



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

Safety Data Sheet
Compile Date:2019-08-22

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:2019-08-22

Page Number: 2 of 7

SECTION 1 – IDENTIFICATION

Product name: Potassium Chloride Extended-release Tablets, 20 mEq (1500 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

Classification of the substance or mixture Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.
This substance is not classified as dangerous according to Directive 67/548/EEC.

Label elements The product does not need to be labelled in accordance with EC directives or respective national laws.

Other hazards This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	CAS No.	%	Classification
Potassium Chloride	7447-40-7	85-95	
Polyvinyl Acetate	9003-20-7	1-3	
Hydrogenated Vegetable oil	68334-00-9	1-5	

SECTION 4 – FIRST-AID MEASURES

Skin contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.



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

Safety Data Sheet
Compile Date:2019-08-22

Page Number: 3 of 7

Eye contact:	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Inhalation:	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary

SECTION 5 – FIRE-FIGHTING MEASURES

Hazard burning emissions:	CO, CO2.
Extinguisher Media:	Water spray, dry chemical, carbon dioxide (CO2), or foam

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Emergency response:	Segregate the spilling areas and control personnel access. Emergency response personnel were proposed to wear dustproof masks and working clothes to prevent contact the spills directly. For little quantity spills, clean up carefully to prevent any dust rising, and place the spills in bags and transfer to safety areas. For large quantity spills, collect and transfer to waste disposal areas for further disposal.
---------------------	---

SECTION 7 – HANDLING AND STORAGE

Attentions:	Operate in sealed containers, and equip with local exhaust system. Operators should be trained before starting working. Ensure they could operate following related procedures strictly and wear rubber gloves. Avoid dust producing. Load or unload lightly, to prevent containers damage.
-------------	---



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

Safety Data Sheet
Compile Date:2019-08-22

Page Number: 4 of 7

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limit	No data
Engineering Controls	No special provisions are required under normal product use conditions. When handling bulk formulation, use in a well-ventilated area.
Eye protection	Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.
Gloves	Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.
Respirators	Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator should be worn when exposures are expected to exceed the applicable limits.
Other Equipment or procedures	Not needed during normal product use.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	White, oval, biconvex, film-coated tablets, debossed with “YH 155” 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

SECTION 10 – STABILITY AND REACTIVITY

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



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

Safety Data Sheet
Compile Date:2019-08-22

Page Number: 5 of 7

SECTION 11 – TOXICOLOGICAL INFORMATION

Oral Toxicity	Potassium chloride has produced fatalities in humans at oral dosages of 20-60 mg/kg.
Inhalation Toxicity	No studies have been conducted.
Skin Effects	No studies have been conducted.
Eye Effects	No studies have been conducted.
Sensitisation	No studies have been conducted.
Genetic Toxicity	No studies have been conducted.
Carcinogenicity	No studies have been conducted.
Reproductive Effects	No studies have been conducted.
Target Organ Effects	In humans, target organ(s) include: cardiovascular system, gastrointestinal tract. Accidental ingestion of 20 to 60 mg/kg potassium chloride produced cardiac arrhythmias and death. Other effects from ingestion included nausea, vomiting, and changes in blood clotting factors.
Other Adverse Effects	None known for this material in humans

SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity information	No study data
-------------------------	---------------

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



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

Safety Data Sheet
Compile Date:2019-08-22

Page Number: 6 of 7

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.

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



人福医药

YICHANG HUMANWELL ORAL SOLID DOSAGE PLANT

宜昌人福口服固体制剂厂

Safety Data Sheet

Compile Date:2019-08-22

Page Number: 7 of 7

Plant assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data.