



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: Bupropion Hydrochloride Extended-release Tablets
USP(SR), 100&150&200mg
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.
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



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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 3 – COMPOSITION/INFORMATION ON INGREDIENTS

100mg			
Ingredients	CAS No.	%	Classification
Bupropion Hydrochloride, USP	31677-93-7	20-30	Acute Tox. 4, H302
Povidone, USP	9003-39-8	1-10	-
L-Cysteine Hydrochloride Monohydrate, USP	7048-04-6	1-10	-
Hydroxypropyl cellulose	9004-64-2	5-15	-
Microcrystalline Cellulose	9004-34-6	45-65	-

150mg			
Ingredients	CAS No.	%	Classification
Bupropion Hydrochloride, USP	31677-93-7	30-40	Acute Tox. 4, H302
Povidone, USP	9003-39-8	1-10	-
L-Cysteine Hydrochloride Monohydrate, USP	7048-04-6	1-10	-
Hydroxypropyl cellulose	9004-64-2	5-15	-
Microcrystalline Cellulose	9004-34-6	35-55	-

200mg			
Ingredients	CAS No.	%	Classification
Bupropion Hydrochloride, USP	31677-93-7	45-55	Acute Tox. 4, H302
Povidone, USP	9003-39-8	1-10	-
L-Cysteine Hydrochloride Monohydrate, USP	7048-04-6	1-10	-
Hydroxypropyl cellulose	9004-64-2	5-15	-
Microcrystalline Cellulose	9004-34-6	25-45	-



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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.

SECTION 5 – FIRE-FIGHTING MEASURES

Hazard burning emissions:	CO, CO ₂ .
Extinguisher Media:	Water spray, foam as appropriate for surrounding fire and materials, dry powder, and carbon dioxide.

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.
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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 form light.
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SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limit	No data
Occupational Hygiene Air Monitoring	No data
Methods	
Engineering Controls	Seal well, and install local exhaust system, and equip with safety shower and eye washing facility.
Eye protection	Safety glasses with side-shields.
Gloves	Wear protective gloves and protective clothing.
Respirators	If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.
Other Equipment or procedures	Prohibit smoking, eating or drinking at production site. Change and clean working clothes in time. Don't drink liquor before working. Shower with warm water. Carry out health examination before employment and periodical re-examination after employment.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	100mg : Light blue, film coated, round, biconvex tablets, debossed with “YH” and “133” on one side and plain on the other side. 150mg : Purple, film coated, round, biconvex tablets, debossed with “YH” and “177” on one side and plain on the other side. 200mg : Pink film coated, round, biconvex tablets, debossed with “YH” and “132” on one side and plain on the other side.
pH:	No study data
Melting Point:	No study data
Flash point:	No study data
Burning temperature	No study data



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SECTION 10 – STABILITY AND REACTIVITY

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

SECTION 11 – TOXICOLOGICAL INFORMATION

Oral Toxicity	Adverse effects might occur following ingestion
Inhalation Toxicity	No studies have been conducted.
Skin Effects	No studies have been conducted.
Eye Effects	No studies have been conducted.
Sensitisation	Sensitisation (allergic skin reaction) is not expected. Assessment based upon effects of structurally similar substances.
Genetic Toxicity	Not expected to be genotoxic under occupational exposure conditions
Carcinogenicity	Not expected to produce cancer in humans under occupational exposure conditions
Reproductive Effects	No studies have been conducted.

SECTION 12 – ECOLOGICAL 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

Disposal measures for waste

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

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.

SECTION 16 – OTHER INFORMATION

Preparing Department:

The SDS was prepared by EHS Department of Yichang Humanwell Oral Solid Dosage Plant.

Disclaime

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



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