation No known significant effects or critical hazards.  
 Skin contact No known significant effects or critical hazards

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Ingestion Adverse symptoms may include the following:  
irritation  
redness

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

Notes to Physician In case of inhalation of decomposition products in a fire, symptoms may be delayed.

The exposed person may need to be kept under medical surveillance for 48 hours

Specific treatments No specific treatment

Protection of first-aiders No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

**SECTION 5. FIRE-FIGHTING MEASURES**

**5.1 Extinguishing media**

Suitable extinguishing media

Use an extinguishing agent suitable for the surrounding fire.  
No information available

**5.2 Special hazards arising from the substance or mixture**

No specific fire or explosion hazard.  
Decomposition products may include the following materials:  
carbon dioxide  
carbon monoxide  
nitrogen oxides  
sulfur oxides

**5.3 Advice for firefighters** No special measures are required.

**5.4 Further information** no data available.

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

**6.1 Personal precautions, protective equipment and emergency procedures**

Wear respiratory protection. Avoid dust/aerosol formation. Avoid breathing dust, vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. For personal protection see section 8.

**6.2 Environmental precautions**

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

**6.3 Methods and materials for containment and cleaning up**

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

**6.4 Reference to other sections**

For disposal see sections 8 and 13

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**SECTION 7. HANDLING AND STORAGE**

**7.1 Precautions for safe handling**

Avoid contact with skin and eyes and clothing. Avoid formation of dust/aerosols. Provide appropriate exhaust ventilation at places where dust/aerosol is formed. For precautions see section 2.2.

**7.2 Conditions for safe storage, including any incompatibilities**

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

**7.3 Specific end use(s)**

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

**SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

**8.1 Control parameters**

Components with workplace control parameters  
Not available

**8.2 Exposure controls**

**Appropriate engineering controls**

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product

**Personal protective equipment**

**Eye/face protection**

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as EN 166(EU) and or NIOSH (US).

**Skin protection**

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

**Full contact**

Material: Disposable gloves

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

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Body Protection	Complete suit protecting against chemicals, the type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Respiratory protection	Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N99 (US) or type P2 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as CEN (EU) and/or NIOSH (US)
Control of environmental exposure	Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**9.1 Information on basic physical and chemical properties**

- a) Appearance                      Physical state: Solid. [Powder cake.]  
    Colour: White to off-white
- b) Odour                                No odor.
- c) Odour Threshold                Not available.
- d) pH                                    Not available
- e) Melting point/freezing point  
    177 to 181°C (350.6 to 357.8°F)
- f) Initial boiling point and boiling range  
    Not available
- g) Flash point                        Not available
- h) Evaporation rate                Not available
- i) Flammability (solid, gas)      Not available
- j) Upper/lower flammability or explosive limits  
    Not available
- k) Vapour pressure                Not available
- l) Vapour density                    Not available
- m) Relative density                Not available
- n) Water solubility                Not available
- o) Partition coefficient: n-octanol/water  
    Not available
- p) Auto-ignition temperature  
    Not available
- q) Decomposition temperature  
    Not available
- r) Viscosity                            Not available
- s) Explosive properties            Not available
- t) Oxidizing properties            Not available

**9.2 Other safety information**

No information available

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**SECTION 10. STABILITY AND REACTIVITY**

- 10.1 Reactivity** No specific test data related to reactivity available for this product or its ingredients
- 10.2 Chemical stability** Stable under recommended storage conditions
- 10.3 Possibility of hazardous reactions** None under normal process
- 10.4 Conditions to avoid** Do not expose to extreme temperatures
- 10.5 Incompatible materials** Reactive or incompatible with the following materials: oxidizing materials.
- 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 There is no data available
- Skin corrosion/irritation There is no data available
- Serious eye damage/eye irritation No information available
- Sensitisation No information available
- Mutagenicity No information available
- Carcinogenicity There is no data available
- Reproductive toxicity There is no data available
- Specific target organ toxicity - single exposure

Name	Category	Route of exposure	Target organs
Phentolamine mesilate	Category 3	Not applicable.	Respiratory tract irritation

Specific target organ toxicity - repeated exposure  
There is no data available

Aspiration hazard There is no data available

Numerical measures of toxicity

Acute toxicity estimates:

Route	ATE value
Oral	2994 mg/kg
Dermal	6586.8 mg/kg
Inhalation (vapors)	65.87 mg/L

