

SAFETY DATA SHEET

1. IDENTIFICATION

Product Identifier:

Material Name: Metformin Hydrochloride ER Tablets
Trade Name: Not established
Chemical Family: Mixture

Relevant Identified Uses of the Substances or Mixture and Uses Advised Against

Intended Use: It is oral antihyperglycemic drugs used in the management of type 2 diabetes.

Manufacturer Information

Company name CSPC Ouyi Pharmaceutical Co., Ltd.
Address No.276 Zhongshan West Road Shijiazhuang 050051,China
Telephone + 86-311-87896575
Website www.ouyipharma.com
Eemergency phone number +86-311-87896581

2. HAZARDS IDENTIFICATION

Harmful in contact with skin and if swallowed.

Risk Phrases: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Damage to liver.

Adverse human health effects : This material may induce blood disorders and/or aggravate pre-existing blood disorders, and cardiac disorders. Exposure may produce an allergic reaction, hypoglycaemia, and gastrointestinal disorders.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Metformin hydrochloride	1115-70-4	214-230-6	Xn; R21/22, R52-53	500 or 750 mg
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Magnesium stearate	557-04-0	209-150-3	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Carboxymethylcellulose sodium	9004-32-4	Not Listed	Not Listed	*
Copovidone	25086-89-9	Not Listed	Not Listed	*
Hypromellose	9004-65-3	Not Listed	Not Listed	*

4. FIRST AID MEASURES

Inhalation: Assure fresh air breathing. Rest. If you feel unwell, seek medical advice.

Skin contact: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

Eye contact: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking, tears or redness persists.

Ingestion: Rinse mouth. If swallowed, seek medical advice immediately and show this container or label.

In case of reactions described in hazards identification or other severe, immediate or persisting symptoms seek medical advice and call the nearest poison centre. Show the label and this safety data sheet.

5. FIRE FIGHTING MEASURES

Extinguishing media - Suitable extinguishing media: Water spray, Carbon dioxide and Dry powder
- Unsuitable extinguishing media: Do not use a heavy water stream.

Surrounding fires: Use water spray or fog for cooling exposed containers.

Protection against fire: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous combustion products: Incomplete combustion will generate poisonous carbon monoxide, carbon dioxide and other toxic gases.

6. ACCIDENTAL RELEASE MEASURES

General precautions: Remove ignition sources. Evacuate area.

Personal precautions: Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

Clean up methods: To clean the floor and all objects contaminated by this material, use: Water. /Detergent. Avoid dust production. Ensure adequate ventilation.

7. HANDLING AND STORAGE

Personal protection: Avoid all unnecessary exposure. Ensure prompt removal from eyes, skin and clothing.

Technical protective measures: Material should be handled in a laboratory hood whenever possible.

Handling: Handle in accordance with good industrial hygiene and safety procedures.
METFORMIN HYDROCHLORIDE CRS is not intended for long-term storage.

Storage: Keep container tightly closed in a cool, well ventilated place. Storage - away from: All heat sources, including direct sunlight. Open flame. Sources of ignition. Sparks. Incompatible materials, see §10

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal protection:

Respiratory protection: Wear approved mask. (P2) In case of insufficient ventilation, wear suitable respiratory equipment.

Hand protection: Wear suitable gloves resistant to chemical penetration.

Skin protection: Wear suitable protective clothing.

Eye protection: Chemical goggles or safety glasses.

Industrial hygiene: Provide local exhaust or general room ventilation.

9. PHYSICAL AND CHEMICALS PROPERTIES

Physical State:	Tablets	Color:	White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability and reactivity:	Stable under normal conditions of use.
Materials to avoid:	Alkali. Strong oxidizers
Conditions to Avoid:	None known.
Hazardous decomposition products:	Carbon monoxide, Carbon dioxide, Nitrogen oxides and Chlorides. When heated to decomposition, emits dangerous fumes.
Hazardous reactions:	None under normal conditions.
Hazardous polymerization:	Will not occur.

