NerPharMa

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-imidizole 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.

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

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

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 appropriatecontainment 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 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.

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

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

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

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) databeses
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

Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Item | [ ] Final Version | Date: 3/5/2018

PRODUCT INFORMATION

Company Name: TAGI Pharma, Inc.
Application: ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 207686
DUNS: 963322560
Proprietary Name (if Applicable) and Established Name:
Selling Unit NDC: 51224-012-10
Individual Unit NDC:
UPC:
UDI:
CVX Code:
MVX Code:
Description: Phentolamine Mesylate for injection, USP 5mg/vial. For IM or IV use Lyophilized
Active Ingredient(s): Phentolamine Mesylate for Injection, USP 5mg
URL for Additional Product Information: www.tagipharma.com

Address: 722 Progressive Lane
Address 2: Room 205
City: South Beloit
State: IL
Zip: 61086
Key Contact: Melissa Bradley
Email: mbradley@tagipharma.com
Phone Number: 815-624-7685
Fax: 815-624-7687
Product Therapeutic Classification:

ADDITIONAL PRODUCT INFORMATION

Is the Product...
a legend device? No
reverse numbered? No
co-licensed? No
Is the Product... Direct-Ship Only
Is the Product... Neither

If Unit Dose, is item bar coded to unit dose for hospital scanning?
If Unit Dose NDC, indicate NDC here:
Country of Origin: Italy
Is this product covered under the Trade Agreements Act (TAA)? Yes

PRODUCT DESCRIPTION INFORMATION

Size:
Strength: 5mg
Dosage Form: Vial
Product Shape:
Product Color: White or off-white, crystalline powder
Product Imprint:

FOR GENERIC DRUG PRODUCTS

[ ] Authorized Generic *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating: AP
II. Generic Equivalent to What Brand?: Regitine

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes
GLN:
Is product exempt from DSCSA? No
If yes, select exemption:
Other exemption - Write in:
Is product repackaged? No
Is product sold by manufacturer's exclusive distributor? No
If Yes, was original product purchased direct from mfr?
Has FDA granted waiver/exception/exemption for product? No
If yes, attach documentation from FDA.

GTIN PRODUCT INFORMATION

Serialized? No
If not, when? 11/1/2018
Items aggregated?

Level	Saleable Unit			Quantity	GTIN-14
Item		2D	Linear		
Box/Carton/Bundle/Inner Pack		2D	Linear		
Case		2D	Linear		
Pallet		2D	Linear		
		2D	Linear		
		2D	Linear		
		2D	Linear		
		2D	Linear		

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.
Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F
Other Temperature Range Requirement (write in): with excursions between 15°to 30°C)
Is this product to be shipped to customers on ice? No
Is this product to be shipped to customers on dry ice? No

b. Contact for temperature excursion questions:
Name: Mat Mathis
Number: 815-624-7685
Group E-mail: mmathis@tagipharma.com

c. Special regulations for product in any states? No
Special returns requirements for this product?

d. Store product (unit of sale) upright? Yes
Protect product (unit of sale) from light? Yes

e. Shelf life: 24 Months
Initial shelf life at launch (if different): Months

ORDER INFORMATION

Unit of Sale

	Bottle
	Box/Carton
	Ampule
	Glass
	Tube
	Vial Liquid Sgl
	Vial Liquid Multi
x	Vial Powder Sgl
	Vial Power Multi
	Other: Write In

What is the NDC selling unit?
1 box of 10 vials
(Write-in, e.g. 1 Box of 10 Vials)
Minimum order quantity? No
If Yes, how many of which package type?
Each
Inner/Carton/Pack
Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
(Write-in, e.g. 1 Vial)
Rx billing unit to pharmacy:
Each
Gram
Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	1 oz	1.375	2.5	1.375		1
Box/Carton/Bundle/ Inner Pack:						
Case:	10oz	6.875	2.5	2.75		10
Pallet:						
UPC:	Case:					
	Carton:					

COST INFORMATION

Regular Cost
Invoice Cost (WAC) ($): $4,180.00
Federal Excise Tax Per Unit of Sale
As of date: 3/5/2018

WHOLESALER USE ONLY

Vendor #:
Whsl. Code #:
Fineline Code:

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature: Melissa Bradley

HDA

Standard Pharmaceutical Product Information (Page 2)

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?

Is the product a CA Prop 65 carcinogen? 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#

SDS Hazard Classification

- ☐ Organic
- ☐ Inorganic
- ☐ Steroid/Androgen
- ☐ Corrosive
- ☐ Oxidizer
- ☐ 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, iPledge 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

ADD'L 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 I 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, 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 tel. # if product received damaged: 815-624-7685

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@tagipharma.com

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

HDA

Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product

Purchase orders may be accepted by:

a. EDI	Yes		
b. Autofax	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:

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier

Cut off time: 12:00 PM Central

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:

x	Monday
x	Tuesday
x	Wednesday
x	Thursday
	Friday

Priority Overnight receipt available: Yes

PO Receipt Cut off time: 12:00 PM

Saturday Overnight receipt available:

PO Receipt Cut off time:

Order receipt method: Phone: Phone #:

Fax: Fax #:

EDI:

Overnight Fees apply:

Other fees apply:

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:

Other Data Information Required to Process PO:

Patient Procedure Date:

Physician Name:

Physician/Clinic Phone #

Physician State License #

Physician/Clinic DEA #:

Physician/Clinic Specialty:

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, Missippi and North Carolina. Requests can be made via fax or email customercare@ta

Miscellaneous Notes:

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?

Is product order for restocking purposes?