



YICHANG HUMANWELL ORAL SOLID DOSAGE PLANT
宜昌人福口服固体制剂厂

Safety Data Sheet
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SECTION 1 – IDENTIFICATION

Product name: Tolterodine Tartrate Extended-release Capsules, 4 mg
Manufacturer: Yichang Humanwell Oral Solid Dosage Plant
519 Donglin Rd, Yichang, Hubei 443112 China
Tel:86 717 7108087
Emergency Contact Phone No.: 86 532 83889090

SECTION 2 – HAZARD(S) IDENTIFICATION

Physical hazards Not classified.
OSHA hazard(s) Not classified.
Label elements 
Signal word Warning
Ingestion Inhalation or oral administration
Health Hazard: Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, indigestion
Environmental Hazard Environment properties have not been investigated. Releases to the environment should be avoided.

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	CAS No.	%	Classification
Tolterodine Tartrate	124937-52-6	0.01-0.05	Category 3
Ethylcellulose	9004-57-3	20-35	-
Hydroxypropyl methylcellulose	9004-65-3	2-5	-
Sugar Spheres	57-50-1	50-60	-

SECTION 4 – FIRST-AID MEASURES



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Skin contact:	Remove contaminated clothing and shoes. Clean the contaminated skin with soap and lots of water at least 15 minutes.
Eye contact:	Draw the eyelid, and clean with water. Obtain medical attention.
Inhalation:	Allow the victim to rest in a well-ventilated area. Seek immediate medical attention.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

SECTION 5 – FIRE-FIGHTING MEASURES

Fire Fighting Protective Equipment	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Extinguisher Media:	Water spray, foam, dry chemical or CO ₂

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Emergency response:	Small spillages: Absorb with a wet disposable towel and collect in a plastic bag designed for pharmaceutical waste. Large spillages: Ensure suitable personal protection during removal of spillages. Ensure adequate ventilation. In case of accident, avoid breathing dust from crushed tablets. Transfer spilled tablets to a suitable container for disposal. Wash the spillage area with water.
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SECTION 7 – HANDLING AND STORAGE

Attentions:	No special precautions are necessary when handling packed product. In case of accident,
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avoid breathing dust from crushed tablets. A void contact with skin and eyes. Follow procedures specified in the National Fire Protection Association Codes and Standards for handling combustible dusts.

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limit	No data
Occupational Hygiene Air Monitoring Methods	No data
Engineering Controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Eye protection	Wear safety glasses or goggles if eye contact is possible.
Gloves	Impervious gloves.
Respirators	Wear suitable respiratory protective equipment.
Other Equipment or procedures	Eyewash station and safety shower in work area.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Size '3' capsule with opaque powder blue cap and body, imprinted with  on the cap and '131' on the body in black ink, containing white to off-white pellets.
pH:	No study data
Melting Point:	No study data
Flash point:	No study data
Burning temperature	No study data

SECTION 10 – STABILITY AND REACTIVITY



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Stability	Stable
Materials or Conditions to Avoid:	Strong acids, strong base, strong oxidizing agents. Avoid direct sunlight, conditions that might generate heat and dispersion as a dust cloud.

SECTION 11 – TOXICOLOGICAL INFORMATION

Inhalation Toxicity	Ingestion of this material may cause effects similar to those seen in clinical use including dizziness, drowsiness, muscle weakness.
Skin Effects	No studies have been conducted.
Eye Effects	May cause eye irritation. May cause excessive watering of the eye.
Ingestion	Adverse effects similar to inhalation may occur.

SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity information	The environmental impact of this product has not been fully investigated. Releases to the environment should be avoided.
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SECTION 13 – DISPOSAL CONSIDERATIONS

Disposal measures for waste	Bury on an authorized landfill site or incinerate under approved controlled conditions, using incinerators suitable for the disposal of noxious chemical waste. Disposal should be in accordance with local, state or national legislation.
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SECTION 14 – TRANSPORT INFORMATION

Storage Condition	Preserve in tight and light resistant containers.
Transportation	The SDS should be accompanied with each shipment, which could be the reference for emergency cases. Check the seals and the completeness of the packages before shipment, and ensure no spills, collapses, falling, or damages during transportation. Prevent from shipping with acid, oxidants, food or food additives. Protect from insolation, rain, and high temperature.

SECTION 15 – REGULATORY INFORMATION

European information	Transportation and shipping of this material is not restricted. It has no known significant hazard requiring special packaging or label for air, maritime, US or European ground transport purposes.
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SECTION 16 – OTHER INFORMATION

Preparing Department:	The SDS was prepared by EHS Department of Yichang Humanwell Oral Solid Dosage Plant.
Disclaimer:	The information and recommendations contained herein are based upon the SDS of API believed to be reliable. However, Yichang Humanwell Oral Solid Dosage Plant does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS



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