



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

Safety Data Sheet
Compile Date:2021-04-23

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SECTION 1 – IDENTIFICATION

Product name: Mycophenolic Acid Delayed release Tablets,360mg&180mg
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 Not classified.
OSHA hazard(s) Not classified.
Label elements



Signal word Warning
Hazard statement Harmful if swallowed.
Causes skin irritation.
Harmful if inhalation.
Other hazards Not classified.

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

360mg&180mg			
Ingredients	CAS No.	%	Classification
Mycophenolate Sodium	37415-62-6	40-70%	-
Povidone	9003-39-8	1-10%	-
Lactose Monohydrate	64044-51-5	1-10%	-
Crospovidone	25249-54-1	1-10%	-

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. Get medical advice/attention.



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Eye contact:	Draw the eyelid, and clean with water and lots of water at least 15 minutes. Obtain medical attention.
Inhalation:	Remove casualty to fresh air and keep warm and at rest. In case of irregular breathing or respiratory arrest provide artificial respiration.
Ingestion:	Rinse mouth immediately and drink large quantities of water Consult a physician.

SECTION 5 – FIRE-FIGHTING MEASURES

Advice for firefighters:	Wear a self-contained breathing apparatus and chemical resistant suit.
Hazard burning emissions:	Toxic fumes may be liberated in case of fire.
Extinguisher Media:	Water spray. Carbon dioxide. Dry extinguishing powder. Foam.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Emergency response:	Use appropriate personal protective equipment. Remove all sources of ignition. Clean contaminated objects and areas thoroughly observing environmental regulations. Do not allow to enter into surface water or drains. Inform the relevant authorities if the product has caused environmental pollution. Dangerous areas must be delimited and marked with appropriate warning and safety signs. Avoid generation of dust. Wet clean or vacuum up solids. Collect in closed containers for disposal.
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SECTION 7 – HANDLING AND STORAGE



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Attentions:

All work processes must always be designed so that the inhalation/skin contact/eye contact is excluded.

Only trained and authorised personnel is allowed to handle the substance. Ensure adequate ventilation/exhaustion at workplace.

Keep away from heat sources (e.g. hot surfaces), sparks and open flames. Provide adequate ventilation as well as local exhaustion at critical locations. Transfer and handle product only in closed systems. Use isolated drainage to prevent discharge to soil. Wet scrubber for elimination of volatile components from waste gases.

Keep/Store only in original container.

Suitable material for Container: Polyethylene bags inside of Aluminum foil, Aluminum foil inside of polyethylene drum.

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	Suitable eye protection: Eye glasses with side protection. Face protection shield. (DIN EN 166)
Skin	Wear suitable protective clothing depending on activity and possible exposure: apron, protecting boots, chemical-protection suit or air fed suit with exhaust valve.
Respirators	In case of inadequate ventilation wear respiratory protection.



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SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	360mg : Orange film-coated ovaloid tablets, debossed with “A121” on one side and plain on the other side. 180mg : Green film-coated round tablets, debossed with “A” and “122” 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

Chemical stability:	Stable under ambient temperatures and pressures.
Conditions to avoid:	Electrostatic discharge, heat, humidity, etc.
Incompatible materials:	Strong oxides, strong acids, strong bases.
Hazardous decomposition products:	No information available.

SECTION 11 – TOXICOLOGICAL INFORMATION

Acute toxicity	No information available.
Skin Effects	Causes skin irritation.
Serious eye damage/eye irritation	Causes serious eye irritation.
Respiratory or skin sensitisation	No information available.
Germ cell mutagenicity	No indications of human germ cell mutagenicity exist.
Carcinogenicity	No information available.



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Reproductive toxicity

Evidence exists for human reproductive toxicity.

SECTION 12 – ECOLOGICAL INFORMATION

Bioaccumulative potential

Partition coefficient n-octanol /water (log Kow):
2.80 (esimated, Drugbank)

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

This safety datasheet complies with the



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requirements of Regulation (EC) No. 1907/2006.

SECTION 16 – OTHER INFORMATION

Preparing Department:

The SDS was prepared by EHS Department of Yichang Humanwell Oral Solid Dosage Plant.

Disclaimer:

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