



MSN Laboratories Private Limited
R&D Center, Formulation Division.

SAFETY DATA SHEET		
Product Name	Doxepin Hydrochloride Capsules USP 10 mg, 50 mg, 75 mg and 100 mg	Page No 1 of 4

1. Identification of the substance/mixture and the company/undertaking

Product Name: Doxepin Hydrochloride Capsules USP 10 mg, 50 mg, 75 mg and 100 mg

Chemical Family: Mixture

Intended use: pharmaceutical product used as Anti Depressant

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

Exposure: Inhalation, Ingestion, Skin contact, Eye contact

Target Organs: eye, skin, mucous membranes, gastrointestinal system

Acute Effects: May cause eye irritation., May cause skin irritation., May cause gastrointestinal effects.,

Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite.

3. Composition/Information on Ingredients

C.A.S. No : : 1229-29-4

Molecular Formula : $C_{19}H_{21}NO.HCl$

Molecular Weight : 315.84 g/mol

Chemical Name : 1-Propanamine, 3-dibenz[b,e]oxepin-11(6H)ylidene-N,N- dimethyl, hydrochloride

4. First Aid Measures

Eye contact

- Rinse immediately with tap water for 10 minutes - open eyelids forcibly
- consult a physician if irritation persists

Skin contact

- Remove immediately contaminated clothes, wash affected skin with water and soap
 - do not use any solvents
 - consult a physician if skin irritation persists



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Inhalation

- Remove the casualty to fresh air and keep him/her calm
- get medical treatment

Ingestion

- Summon a physician immediately
- let drink repeatedly plenty of water and induce vomiting (only if conscious), repeat several times

Note to physician

- treat symptomatically
- in case of accidental exposure, keep a sample of urine in order to determine the content of fluoro- β -alanine

5. Fire Fighting Measures

- Suitable extinguishing media** - Water spray jet, dry powder, foam, carbon dioxide
- Flash point (liquid)** - Not applicable
- Specific hazards**
- Very high probability of ignition of dust whirled up
 - Formation of toxic and corrosive combustion gases (hydrogen fluoride, nitrogen oxides) possible
 - Consider danger for the environment: dike spilled liquid
- Protection of fire-fighters**
- Precipitate gases/vapours/mists with water spray
 - Use self-contained breathing apparatus
 - Avoid skin contact

6. Accidental Release Measures

Personal precautions - ensure adequate ventilation

- keep people away and stay on the upwind side

Environmental protection - do not allow to enter drains or waterways

- if the substance reaches waters or the sewer system, inform the competent authority
- the solvent should be held back due to environmental protection

Methods for cleaning up - collect spilled material (avoid dust formation) and hand over to waste removal in sealed containers

7. Handling and Storage

General Handling: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Releases to the environment should be avoided.

Storage Conditions:

Store at 20°-25°C (68°-77°F). [See USP controlled room temperature.]
Dispense in a tight, light-resistant container with child-resistant closure



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8. Exposure Controls/Personal Protection

Personal protective equipment

- | | |
|---|---|
| Hand protection | - Protective gloves (eg made of neoprene, nitrile or butyl rubber) |
| Eye protection | - Safety glasses |
| General protective and hygiene measures | - Instruction of employees mandatory
- Shower after work recommended |

9. Physical and Chemical Properties

Appearance :

- 10 mg:** Capsules with Yellow opaque body imprinted with "10 mg" in black ink and Yellow opaque cap imprinted with "MD12" in black ink filled with White to off white powder, free from physical defects
- 25 mg :** Capsules with White opaque body imprinted with "25 mg" in black ink and Yellow opaque cap imprinted with "MD13" in black ink filled with White to off white powder, free from physical defects
- 50 mg:** Capsules with Ivory opaque body imprinted with "50 mg" in black ink and Ivory opaque cap imprinted with "MD14" in black ink filled with White to off white powder, free from physical defects
- 75 mg:** Capsules with Green opaque body imprinted with "75 mg" in black ink and Green opaque cap imprinted with "MD15" in black ink filled with White to off white powder, free from physical defects
- 100 mg:** Capsules with White opaque body imprinted with "100 mg" in black ink and Green opaque cap imprinted with "MD16" in black ink filled with White to off white powder, free from physical defects

10. Stability and Reactivity

Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Products: None known

11. Toxicological Information

- | | |
|------------------------------|--|
| Sensitization | - Slightly sensitizing (several species) |
| Subchronic toxicity | - High doses may damage proliferating cells (e.g. bone marrow, leucocytes) |
| Mutagenicity | - May cause mutations in vitro (clastogenic effect in lymphocytes) lymphocyte test; evidence of clastogenicity |
| Reproductive toxicity | - Suspected to be teratogenic and to lower parental fertility |
| Note | - May cause diarrhea, nausea, vomiting, loss of appetite, irritation of mucous membranes and alteration of the hemopoietic system (leukopenia) in dependence of the dose
- Cytostatics are potentially carcinogenic |



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12. Ecological Information

Not applicable

13. Disposal Considerations

Waste Disposal Method: Dispose of waste according to prescribed federal, state, local and competent authority guidelines.

14. Transport Information

DOT Not regulated by U.S. DOT or IATA

15. Regulatory Information

TSCA Status

- FDA Exemption - not on inventory

Reporting Requirements

- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.

- State and local regulations vary and may impose additional reporting requirements

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.