Other Information There is no data available

**SECTION 12. ECOLOGICAL INFORMATION**

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**12.1 Toxicity**

Ecotoxicity effects            No information available

**12.2 Persistence and degradability**

No information available

**12.3 Bioaccumulative potential**

No information available

**12.4 Mobility in soil**

No information available

**12.5 Results of PBT and vPvB assessment**

No information available

**12.6 Other adverse effects**

Endocrine disruptor information No information available

**SECTION 13. DISPOSAL INFORMATION**

**13.1 Waste treatment methods**

Waste from residues/ unused products            Dispose in accordance to local regulations  
Contaminated packaging    Empty containers should be taken for local recycling, recovery or waste disposal

**SECTION 14. TRANSPORT INFORMATION**

**14.1 UN-No**

Not hazardous for transport

**14.2 Proper Shipping Name (PSR)**

Not hazardous for transport

**14.3 Transport hazard class(es)**

ADR / RID / AND (land transport) Not hazardous for transport

IMDG (sea transport)            Not hazardous for transport

IATA / ICAO (air transport)        Not hazardous for transport

**14.4 Packaging group**

Not hazardous for transport

**14.5 Environmental hazards**

Marine Pollutant            No information available

**14.6 Special precautions for users**

No information available

**14.7 Transport in bulk according to annex II of MARPOL 73/78 and IBC code**

Technical name            No information available

Ship type            No information available

Annex II            No information available

**SECTION 15. REGULATORY INFORMATION**

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This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

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

Regulation 1907/2006/EC (REACH) and successive modifications

Regulation 1272/2008 (CLP) and successive modifications

D.LGS 81/2008 and successive modifications and Dir. 2009/161/EU

REGULATION (EU) 2015/830

**15.2 Chemical Safety Assessment**

No information available

**SECTION 16. OTHER INFORMATION**

**CLP/GHS - Regulation**

**Hazard statements**

**Full text of H-statements referred under sections 2 and 3**

H302: Harmful if swallowed

H315 Causes serious irritation

H319 Causes skin irritation

Training appropriate for workers is required to ensure protection of human health and environment

Application/Drug Class                      Anti hypertensive

**Source of data**

RETECS REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES

ACGIH AMERICAN CONFERENCE OF INDUSTRIAL HYGIENISTS

HSDB HAZARDOUS SUBSTANCES DATA BANK

NIOSH NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

IARC INTERNATIONAL AGENCY FOR RESEARCH ON CANCER

ECHA (European chemical agency) databases

FDA (Food and Drug administration) database

EMA (European Medicines agency)

ChemAdvisor

Chemspider database

MSDS Creation Date: 6/2/2018

Issue # 01

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*indirect, incidental, consequential, or exemplary damages howsoever arising, even if the company has been advised of the possibility of such damages.*

**MSDS released by :**

NerPharMaSrl

MSDS@nmsgroup.it



For Designated Drop Ship Only Products, Please Use Page 3

**MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION**

Is this product (check all that apply):

- a. Cytotoxic?  No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  No
- Is the product a CA Prop 65 reproductive toxicant?  No
- Does the product label bear a CA Prop 65 warning?  No

- c. Contact Hazard?  No
- d. Does this product require special clean-up instructions?  No
- (If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP?  No

Is this product regulated for shipment by DOT or IATA?  No

(If yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?  No

Is the product restricted for air shipment? If so, indicate restriction:

Passenger

Cargo

Passenger & Cargo

Is this a reportable quantity?  No

RQ Threshold:

Is this a marine pollutant?  No

Is this product shipped utilizing an authorized DOT exception or Special Permit?  No

(If yes, identify method below)

- Limited Quantity
- Consumer Commodity (ORM-D)
- Small Quantity (49 CFR 173.4)
- Special Permit: DOT-SP
- Special Provision (listed in Column 7 of 49 CFR 172.101):
- SP#

**ADDITIONAL STORAGE INFORMATION**

Is the Product...:

- Controlled Substance?  No
- Controlled by State(s)?  No
- ARCOS Reportable?  No
- Schedule No. (inc. N for non-narcotic)
- Controlled Substance Code
- Listed Chemical (List 1 or II)  No
- If yes, indicate which:
- Is it a scheduled listed chemical product?

