

1. PRODUCT AND COMPANY IDENTIFICATION**1.1 Product identifiers**

Product name : Phentermine hydrochloride

Product Number : P8653

Brand : Sigma

CAS-No. : 1197-21-3

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

Identified uses : Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheetCompany : Sigma-Aldrich
3050 Spruce Street
SAINT LOUIS MO 63103
USA

Telephone : +1 800-325-5832

Fax : +1 800-325-5052

1.4 Emergency telephone number

Emergency Phone # : (314) 776-6555

2. HAZARDS IDENTIFICATION**2.1 Classification of the substance or mixture****GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)**

Acute toxicity, Oral (Category 3), H301

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 GHS Label elements, including precautionary statements

Pictogram



Signal word : Danger

Hazard statement(s)

H301 : Toxic if swallowed.

Precautionary statement(s)

P264 : Wash skin thoroughly after handling.
P270 : Do not eat, drink or smoke when using this product.
P301 + P310 : IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P321 : Specific treatment (see supplemental first aid instructions on this label).
P330 : Rinse mouth.
P405 : Store locked up.
P501 : Dispose of contents/ container to an approved waste disposal plant.**2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none**

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Formula : C₁₀H₁₅N · HCl
Molecular Weight : 185.69 g/mol
CAS-No. : 1197-21-3
EC-No. : 214-821-9

Hazardous components

Component	Classification	Concentration
Phentermine hydrochloride	Acute Tox. 3; H301	-

For the full text of the H-Statements mentioned in this Section, see Section 16.

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. Move out of dangerous area.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

no data available

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Carbon oxides, nitrogen oxides (NO_x), Hydrogen chloride gas

5.3 Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

5.4 Further information

no data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation.

Evacuate personnel to safe areas. Avoid breathing dust.

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 section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.
For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

7.3 Specific end use(s)

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

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 NIOSH (US) or EN 166(EU).

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.

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 NIOSH (US) or CEN (EU).

Control of environmental exposure

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

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

- | | |
|---------------------------------|-------------------|
| a) Appearance | Form: solid |
| b) Odour | no data available |
| c) Odour Threshold | no data available |
| d) pH | no data available |
| e) Melting point/freezing point | no data available |

f) Initial boiling point and boiling range	no data available
g) Flash point	no data available
h) Evaporation rate	no data available
i) Flammability (solid, gas)	no data available
j) Upper/lower flammability or explosive limits	no data available
k) Vapour pressure	no data available
l) Vapour density	no data available
m) Relative density	no data available
n) Water solubility	no data available
o) Partition coefficient: n-octanol/water	no data available
p) Auto-ignition temperature	no data available
q) Decomposition temperature	no data available
r) Viscosity	no data available
s) Explosive properties	no data available
t) Oxidizing properties	no data available

9.2 Other safety information

no data available

10. STABILITY AND REACTIVITY

10.1 Reactivity

no data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

no data available

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

Other decomposition products - no data available

In the event of fire: see section 5

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

LD50 Oral - rat - 188.0 mg/kg

Inhalation: no data available

Dermal: no data available

no data available

Skin corrosion/irritation

no data available

Serious eye damage/eye irritation

no data available

Respiratory or skin sensitisation

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

no data available

no data available

Specific target organ toxicity - single exposure

no data available

Specific target organ toxicity - repeated exposure

no data available

Aspiration hazard

no data available

Additional Information

RTECS: SH4950000

12. ECOLOGICAL INFORMATION**12.1 Toxicity**

no data available

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

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects

no data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)

UN number: 2811 Class: 6.1 Packing group: III
Proper shipping name: Toxic solids, organic, n.o.s. (Phentermine hydrochloride)
Marine pollutant: No
Poison inhalation Hazard: No

IMDG

UN number: 2811 Class: 6.1 Packing group: III EMS-No: F-A, S-A
Proper shipping name: TOXIC SOLID, ORGANIC, N.O.S. (Phentermine hydrochloride)
Marine pollutant: No

IATA

UN number: 2811 Class: 6.1 Packing group: III
Proper shipping name: Toxic solid, organic, n.o.s. (Phentermine hydrochloride)

15. REGULATORY INFORMATION

SARA 302 Components

SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards

Acute Health Hazard

Massachusetts Right To Know Components

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components

	CAS-No.	Revision Date
Phentermine hydrochloride	1197-21-3	

New Jersey Right To Know Components

	CAS-No.	Revision Date
Phentermine hydrochloride	1197-21-3	

California Prop. 65 Components

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3.

Acute Tox.	Acute toxicity
H301	Toxic if swallowed.