11. TOXICOLOGICAL INFORMATION

RTECS nr: DU1800000 (See actual entry in RTECS for complete information.)

Rat oral LD50 [mg/kg]:	1770
Rabbit dermal LD50 [mg/kg]:	No data available.
Rat inhalation LC5 [mg/L/4h]:	No data available.
Acute toxicity:	Cardiac disorders. Hypoglycaemia. Gastrointestinal disorders. This material may induce blood disorders and/or aggravate pre-existing blood disorders.
Chronic toxicity:	Damage to live.
Sensitization:	No data available.

12. ECOLOGICAL INFORMATION

Ecological effects information:	Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
LC50-96 Hour - fish [mg/L]:	No data available.
EC50-48 Hour-Daphnia magna [mg/L]	52
IC50-72h-Algae [mg/L]:	No data available.
Biodegradation [%]:	Carbon monoxide, Carbon dioxide, Nitrogen oxides and Chlorides. When heated to decomposition, emits dangerous fumes.
Persistence - degradability:	Partially biodegradable.
Log P octanol / water at 20°C:	- 2.64 (metformin)
Bioaccumulative potential:	No data available.

13. DISPOSAL CONSIDERATIONS

General: Dispose of this material and its container at hazardous or special waste collection point. Dispose in a safe manner in accordance with local/national regulations.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Marine pollutant: None-hazardous for sea transport.

15. REGULATORY INFORMATION

Symbol(s): Xn: Harmful

R Phrase(s): R21/22: Harmful in contact with skin and if swallowed.

R52/53: Harmful to aquatic organisms, and may cause long-term adverse effects in the aquatic

environment.

S Phrase(s): S24: Avoid contact with skin.

S36/37: Wear suitable protective clothing and gloves.

S51: Use only in well-ventilated areas.

S59: Refer to manufacturer/supplier for information on recovery/recycling.

S61: Avoid release to the environment. Refer to special instructions/Safety datasheets.

16. OTHER INFORMATION

Data Sources:	Publicly available toxicity information. Safety data sheets for individual ingredients.
Issue Date:	05/2016
Prepared by:	CSPC Ouyi Pharmaceutical Co., Ltd.

DISCLAIMER: This information is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes.



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014 Introduction Type: New Item Final Version Date: 7/14/2016

PRODUCT INFORMATION

Company Name: TGI Pharma, Inc. Application: ANDA

Application Number for NDA/ANDA/BLA, Med Device: A078321

Rx Product/Proprietary Name: Metformin Hydrochloride Extended-Release Tablets, USP

NDC: 51224-107-60 UPC:

CVX Code: Metformin Hydrochloride Extended-Release Tablets, USP - 750mg 500d Tablets

Description: Metformin Hydrochloride

Active Ingredients: Metformin Hydrochloride

URL for Additional Product Information: www.tgipharma.com

Address: 722 Progressive Lane, South Beloit, IL 61080

Key Contact: Melissa Bradley, Email: mbradley@tgipharma.com

Phone Number: 815-624-7685, Fax: 815-624-7014

FOR GENERAL DRUG PRODUCTS

I. Orange Book Rating: AB II. Brand Name: Metformin Hydrochloride Extended-Release Tablets, USP

III. Generic Equivalent for Brand: Metformin Hydrochloride Extended-Release Tablets, USP

Does supplier meet DSCSA definition of manufacturer? Yes No

Is product exempt from DSCSA? Yes No

If yes, select exemption: Other exemption - Write in: _____

Is product repackaged? No Yes

Is product sold by manufacturer's exclusive distributor? No Yes

Are any waivers granted for product (Dbarcode)? No Yes

If yes, attach documentation from FDA _____

DRUG SUPPLY CHAIN SECURITY (DSCSA) INFORMATION

DUNS: 963322560

If yes, was original product purchased direct from mfr? Yes No

If yes, attach documentation from FDA _____

ADDITIONAL PRODUCT INFORMATION

Is the Product... Legend Device? No Yes

State Control? No Yes

ARCOS reportable? No Yes

Co-Licensed? No Yes

Controlled Substance? No Yes

Schedule No.? _____

(incl. N for non-narcotic)

