



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

Safety Data Sheet
Compile Date: 2016-11-18

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SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product name: SDS for Bupropion Hydrochloride Extended-release
Tablets USP (XL), 150 mg and 300 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.

Health hazards Acute toxicity, oral Category 4

OSHA hazard(s) Not classified.

Label elements



Signal word Warning

Hazard statement Harmful if inhaled.
Causes skin irritation.
Causes serious eye irritation.
May cause respiratory irritation.

Ingestion Inhalation or oral administration

Health Hazard: Adverse effects might occur following ingestion; Minor irritation might occur following direct contact with intact skin; Minor irritation might occur following direct contact with eyes. Adverse effects might occur in the following organ(s) following overexposure: liver.

Environmental Hazard Toxic to aquatic organisms

Fire and Explosion This material is classified as a non-combustible solid and will not support propagating combustion.



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SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	CAS No.	%	Classification
Bupropion Hydrochloride	31667-93-7	50-80	Acute Tox. 4, H302
polyvinyl alcohol	9002-89-5	10-25	-
Magnesium Stearate	557-04-0	1-10	-
Ethyl Cellulose	9004-57-3	0-5	-
Colloidal Silicon Dioxide	112945-52-5	0-5	-
Titanium dioxide	13463-67-7	0-5	-

SECTION 3 – HAZARD INFORMATION

Ingestion:	Inhalation or oral administration
Health Hazard:	Adverse effects may include muscle pain, sore throat, agitation, anxiety, severe headache, skin rash, hives, or itching, buzzing or ringing of the ears, abdominal pain, decreased appetite, constipation, dizziness, dry mouth, increase sweating, trouble sleeping, nausea or vomiting, trembling or shaking, unusual weight loss, blurred vision, drowsiness, fast or irregular heartbeat, change in sense of taste, and increase in urinary frequency. Possible allergic reaction to material if inhaled, ingested or in contact with skin.
Environmental Hazard	This material is very toxic to algae, toxic to daphnids, and harmful to fish. It is not toxic to activated sludge microorganisms or to the microorganisms Pseudomonas. This material is inherently biodegradable and not expected to persist in the environment.
Fire and Explosion	This material is classified as a non-combustible solid and will not support propagating combustion.

SECTION 4 – FIRST AID MEASURES

Skin contact:	May cause irritation. Flush with copious quantities of water.
Eye contact:	Causes irritation. Avoid contact. Flush with copious quantities of water.
Inhalation:	May cause irritation. Remove to fresh air.



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SECTION 5 – FIRE-FIGHTING MEASURES

Hazard burning emissions: CO, CO₂.
Extinguisher Media: Water spray, dry chemical, carbon dioxide (CO₂), or foam.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Emergency response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site.

SECTION 7 – HANDLING AND STORAGE

Attentions: As a general rule, when handling the material avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling. Store at room temperature and protect from light.

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limit	No data
Engineering Controls	No special provisions are required under normal product use conditions. When handling bulk formulation, use in a well-ventilated area.
Eye protection	Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.
Gloves	Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.
Respirators	Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator should be worn when exposures are expected to exceed the applicable limits.
Other Equipment or procedures	Not needed during normal product use.



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SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	150 mg-White to pale yellow round biconvex tablet with imprinting “YH102” on one side and plain on the other side. 300 mg-White to pale yellow round biconvex tablet with imprinting “YH101” on one side and plain on the other side.
pH:	No study data
Melting Point: Flash	No study data
point: Burning	No study data
temperature	No study data

SECTION 10 – STABILITY AND REACTIVITY

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

SECTION 11 – TOXICOLOGICAL INFORMATION

Oral Toxicity	No studies have been conducted.
Inhalation Toxicity	No studies have been conducted.
Skin Effects	No studies have been conducted.
Eye Effects	No studies have been conducted.
Sensitisation	No studies have been conducted.
Genetic Toxicity	No studies have been conducted.
Carcinogenicity	No studies have been conducted.
Reproductive Effects	No studies have been conducted.
Target Organ Effects	Central nervous system
Other Adverse Effects	None known for this material in humans

SECTION 12 – ECOTOXICITY INFORMATION

ECOTOXICITY INFORMATION	This material is toxic to algae, toxic to daphnids, and harmful to fish. It is not toxic to activated sludge microorganisms or to the microorganisms Pseudomonas. This material is inherently biodegradable and not expected to persist in the environment.
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SECTION 13 – DISPOSAL CONSIDERATIONS

Waste disposal methods	Disposal should be made in accordance with country, federal, state and local regulations.
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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

Transport information	Transportation and shipping of this material is not restricted. It has no known, significant hazards requiring special packaging or labeling 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 FOR A PARTICULAR PURPOSE. Adjustment to



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