



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

Safety Data Sheet
Compile Date:2022-07-14

Page Number: 1 of 7

Table of Content

SECTION 1 – IDENTIFICATION
SECTION 2 – HAZARD(S) IDENTIFICATION
SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS
SECTION 4 – FIRST-AID MEASURES
SECTION 5 – FIRE-FIGHTING MEASURES
SECTION 6 – ACCIDENTAL RELEASE MEASURES
SECTION 7 – HANDLING AND STORAGE
SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION
SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES
SECTION 10 – STABILITY AND REACTIVITY
SECTION 11 – TOXICOLOGICAL INFORMATION
SECTION 12 – ECOLOGICAL INFORMATION
SECTION 13 – DISPOSAL CONSIDERATIONS
SECTION 14 – TRANSPORT INFORMATION
SECTION 15 – REGULATORY INFORMATION
SECTION 16 – OTHER INFORMATION



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


Safety Data Sheet
Compile Date:2022-07-14

Page Number: 2 of 7

SECTION 1 – IDENTIFICATION

Product name: Diltiazem Hydrochloride Extended-Release Tablets (LA)
120mg &180mg &240 mg & 300 mg &360 mg & 420 mg
Manufacturer: Yichang Humanwell Oral Solid Dosage Plant
519 Donglin Rd, Yichang, Hubei 443112 China
717 7108087
Emergency Contact Phone No.: 86 532 83889090

SECTION 2 – HAZARD(S) IDENTIFICATION

Physical hazards	Not classified.
Health hazards	Acute toxicity, oral
OSHA hazard(s)	Not classified.
Label elements	
Signal word	Warning
Hazard statement	Harmful if swallowed when not comply with medical advice. Adverse effects might puffiness, headache, nausea, dizziness, rash and weakness.
Ingestion	Oral administration.

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	CAS No.	%	Classification
Diltiazem Hydrochloride	33286-22-5	20-50	Acute Tox. 4 , H302
Sugar Spheres	NA	5-20%	
Ethylcellulose	9004573	2%-8%	
Plasdone	9003398	0%-10%	
Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion	9010882	2%-8%	



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

Safety Data Sheet
Compile Date:2022-07-14

Page Number: 3 of 7

Hypromellose	9004653	5-15%
Talc	14807966	0-10%

SECTION 4 – FIRST-AID MEASURES

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 or eyewash solution. Obtain medical attention.
Inhalation:	Allow the victim to rest in a well-ventilated area. Seek immediate medical attention.
Ingestion:	If swallowed, rinse mouth with water (only if the person is conscious). Do not give anything by mouth to an unconscious or convulsing person. Do not under any circumstances induce vomiting. Seek medical treatment.

SECTION 5 – FIRE-FIGHTING MEASURES

Fire Fighting Protective Equipment	A self-contained breathing apparatus and suitable protective clothing should be worn in fire conditions.
Extinguisher Media:	Extinguish with carbon dioxide, dry chemical, foam or waterspray.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Emergency response:	<p>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.</p> <p>LARGE SPILL: Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary</p>
---------------------	---



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

Safety Data Sheet
Compile Date:2022-07-14

Page Number: 4 of 7

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.
Containment	No special engineering controls are required.
Ventilation	Local exhaust ventilation (LEV) is recommended.
Eye protection	Chemical tight goggles and full face shield.
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:

- 120 mg:** White to off-white, capsule-shaped tablet, debossed with “” on one side and “157” on the other side.
- 180 mg:** White to off-white, capsule-shaped tablet, debossed with “” on one side and “156” on the other side.
- 240 mg:** 240 m White to off-white, capsule-shaped tablet, debossed with “ ” on one side and “155” on the other side.
- 300 mg:** White to off-white, capsule-shaped tablet, debossed with “ ” on one side and “153” on



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

Safety Data Sheet
Compile Date:2022-07-14

Page Number: 5 of 7

the other side.

360 mg: White to off-white, capsule-shaped tablet, debossed with “ ” on one side and “152” on the other side.

420 mg: White to off-white, capsule-shaped tablet, debossed with “ ” on one side and “15” on the other side.

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 under normal conditions.
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.
Hazardous Decomposition Product(s) :	Combustion or thermal decomposition will evolve toxic vapours. May give off toxic fumes in a fire.

SECTION 11 – TOXICOLOGICAL INFORMATION

Acute Toxicity	May cause
Skin Effects	No information available. May be harmful or toxic in contact with skin.
Eye Effects	No information available.
Ingestion	Adverse effects similar to inhalation may occur. No information available

SECTION 12 – ECOLOGICAL INFORMATION

Environmental Fate and Distribution	Adopt good working practices, the product is not released into the environment.
-------------------------------------	---



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

Safety Data Sheet
Compile Date:2022-07-14

Page Number: 6 of 7

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.
-----------------------------	---

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.
----------------------	--



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

Safety Data Sheet
Compile Date:2022-07-14

Page Number: 7 of 7

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 conform to actual conditions of usage may be required. Yichang Humanwell Oral Solid Dosage Plant assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data.