**CLASS OF TRADE RESTRICTION:**

No restriction, select "Yes" if sold to retail pharmacy, hospice, clinic, and physician offices  Yes

Restricted to retail pharmacy only:  No

Restricted to hospital, clinics, and physician offices only:  No

Restricted from US territories? (explain in comments)  No

Comments:

**SDS Hazard Classification**

- Organic  Corrosive
- Inorganic  Oxidizer
- Steroid/Androgen  Contact Hazard
- Aerosol Class: Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug?  No

If yes, indicate which:

**Hazardous Waste Identification**

EPA Hazardous Waste Code:

**REMS or REGISTRY RESTRICTIONS**

Is there a REMS on this product?  No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, I pledge program?)

**REMS:**

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively?

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

DEA #:

PCPDP #:

NPI #:

Comments:

Registry:

Registry Program Contact Name:  Phone:

Comments:

**RETURN INSTRUCTIONS**

Contact tel. # if product received damaged:

Is product returnable for credit:  Yes

URL/link to returns policy:

Special regulations or returns requirements for this product in certain states?  Yes

If so, which states? Other requirements? Comments?

Georgia, Mississippi and North Carolina. Requests can be made via fax or email customercare@jagpharma.com

**MISCELLANEOUS NOTES and/or Image of Product Barcode:**

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete. **Standard Order Receipt and Processing**

Order Method for Designated Drop Ship Product:

Purchase orders may be accepted by:

a. EDI  Yes

b. Autotax  Yes Fax Number: 815-624-7687

c. Fax  Yes Fax Number: 815-624-7687

d. Phone only  Yes Phone No.: 855-225-8244

e. Supplier Web Site only  No Site Address: \_\_\_\_\_

Minimum Order Quantity: \_\_\_\_\_

Supplier's Customer Service Number: 855-225-8244

Contracted 3PL company / contact #: \_\_\_\_\_

Name: \_\_\_\_\_ Phone: \_\_\_\_\_

Purchase order daily receipt cut off time by supplier: 12:00 PM Central

Cut off time: \_\_\_\_\_

Shipping lead time of PO: \_\_\_\_\_ Hours \_\_\_\_\_ Days

Ships same day for next day receipt: \_\_\_\_\_

Ships for second day receipt: \_\_\_\_\_

Ships regular ground for 3-10 days receipt: \_\_\_\_\_

**Expedited Freight Charges or Other Designated Drop Ship Fees:**

Expedited freight fees billed with each order: \_\_\_\_\_

Drop Ship service fee billed with each order: \_\_\_\_\_

Drop Ship miscellaneous fees billed: \_\_\_\_\_

Comments: \_\_\_\_\_

**Overnight and Priority/Overnight PO Processing**

Overnight receipt available:  Yes

PO Receipt cut off time: 12:00 PM

Days of week overnight is available:

<input checked="" type="checkbox"/>	Monday
<input checked="" type="checkbox"/>	Tuesday
<input checked="" type="checkbox"/>	Wednesday
<input checked="" type="checkbox"/>	Thursday
<input type="checkbox"/>	Friday

Priority Overnight receipt available:  Yes

PO Receipt Cut off time: 12:00 PM

**Class of Trade Restriction:**

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes

Restricted to retail pharmacy only:  No

Restricted to hospital, clinics, and physician offices only:  No

Restricted from US territories? (explain in comments)  No

Comments: \_\_\_\_\_

**Return Instructions**

Contact # if product is received damaged: 855-225-8244

Is product returnable for credit:  Yes

URL/link to returns policy: \_\_\_\_\_

Special regulations or returns requirements for this product in certain states?  Yes

If so, which states? Other requirements? Comments? \_\_\_\_\_

Georgia, Mississippi and North Carolina. Requests can be made via fax or email customercare@tfc

**Other Data Information Required to Process PO:**

Patient Procedure Date: \_\_\_\_\_

Physician Name: \_\_\_\_\_

Physician/Clinic Phone #: \_\_\_\_\_

Physician State License #: \_\_\_\_\_

Physician/Clinic DEA #: \_\_\_\_\_

Physician/Clinic Specialty: \_\_\_\_\_

Miscellaneous Notes: \_\_\_\_\_

**ADDITIONAL INFORMATION**

Is product order for scheduled patient procedure? \_\_\_\_\_

Is product order for restocking purposes? \_\_\_\_\_