



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

Safety Data Sheet
Compile Date:2022-03-16

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SECTION 1 – IDENTIFICATION

Product name: Diltiazem Hydrochloride Extended-release Capsules USP (XR), 120mg&180mg&240 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 |
| 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 | 30-50 | Acute Tox. 4 , H302 |
| Hydroxypropyl Methylcellulose Methocel E5 | 9004653 | 1-5 | - |
| Ethylcellulose Dispersion Type B | 9004573 | 5-25 | - |
| Hydroxypropyl Methylcellulose Methocel K100M | 9004653 | 20-45 | - |



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| | | | |
|-------------------------------|---------|-------|---|
| Hydroxypropyl Methylcellulose | 9004653 | 15-25 | - |
| Methocel K15M | | | |
| CAB-O-SIL M-5P, NF | 7631869 | 0.5-5 | - |
| Magnesium Stearate, NF | 557040 | 0.5-5 | - |

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</p> |
|---------------------|--|



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cleaning by spreading water on the contaminated 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. |
| 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: Size ‘SB’ capsule with opaque yellow cap and white body, imprinted with ‘’ and ‘148’ on the cap in black ink, containing 2 white to off-white tablets.

180 mg: Size ‘SA’ capsule with opaque light orange cap and white body, imprinted with ‘’ and ‘149’ on the cap in black ink, containing 3 white to off-white tablets.

240 mg: Size ‘0’ capsule with opaque choc



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brown cap and white body, imprinted with
'A' on the cap and '150' on the body in
black ink, containing 4 white to off-white tablets.

| | |
|---------------------|---------------|
| 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. |
|-------------------------------------|--|



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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. |
|-----------------------------|---|

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. |
|----------------------|--|

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 |



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