

| SAFETY DATA SHEET |                                  | Page No.1 of 4 |
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| Product Name      | Toremifene Citrate Tablets 60 mg |                |

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

**Product Name: Toremifene Citrate Tablets 60 mg**

**Chemical Family:** Mixture

**Intended use:** Pharmaceutical product used as Antineoplastic drug

**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

**Classification of the substance or mixture**

**Regulation (EC) 1272/2008 [GHS] :** Carcinogenic - Category 1B. Germ Cell Mutagenicity - Category 2.

Reproductive Toxicity - Category 1B. Acute toxicity - oral - Category 4. Specific Target Organ

**Label elements**

**CLP/GHS hazard pictogram**



**CLP/GHS signal word :** Danger

**CLP/GHS hazard statements :** H301 Toxic if swallowed

## 3. Composition/Information on Ingredients

**C.A.S. No** : 89778-27-8

**Molecular Formula** :  $C_{26}H_{28}ClNO \cdot C_6H_8O_7$

**Formula Weight** : 598.10

**Chemical name** : 2-{p-[(Z)-4-chloro-1,2diphenyl-1-butenyl]phenoxy}-N,N- dimethylethylamine citrate (1:1)

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#### 4. First Aid Measures

**Immediate Medical Attention Needed :** Yes

##### Eye contact

- If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes.

If irritation occurs or persists, notify medical personnel and supervisor.

##### Skin contact

- Wash exposed area with soap and water and remove contaminated clothing/shoes.

If irritation occurs or persists, notify medical personnel and supervisor.

##### Inhalation

- Immediately move exposed subject to fresh air. If not breathing, give artificial respiration.

If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

##### Ingestion

- Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel.

Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

##### Indication of immediate medical attention and special treatment needed, if necessary

- Material is a cytotoxic analog of the naturally occurring pyrimidine nucleoside, cytidine. Treat symptomatically and supportively. - If accidental exposure occurs to an individual who is also taking one or more concomitant medications, consult the respective package or prescribing information for potential drug interactions.

##### Note to physician

- treat symptomatically

#### 5. Fire Fighting Measures

**Extinguishing media :** Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.

**Specific hazards arising from the substance or mixture :** No information identified. May emit toxic fumes of carbon monoxide, carbon dioxide, and oxides of nitrogen.

**Flammability/Explosively :** Not considered to be a fire hazard. No explosively data available. High concentrations of finely divided airborne organic particles can potentially explode if ignited.

**Advice for firefighters :** Wear full protective clothing and a self-contained breathing apparatus with a full face piece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

#### 6. Accidental Release Measures

**Personal precautions** - If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. Do not breathe dust

**Environmental protection** - Do not empty into drains. Avoid release to the environment.

**Methods for cleaning up** - DO NOT RAISE DUST. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container suitable for disposal in accordance with applicable waste disposal regulations. Decontaminate the area twice.



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## 7. Handling and Storage

**Precautions for safe handling;** Follow recommendations for handling potent cytotoxic pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid breathing dust. Wash thoroughly after handling

**Specific end use(s) :** No information identified

**Storage :** Store at 25°C (77°F). Excursions permitted to 15-30°C (59-86°F) [See USP Controlled Room Temperature.] Protect from heat and light.

## 8. Exposure Controls/Personal Protection

**Respiratory protection:** required when dusts are generated.

**Eye protection:** Required.

**Hand protection:** Required.

**Industrial hygiene:**

Immediately change contaminated clothing. Wash hands and face after working with substance.

## 9. Physical and Chemical Properties

White to off white colored, round shaped, uncoated tablets debossed with "MT" on one side and plain on other side, free from physical defects.

## 10. Stability and Reactivity

**Reactivity:** No information identified.

**Chemical stability :** Rapid decomposition in neutral or alkaline solutions; pharmacological stability not guaranteed beyond expiration date imprinted on package.

**Possibility of hazardous reactions :** Not expected to occur.

**Conditions to avoid :** Avoid extreme temperatures. Avoid direct sunlight.

**Incompatible materials :** No information identified.

**Hazardous decomposition products :** No information identified

## 11. Toxicological Information

**Irritation/Corrosion** No data available.

**Sensitization** No data available.

## 12. Ecological Information

Do not allow product to enter drinking water supplies, waste water or soil

## 13. Disposal Considerations



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#### Waste from residues

- Observe local/national regulations regarding waste disposal
- Incinerate in qualified installation with flue gas scrubbing
- DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.

#### 14. Transport Information

Transport information: Transport in accordance with local, state, federal regulations.

#### 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

#### 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.