



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

SAFETY DATA SHEET

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Product Name TAPENTADOL TABLETS 50 mg, 75 mg, 100 mg

1. Product Information

Product Name: TAPENTADOL TABLETS 50 mg, 75 mg, 100 mg

Chemical Family: Mixture

Intended use: Opioid Analgesic

Details of the manufacturer:

MSN Pharmaceuticals Inc.

20, Duke Road, Piscataway,

New Jersey (NJ) 08854,

United States (USA).

Phone: +1 732-356-9900

Fax: +1 732-356-1279

2. Hazards Identification

Handling should only be performed by personnel trained and familiar with handling of potent active pharmaceutical ingredients Moderate to severe irritant to the skin and eyes.

3. Composition/Information on Ingredients

C.A.S. No : 175591-09-0

Molecular Formula : $C_{21}H_{24}ClNO$

Molecular Weight : 257.80

Chemical Name : 3-[(1R,2R)-3-(dimethylamino)-1-ethyl-2-methylpropyl]phenol monohydrochloride.

4. First Aid Measures

Eye Contact: Check for and remove contact lenses and flush with copious amounts of water; assure adequate flushing by separating the eyelids with fingers; call a physician.

Skin Contact: flush with copious amounts of water; remove contaminated clothing and shoes; call a physician.

Ingestion: If swallowed, wash out mouth with copious amounts of water; call a physician.

Inhalation: If inhaled, remove to fresh air; if breathing is difficult, give oxygen; if breathing stops, give artificial respiration.

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.

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Fire / Explosion Hazards: Not applicable

6. Accidental Release Measures

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections:

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

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°C - 25°C (68°F - 77°F); excursions permitted to 15° C - 30°C (59° F - 86°F) [see USP Controlled Room Temperature], Protect from moisture

8. Exposure Controls/Personal Protection

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

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9. Physical and Chemical Properties

Appearance:

50 mg: Pink, film-coated, round shaped, biconvex tablets debossed with "25" on one side and "T" on other side, free from physical defects

75 mg: Pink, film-coated, round shaped, biconvex tablets debossed with "26" on one side and "T" on other side, free from physical defects

100 mg: Pink, film-coated, round shaped, biconvex tablets debossed with "27" on one side and "T" on other side, 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

Acute toxicity:

LD50 ORAL – RAT LD50 : 4000 mg/kg

Skin corrosion/irritation: no data available

Serious eye damage/eye irritation: no data available

Respiratory or skin sensitization: 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

Teratogenicity: no data available

Specific target organ toxicity – single exposure (GHS): no data available

Specific target organ toxicity – repeated exposure (GHS): no data available

Aspiration hazard: no data available

Potential Health Effects

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Inhalation: May be harmful if inhaled. May cause respiratory tract irritation. **Skin:** May be harmful if absorbed through skin. May cause skin irritation. **Eyes:** May cause eye irritation.

Ingestion: May be harmful if swallowed.

Signs and Symptoms of Exposure: To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Synergistic effects: no data available

Additional information: RTECS: not applicable

12. Ecological Information

Persistence and degradability: No data available

Toxicity: No data available

Bioaccumulative potential: No data available

Mobility in soil: No data available

PBT and vPvB assessment: No data available

Other adverse effects: No data available

13. Disposal Considerations

Product: Dispose of in accordance with local authority regulations.

Contaminated packaging: Packs that cannot be cleaned should be disposed of in the same manner as the contents. **Uncontaminated packaging** can be recycled.

14. Transport Information

DOT (US): Not dangerous goods.

IMDG: Not dangerous goods.

IATA: Not dangerous goods.

15. Regulatory Information

OSHA Hazards: No known OSHA hazards

SARA 302 Components: SARA 302: No chemical 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 II, Section 313.

SARA 311/312 Hazards: No SARA Hazards

Massachusetts Right To Know Components: No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components: No components are subject to the Pennsylvania Right to Know Act.

New Jersey Right To Know Components: No components are subject to the New Jersey Right to Know Act.

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

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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