HMS Rating

Health hazard: 2
Chronic Health Hazard:
Flammability: 0
Physical Hazard 0

NFPA Rating

Health hazard: 2
Fire Hazard: 0
Reactivity Hazard: 0

Further information

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Preparation Information

Sigma-Aldrich Corporation
Product Safety – Americas Region
1-800-521-8956

Version: 5.1

Revision Date: 06/27/2014

Print Date: 10/15/2015



CIDMA Standard Pharmaceutical Product Information

New Item Promotion/Deal Open Stock Post Launch Change

Date: 1-9-13

PRODUCT INFORMATION

Manufacturer/Broker Name: TAGI Pharma, Inc. Number: 51224-203-70 NDA ANDA

Rx Product Name: Phenelzine Hydrochloride, USP NDC 51224-203-70 UPC/GTIN

Product ID Number: Yes No How? 2D RFD Pallet Case Item

Description: Phenelzine Hydrochloride, USP 15mg Capsules

URL for additional product information:

Address: 722 Progressive Lane Rm 205

City, State, Zip: South Beloit, Beloit 51080

Key Contact: Danyce Kemp Email: dkemp@tagipharma.com

Phone Number: 815-624-7685 Fax:

Is the Product... A Direct Ship Item A Drop Ship Item

a. Controlled Drug? Yes No If Yes, Schedule Number: IV

ARCOS reportable? Yes No Biological? Yes No

Co-Licensed? Yes No Repackaged? Yes No

a Legend Device? Yes No Does the product contain DEHP? Yes No

Active ingredient, if product contains a drug: Phenelzine Hydrochloride

Country of Origin: USA

Harmonization Code Number for International Shipping:

Is this product a Hazardous Material or Cytotoxic Agent? *Yes No

*If yes, provide additional information on page 2.

Attach copy of MATERIAL SAFETY DATA SHEET (MSDS) and PACKAGE INSERT

ADDITIONAL PRODUCT INFORMATION

Product Shape

Product Color Gray/Yellow

Product Imprint

Is there a minimum order quantity? Yes No

If yes, how many? 1 Case /6 bottles

Of what package type? Case Carton Item

Shelf life: 24 Months

Initial shelf life at launch (if diff?)

Whsl. Code #:

Fineline Code: Unit Dose Unit of Use

Is Item? Unit Dose Unit of Use

If Unit Dose, is item bar coded to unit dose for hospital scanning? Yes No

SPECIAL HANDLING AND STORAGE REQUIREMENTS

a. Temperature - Indicate the USP temperature range for this product.

I. Freezer - between -25 and -10 C (-13° - 14° F)

II. Cold - between 2 and 8 C (36° - 46° F)

III. Cool - between 8 and 15 C (46° - 59° F)

IV. Controlled Room - between 20 and 25 C (68° - 77° F)

allows for excursions between 15 and 30 C (59° - 86° F)

V. Excessive Heat - above 40 C (>104° F)

VI. Other Temperature Range Requirement (write in)

VII. No Requirement

b. Contact for temperature excursion questions:

Name: Danyce Kemp Number: 815-624-7685

Is this product to be shipped to customers on ice? Yes No

Is this product to be shipped to customers on dry ice? Yes No

c. Special regulations for this product in certain states? *Yes No

Special returns requirements for this product? *Yes No

d. Store product upright? Yes No

Protect product from light? Yes No

*Please provide additional information on page 2.

ITEM AND PACKING INFORMATION

Size/Strength/ Form 15 mg

Unit of Sale Bottle Box Glass Jar Ampule Other:

UPC Code Case: 51224-203-70

Mstr. Shpr. Inner Case Pk 6 bottles 1000 capsules per bottle

Wght. Lbs. Case: 4.6 lbs. Carton: 12.4 oz.

Cube Dimensions Case Depth: 11.25" Height: 6.25" Width: 7.5"

Item Depth: 11.25" Height: 6.25" Width: 3"

Pallet Depth: 11.25" Height: 6.25" Width: 3"

Cases/ Pallet

I. Orange Book Rating: AA

II. Product Color: Gray/Yellow

For Generic Drug Products:

III. Brand Name Equivalent:

IV. Generic Name for Brand: Phenelzine HCl

COST INFORMATION

Regular Cost (\$)

Purchase Allowance OI BB %

DZ EA PPK

Distribution OI BB %

Invoice Cost (\$)

Net Cost (\$)	Mfr's AWP	Avg Retail Price (\$)	SRP (\$)	Excise Tax
\$265.00	\$1195.00			
\$1590.00	\$7170.00			

This offer is made on a proportionally equal basis to all sellers' accounts complete with customer. Signature: Danyce Kemp



HAZARDOUS MATERIAL INFORMATION

Is this product (check all that apply):

a. Cytotoxic?

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?

Yes No
 Yes No

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

Warning appears on label

c. Contact Hazard?

Yes No
 Yes No

d. Does this product require special clean-up instructions?

If yes, attach MSDS with special instructions

DANGEROUS GOODS SHIPPING INFORMATION

Is this product regulated for shipment by the DOT Yes No

(if yes, answer a-d below and provide MSDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

Yes No

Is this product shipped utilizing an authorized DOT exception or Special Permit?

Yes 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# _____

Is the product restricted for air shipment?

Passenger

Cargo

Passenger & Cargo

STORAGE INFORMATION

Please check as appropriate for this product:

Organic

Antineoplastic

Corrosive

Aerosol; Identify NEPA Storage Level:

Precursor

Inorganic

Steroid/Androgen

Oxidizer

Level 1

Level 2

Level 3

Chemical (Describe below):

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (±2.2%)

Other: _____

PRODUCT INFORMATION

Does this product or its components have an MSDS? Yes No

(e.g., chemicals, solutions, products impregnated with solutions, batteries, drugs, etc.)

Attach a copy of MSDS or non-hazard letter.

ADDITIONAL INFORMATION

Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements?

Dispense in a tight container as defined in the USP, with a child-resistant closure(as required).