



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: Esomeprazole Magnesium Delayed-release Capsule,
20&40mg

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 swallowed when not comply with medical advice.
Ingestion	Oral administration.
Health Hazard:	Adverse effects might occur headache, abdominal pain and diarrhea, gastrointestinal disorders, flatulence, nausea and vomiting, and constipation. Other adverse reactions include dermatitis, itching, urticaria, dizziness and dry mouth.
Environmental Hazard	Harmful 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

	20&40mg		
Ingredients	CAS No.	%	Classification
Esomeprazole magnesium trihydrate	217087097	5-25	-
Magnesium Oxide	1309-48-4	0.1-5	-
Hypromellose	9004-65-3	5-25	-
Talc	14807-96-6	5-25	-
Magnesium Stearate	557-04-0	0.1-5	-

SECTION 4 – FIRST-AID MEASURES

Skin contact:	Remove contaminated clothing. Clean the contaminated skin with lots of water.
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 advice.
Ingestion	Wash out the mouth with water and never give the victim anything by mouth.

SECTION 5 – FIRE-FIGHTING MEASURES

Extinguisher Media:	Water spray, foam as appropriate for surrounding fire and materials, dry powder, and carbon dioxide.
Fire-fighting instruction:	As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Emergency response:	SMALL SPILL: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on The contaminated surface and dispose of according to local and regional authority requirements. LARGE SPILL: Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated
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surface and allow to evacuate through the sanitary system.

SECTION 7 – HANDLING AND STORAGE

Attentions: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse. Store locked up.

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.



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SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	40mg: Size '3' capsule with opaque standard blue cap and opaque powder blue body, imprinted with '108' on the cap and '40mg' on the body in black ink, containing light yellow to yellow pellets. 20mg: Size '4' capsule with opaque standard blue cap and opaque powder blue body, imprinted with '109' on the cap and '20mg' on the body in black ink, containing light yellow to yellow 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

Stability:	Stable
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.



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Genetic Toxicity	Not expected to be genotoxic under occupational exposure conditions, may cause pollution.
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	The environmental impact of this product has not been fully investigated.
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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.
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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.

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