



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

人福医药

Safety Data Sheet
Compile Date : 2020-11-17

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 : 2020-11-17

Page Number: 2 of 7


SECTION 1 – IDENTIFICATION

Product name: Guanfacine Hydrochloride Extended-release Tablets,
1&2&3&4mg

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 | H302: Harmful if swallowed when not comply with medical advice. |
| Ingestion | Inhalation or oral administration |
| Health Hazard: | Atmospheric concentrations in excess of the occupational exposure limit may lead to drowsiness, dry mouth, nausea or vomiting, constipation, insomnia, skin rash, itching. |
| Environmental Hazard | The substance is soluble in water. The substance has low potential for bioaccumulation. |

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

| 1&2&3&4mg | | | |
|-------------------------------|------------|--------|---------------------|
| Ingredients | CAS No. | % | Classification |
| Guanfacine Hydrochloride | 29110-48-3 | 0.5-2% | Acute Tox. 3 , H301 |
| Hydroxypropyl Methylcellulose | 9004653 | 20-40% | - |
| Methacrylic Acid Copolymer | 25212888 | 10-30% | - |
| Lactose Monohydrate | 64044515 | 15-25% | - |



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宜昌人福口服固体制剂厂

人福医药

Safety Data Sheet
Compile Date : 2020-11-17

Page Number: 3 of 7

SECTION 4 – FIRST-AID MEASURES

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| 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. Seek medical treatment. |

SECTION 5 – FIRE-FIGHTING MEASURES

| | |
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| 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

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| 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 system.</p> |
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YICHANG HUMANWELL ORAL SOLID DOSAGE PLANT
宜昌人福口服固体制剂厂

Safety Data Sheet
Compile Date : 2020-11-17

Page Number: 4 of 7

SECTION 7 – HANDLING AND STORAGE

| | |
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| 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

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| Occupational Exposure Limit | No data |
| Occupational Hygiene Air Monitoring Methods | No data |
| 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

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| Appearance: | 1mg White to off-white round biconvex tablets, debossed with "YH" on one side and "116" on the other side. 2mg White to off-white biconvex caplets, debossed with "YH" on one side and "117" on the other side. 3mg Orange round biconvex tablets, debossed with "YH" on one side and "118" on the other side. 4mg Orange biconvex caplets, debossed with "YH" on one side and "119" 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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宜昌人福口服固体制剂厂

人福医药

Safety Data Sheet
Compile Date : 2020-11-17

Page Number: 5 of 7

SECTION 10 – STABILITY AND REACTIVITY

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| 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

| | |
|---------------------|--|
| Inhalation Toxicity | Atmospheric concentrations in excess of the occupational exposure limit may lead to drowsiness, dry mouth, nausea or vomiting, constipation, insomnia. |
| Skin Effects | No information available. May be harmful or toxic in contact with skin. |
| Eye Effects | May cause eye irritation. May cause excessive watering of the eye. |
| Ingestion | Adverse effects similar to inhalation may occur. |

SECTION 12 – ECOLOGICAL INFORMATION

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| Environmental Fate and Distribution | The substance is soluble in water. The substance has low potential for bioaccumulation. |
|-------------------------------------|---|

SECTION 13 – DISPOSAL CONSIDERATIONS

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| 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. |
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宜昌人福口服固体制剂厂

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Safety Data Sheet
Compile Date : 2020-11-17

Page Number: 6 of 7

SECTION 14 – TRANSPORT INFORMATION

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|-------------------|---|
| 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 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 |



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Safety Data Sheet

Compile Date : 2020-11-17

Page Number: 7 of 7

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