



SAFETY DATA SHEET

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Product Name Tiagabine Hydrochloride tablets 2 mg, 4 mg, 12 mg and 16 mg**1. Product Information****Product Name :** Tiagabine Hydrochloride tablets 2 mg, 4 mg, 12 mg and 16 mg**Chemical Family:** Mixture**Intended use:** Anti epileptic agent**Details of the manufacturer:**

MSN Laboratories Private Limited.

Formulation Division, Unit - II,

Sy No 1277 & 1319 to 1324

Nandigama Village & Mandal

Ranga Reddy Dist

Telangana State, India.

PIN 509228

Phone: +91 40 3044 9200**2. Hazards Identification****2.1 Classification of the Substance or Mixture:****2.2 Label Elements:****GHS Signal Word:** None**GHS Hazard Phrases:**

Based on evaluation of currently available data this substance or mixture is not classifiable according to GHS.

GHS Precaution Phrases: No phrases apply.**GHS Response Phrases:** No phrases apply.**GHS Storage and Disposal Phrases:**

Please refer to Section 7 for Storage and Section 13 for Disposal information.

2.3 Adverse Human Health Effects and Symptoms:

Material may be irritating to the mucous membranes and upper respiratory tract.

May be harmful by inhalation, ingestion, or skin absorption.

May cause eye, skin, or respiratory system irritation.

To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

3. Composition/Information on Ingredients**C.A.S. No :** : 145821-59-6**Molecular Formula** : $C_{20}H_{25}NO_2S_2.HCl$ **Formula Weight** : 412.01**Chemical Name** : 3-piperidinecarboxylic acid, 1-[4,4-bis(3-methyl-2-thienyl)-3-butenyl]-, hydrochloride, (R)-.**D-Block MASTER**

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4. First Aid Measures

In Case of Inhalation: Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel.
Get immediate medical attention.

In Case of Skin Contact:
Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

In Case of Eye Contact:
Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.

In Case of Ingestion:
Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

5. Fire Fighting Measures

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Carbon monoxide, carbon dioxide, oxides of nitrogen, oxides of sulfur, hydrochloride, and other chlorine-containing compounds

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

6. Accidental Release Measures

6.1 Protective Precautions, Protective Equipment and Emergency Procedures:
Avoid raising and breathing dust, and provide adequate ventilation
As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

6.2 Environmental Precautions: Take steps to avoid release into the environment, if safe to do so.

6.3 Methods and Material For Containment and Cleaning Up:
Contain spill and collect, as appropriate.
Transfer to a chemical waste container for disposal in accordance with local regulations.

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7. Handling and Storage

General Handling:

Avoid breathing dust/fume/gas/mist/vapours/spray
Avoid prolonged or repeated exposure

Storage Conditions: Store tablets at controlled room temperature, between 20-25°C (68-77°F). See USP.
Protect from light and moisture.

8. Exposure Controls/Personal Protection

8.1 Exposure Parameters:

8.2 Exposure Controls:

8.2.1 Engineering Controls (Ventilation etc.):

Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

8.2.2 Personal protection equipment:

Eye Protection: Safety glasses

Protective Gloves: Compatible chemical-resistant gloves

Other Protective Clothing: Lab coat

Respiratory Equipment (Specify Type): NIOSH approved respirator, as conditions warrant.

Work/Hygienic/Maintenance Practices:

Do not take internally.

Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower.

Wash thoroughly after handling.

No data available.

9. Physical and Chemical Properties

Appearance :

2 mg: Light Orange-peach coloured, round shaped, biconvex, film-coated tablets debossed with "MT" on one side and "3" on other side, free from physical defects

4 mg: Yellow coloured, round shaped, biconvex, film-coated tablets debossed with "MT" on one side and "4" on other side, free from physical defects

12 mg: Green coloured, capsule shaped, biconvex, film coated tablets debossed with "MT" on one side and "5" on other side, free from physical defects

16 mg: Blue coloured, capsule shaped, biconvex, film coated tablets debossed with "MT" on one side and "6" on other side, free from physical defects

10. Stability and Reactivity

Reactivity: No data available

Stability: Stable

Stability Note(s): Stable if stored in accordance with information listed on the product insert.

Polymerization: Will not occur

Conditions To Avoid: No data available

Incompatibility - Materials to Avoid: strong oxidizing agents

Hazardous Decomposition or Byproducts:

carbon dioxide, carbon monoxide, hydrogen sulfide, nitrogen oxides and phosgene

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11. Toxicological Information

Information on Toxicological Effects:

The toxicological effects of this product have not been thoroughly studied.

Tiagabine (hydrochloride) - Toxicity Data: Intraperitoneal TDLO (mouse): 0.1 mg/kg; Oral TDLO (woman): 1.44 mg/kg; Oral TDLO (rat): 30 mg/kg;

Chronic Toxicological Effects:

Tiagabine (hydrochloride) - Investigated as a drug.

Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here.

See actual entry in RTECS for complete information.

Tiagabine (hydrochloride) RTECS Number: TM6128245

12. Ecological Information

Toxicity: Avoid release into the environment.

Runoff from fire control or dilution water may cause pollution

Persistence and Degradability: No data available.

Bioaccumulative Potential: No data available.

Mobility in Soil: No data available

Results of PBT and vPvB assessment: No data available

Other adverse effects: No data available

13. Disposal Considerations

Waste Disposal Method: Dispose in accordance with local, state, and federal regulations.

14. Transport Information

DOT (US): Not dangerous goods.

European ADR/RID: Not dangerous goods.

ICAO/IATA: Not dangerous goods.

15. Regulatory Information

Hazard Class: N/A

Identification Number: N/A

Packing Group: N/A

Label: N/A

Emergency Response Guide Book: N/A

Special precautions for users: N/D

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16. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.

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