Controlled Substance Code: _____

Hazardous Material/Cytotoxic Agent? No Yes

Is item... Neither Yes

If Unit Dose, is item bar coded to unit dose for hospital scanning? Yes No

Is it reverse numbered? Yes No

PHARMACY ORDER BILL UNIT

Rec. sell unit to customer? Yes No

(White-in, e.g. 1 Vial)

Other Product Information

Size/Strength/Form: 750mg/500 tablets

Product Shape: Capsule shaped tablets

Product Color: White

Product Imprint: OE on one side and 585 on the other side

ORDER INFORMATION

Unit of Sale: Bottle Box/ Carton Ampule Glass Tube

What is the NDC selling unit? 1 bottle of 500 tablets

(White-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes No

If Yes, how many of which package type? 6 Each

Inner/ Carton/ Pack Case

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Depth	Height	Width	Volume (Cubes)	# Pieces:
Box/ Carton:	1.10 lbs		6.93"		3.88"	
Case:	10.1 lbs	6.97"	11.81"	7.87"		
Pallet:						
Case:						
Carton:						

SPECIAL HANDLING AND STORAGE REQUIREMENTS

a. Temperature - Indicate the USP temperature range for this product.

I. Freezer - between -25 and -10 C (-13° - 14° F)

II. Cold - between 2 and 8 C (36° - 46° F)

III. Cool - between 8 and 15 C (46° - 59° F)

IV. Controlled Room - between 20 and 25 C (68° - 77° F)

allows for excursions between 15 and 30 C (59° - 86° F)

V. Avoid Excessive Heat - above 40 C (>104° F)

VI. Other Temperature Range Requirement (write in) _____

VII. No Requirement

b. Contact for temperature excursion questions:

Name: Mat Mathis

Number: 815-624-7685

Is this product to be shipped to customers on dry ice? No Yes

Is this product to be shipped to customers on dry ice? No Yes

c. Special regulations for product in certain states? No Yes

Special returns requirements for this product? No Yes

d. Store product (unit of sale) upright? Yes No

Protect product (unit of sale) from light? Yes No

e. Shelf life: 24 Months

Initial shelf life at launch (if different): _____ Months

COST INFORMATION

Regular Cost Per Unit of Sale (\$): \$104.24

Invoice Cost (WAC) (\$): _____

Federal Excise Tax Per Unit of Sale: _____

Vendor #: _____

Whsl. Code #: _____

Fileline Code: _____

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

Signature: Melissa Bradley

As of date: 7/14/2016

*Please provide any additional information on page 2.

For Designated Drop Ship Only Products, Please Use Page 3
MATERIAL HAZARD CLASSIFICATION AND TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic? No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No

Carcinogen
 Reproductive Toxicant
 Both
 Warning appears on label

c. Contact Hazard? Yes

d. Does this product require special clean-up instructions? Yes

(if yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Hazardous Waste Identification

EPA Hazardous Waste Code:

Is this product regulated for shipment by the DOT?

Is this a reportable quantity? No

RQ Threshold:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?

No (if yes, identify method below)

Limited Quantity
 Consumer Commodity, ORM-D
 Small Quantity (49 CFR 173.4)
 Special Permit, DOT-SP
 Special Provision (listed in Column 7 of 49 CFR 172.101);
 SP#

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

Passenger
 Cargo
 Passenger & Cargo

ADDITIONAL STORAGE INFORMATION

Please check as appropriate for this product:

Organic Inorganic
 Antineoplastic Steroid/Androgen
 Corrosive Oxidizer
 Aerosol Class, Identify NFPA Storage Level:

ADDITIONAL PRODUCT INFORMATION - Serialization

Serialized?	Level	How?	RFID	GTIN-14
If not, when? <input type="text"/>	Item <input type="text"/>	Linear <input type="text"/>	RFID <input type="text"/>	<input type="text"/>
Items aggregated to case? <input type="text"/>	Box/Carion <input type="text"/>	Linear <input type="text"/>	RFID <input type="text"/>	<input type="text"/>
	Case <input type="text"/>	Linear <input type="text"/>	RFID <input type="text"/>	<input type="text"/>
	Pallet <input type="text"/>	Linear <input type="text"/>	RFID <input type="text"/>	<input type="text"/>

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (for example, Pledge program?)

