

宜昌人福口服固体制剂厂

## **Safety Data Sheet**

Compile Date: 2021-03-16

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



宜昌人福口服固体制剂厂

### **Safety Data Sheet**

Compile Date: 2021-03-16

Page Number: 2 of 7

#### SECTION 1 - IDENTIFICATION

Product name: Ibuprofen Tablets USP, 400mg & 600mg & 800 mg

Manufacturer: Yichang Humanwell Oral Solid Dosage Plant

519 Donglin Rd, Yichang, Hubei 443112 China

Tel:86 717 7101199

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 inhaled.

Ingestion Inhalation or oral administration

Health Hazard: Adverse effects might occur following ingestion;

Minor irritation might occur following direct contact with intact skin; Minor irritation might

occur following direct contact with eyes.

Environmental Hazard Toxic to aquatic organisms

Fire and Explosion This material is classified as a non-combustible

solid and will not support propagating

combustion.

#### SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

400 mg & 600 mg & 800 mg

Ingredients	CAS No.	%	Classification
Ibuprofen	15687-27-1	75-95	Acute Tox 4, H302
Hydroxypropyl Methylcellulose	9004-65-3	1-10	-
Croscarmellose Sodium	74811-65-7	1-10	-
Colloidal Silicon Dioxide	7631-86-9	1-10	-



宜昌人福口服固体制剂厂

### **Safety Data Sheet**

Compile Date: 2021-03-16

Page Number: 3 of 7

#### 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. Obtain

medical attention.

Inhalation: Allow the victim to rest in a well-ventilated area.

Seek immediate medical attention.

#### SECTION 5 – FIRE-FIGHTING MEASURES

Hazard property: Combustible at high temperature with naked

flame. React' when strong oxidizing agents.

Hazard burning emissions: Carbon monoxide, carbon dioxide

Extinguisher Media: Water spray, foam as appropriate for surrounding

fire and materials, dry powder, and carbon

dioxide.

#### 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 surface and allow to evacuate through the sanitary

system.



宜昌人福口服固体制剂厂

### **Safety Data Sheet**

Compile Date:2021-03-16

Page Number: 4 of 7

#### 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.



宜昌人福口服固体制剂厂

### **Safety Data Sheet**

Compile Date: 2021-03-16

Page Number: 5 of 7

# SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Appearance: 400mg: White to off-white, oval shaped, biconvex

film coated tablets, debossed with "157" on one

side and plain on the other side.

**600mg:** White to off-white, capsule shaped, biconvex film coated tablets, debossed with "152"

on one side and plain on the other side.

**800mg:** White to off white, capsule shaped, biconvex film coated tablets, debossed with "151"

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

Stabitily Stable

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.

# 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 (allergic skin reaction) is not

expected. Assessment based upon effects of

structurally similar substances.

Genetic Toxicity Not expected to be genotoxic under occupational

exposure conditions

Carcinogenicity Not expected to produce cancer in humans under



宜昌人福口服固体制剂厂

## **Safety Data Sheet**

Compile Date: 2021-03-16

Page Number: 6 of 7

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.

#### 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 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



宜昌人福口服固体制剂厂

### **Safety Data Sheet**

Compile Date:2021-03-16

Page Number: 7 of 7

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

FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be

required. Yichang Humanwell Oral Solid Dosage

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