CLASS OF TRADE RESTRICTION

No restriction: Select "YES" if sold to retail pharmacy, hospital, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

RETURN/INSTRUCTIONS

Contact tel # if product received damaged:

Is product returnable for credit: Yes

URL/link to returns policy:

Special regulations or returns requirements for this product in certain states? Yes

If so, which states? Other requirements? Comments?

Georgia, Mississippi and North Carolina. Requests can be made via fax: 815-624-7687 or email: customercare@lagpharma.com

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

N/A

Release DATE:



Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNATED DROP SHIP PRODUCT ONLY - If not a designated drop ship, do not complete.

Order Method (for Designated Drop Ship Product)

Purchase orders may be accepted by:

a. EDI	Yes	Fax Number:	815-624-7687
b. Autotax	Yes	Fax Number:	815-624-7687
c. Fax	Yes	Phone No.:	800-397-9228
d. Phone only	Yes	Site Address:	
e. Supplier Web Site only	No		

Minimum Order Quantity: 6 bottles

Supplier's Customer Service Number: 800-397-9228

Contracted 3PL company / contact #: _____

Name: _____ Phone: _____

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier: 12:00 PM Central

Cut off time: _____ Hours _____ Days

Shipping lead time of PO: _____

Ships same day for next day receipt: No

Ships for second day receipt: No

Ships regular ground for 3-10 days receipt: Yes

Expeditied Freight Charges or Other Designated Drop Ship Fees:

Expeditied freight fees billed with each order: Yes

Drop Ship service fee billed with each order: No

Drop Ship miscellaneous fees billed: No

Comments: _____

Overnight and Priority Overnight PO Processing

Overnight receipt available: Yes

PO Receipt cut off time: 12:00 PM Central

Days of week overnight is available:

<input checked="" type="checkbox"/>	Monday
<input checked="" type="checkbox"/>	Tuesday
<input checked="" type="checkbox"/>	Wednesday
<input checked="" type="checkbox"/>	Thursday
<input type="checkbox"/>	Friday

Priority Overnight receipt available: Yes

PO Receipt Cut off time: 12:00 PM

Class of Trade Restriction:

No restriction: Selected YES if sold to retail pharmacy, hospitals, clinics and physician offices

Restricted to retail pharmacy only: Yes

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments: _____

REMS or Registry Restrictions

REMS: No

REMS Program Manager Name: _____ Phone: _____

Supplier Manages REMS registry exclusively: _____

Wholesale distributor support: _____

Provider Name: _____

Site Enrollment Number assigned by Supplier: _____

DEA #: _____

PCPDP #: _____

NPI #: _____

Comments: _____

Registry: _____

Registry Program Contact Name: _____ Phone: _____

Comments: _____

Return Instructions

Contact # if product is received damaged: 800-397-9228

Is product returnable for credit: Yes

URL/link to returns policy: N/A

Special regulations or returns requirements for this product in certain states? Yes

If so, which states? Other requirements? Comments? _____

ADDITIONAL INFORMATION

Other Data Information Required for Process PO: _____

Patient Procedure Date: _____

Physician Name: _____

Physician/Clinic Phone #: _____

Physician State License #: _____

Physician/Clinic DEA #: _____

Physician/Clinic Specialty: _____

Miscellaneous Notes: _____

Is product order for scheduled patient procedure? _____

Is product order for restocking purposes? _____