

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078947741

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078947742



# SAFETY DATA SHEET

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## 1. Identification of the substance/preparation and the company/undertaking

<b>GHS product identifier</b>	
<b>Product name</b>	TELMISARTAN TABLETS
<b>Other means of identification</b>	Not available
<b>Synonym(s)</b>	Formulated Product TELMISARTAN Tablets, 20mg TELMISARTAN Tablets, 40 mg TELMISARTAN Tablets, 80 mg
<b>UN-Number</b>	n/a
<b>Recommended use</b>	Medicinal Product
	This safety data sheet is to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.
<b>Recommended restrictions</b>	No other uses are advised.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Manufacturer</b>	Zhejiang Huahai Pharmaceutical Co Ltd
	Xunqiao, Linhai, Zhejiang 317024, China
<b>Normal business hour Beijing time 8:00AM-5:00PM</b>	Phone no 008657685016633
<b>Email Address</b>	liangguochen@huahaipharm.com
<b>Emergency telephone number</b>	008657685016633

## 2. Hazards Identification

<b>Classified hazards</b>	
Physical hazards:	Not classified.
Health hazards:	Not classified.
OSHA defined hazards:	Not classified.
Environment hazards ;	Not classified.
<b>Label elements</b>	
<b>INDICATIONS AND USAGE</b>	
Telmisartan is an angiotensin IIreceptor blocker(ARB)indicated for: Treatment of hypertension,to lower blood pressure.Lowering blood pressure reduces the risk of fatal cardiovascular events,primarily strokes and myocardial infarctions.	
<b>WARNINGS AND PRECAUTIONS</b>	
Avoid fetal or neonatal exposure.	



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Hypotension: Correct any volume or salt depletion before initiating therapy. Observe for signs and symptoms of hypotension.  
Monitor carefully in patients with impaired hepatic or renal function.  
Avoid concomitant use of an ACE inhibitor and angiotensin receptor blocker.

### Hazard(s) not otherwise classified (HNOC)

Available hazard identification for Active Pharmaceutical Ingredient (API) alone:



Pictogram:

Signal word:

Warning

Hazard statement(s)

This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

Precautionary Statements

Prevention

Observe good industrial hygiene practices.

Response

Wash hands after handling.

Storage:

Store at 25°C (77°F); excursions permitted to 15 - 30 °C (59 - 86 °F).

Disposal:

Dispose of contents/container in accordance with local/regional/national/international regulations. Incineration of waste at an approved USEPA incinerator is recommended.

OTHER INFORMATION: No additional information

### 3. Composition/Information on ingredients

#### Mixtures

Hazardous components Chemical name	Common name and synonyms	CAS number	%
TELMISARTAN		144701-48-4	15-20
MANNITOL		69-65-8	70-80
Other components below reportable levels			<10

### 4. First aid measures

Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Inhalation	If dust from the material is inhaled, remove the affected person immediately to fresh air. Call a physician if symptoms develop or persist.
Ingestion:	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Most common side effects are dizziness, fatigue, and musculoskeletal pain. Persistent dry cough has been associated with ACE-inhibitor use.
Indication of immediate medical attention and	Provide general supportive measures and treat symptomatically.



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special treatment needed	
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

### 5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire-fighting equipment /instructions	Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

### 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures:	Keep unnecessary personnel away. Wear appropriate personal protective equipment (See Section 8).
Methods and materials for containment and cleaning up	Sweep up and place into a proper container for disposal. Minimize dust generation and accumulation. Collect dust using a vacuum cleaner equipped with HEPA filter. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

### 7. Handling and storage

#### Precautions for safe handling

Precautions for safe handling	Avoid contact with eyes, skin, and clothing. Avoid breathing dust. Wash hands thoroughly after handling.
Conditions for safe storage, including any incompatibilities	Store at 25°C (77°F); excursions permitted to 15 - 30 °C (59 - 86 °F). Store away from incompatible materials (see Section 10 of the SDS).



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## 8. Exposure controls/personal protection

Occupational exposure limits			
Chemical name	Type	values	Note/Form
US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)			
TELMISARTAN (CAS 144701-48-4 )	PEL	5 mg/m3 15 mg/m3	Respirable fraction. Total dust.
US. OSHA Table Z-3 (29 CFR 1910.1000)			
TELMISARTAN (CAS 144701-48-4 )	TWA	5 mg/m3 15 mg/m3 50 mppcf 15 mppcf	Respirable fraction. Total dust. Total dust. Respirable fraction.
US. ACGIH Threshold Limit Values			
TELMISARTAN (CAS 144701-48-4 )	TWA	3 mg/m3 10 mg/m3	Respirable particles. Inhalable particles.
Biological limit values	No biological exposure limits noted for the ingredient(s).		
Appropriate engineering controls	Ventilation should be matched to conditions.		
Individual protection measures, such as personal protective equipment			
Eye/face protection	None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.		
Hand protection	For consumer use, no unusual precautions are necessary.		
Other	None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.		
Respiratory protection	None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type:  Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.		
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.		
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.		



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## 9. Physical and chemical properties

Physical state	Solid.		
Form	Tablet.		
Color	Strengths(mg)	Color	
	20	White to off-white	
	40	White to off-white	
	80	White to off-white	
Odor	Not available.		
Odor threshold	Not available.		
pH	Not available.		
Melting point/range	Not available.		
Boling point/boiling range	Not available.		
Flash point	Not available.		
Evaporation rate	Not available.		
Flammability (solid, gas)	Not available.		
Flammability limits in air	Not available.		
Flammability limit – upper (%)	Not available.		
Flammability limit – lower (%)	Not available.		
Explosive limit – lower (%)	Not available.		
Explosive limit – upper (%)	Not available.		
Vapor pressure	Not available.		
Vapor density	Not available.		
Specific gravity	Not available.		
Water solubility	Not available.		
Solubility in other solvents	Not available.		
Partition coefficient: (n-octanol/water)	Not available.		
Auto-ignition temperature	Not available.		
Decomposition temperature	Not available.		
Viscosity	Not available.		

Product Description		
Strengths	Product Description	
20	White to off-white, round, biconvex tablets debossed with "511" on one side and "S" on the other side.	
40	White to off-white, oval, biconvex tablets debossed with "512" on one side and "S" on the other side.	
80	White to off-white, oval, biconvex tablets debossed with "513" on one side and "S" on the other side.	



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### 10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reaction	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Incompatible material	Strong oxidizing agents.
Hazardous decomposition products	Carbon oxides.
Other decomposition products - no data available	

### 11. Toxicological information

Information on likely routes of exposure		
Ingestion	Ingestion may cause irritation and malaise.	
Inhalation	Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Inhalation of dusts may cause respiratory irritation.	
Skin contact	Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust or powder may irritate the skin.	
Eye contact	Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust may irritate the eyes.	
Symptoms related to the physical, chemical and toxicological characteristics	Most common side effects are dizziness, fatigue, and musculoskeletal pain. Persistent dry cough has been associated with ACE-inhibitor use.	
Acute toxicity	May be harmful if swallowed in large quantities.	
Components	Species	Test Results
Telmisartan (CAS 144701-48-4)		
Acute Oral LD50	Rat	> 2000 mg/kg
Mannitol (CAS 69-65-8)		
Acute Oral LDmin.	Mouse	13,500 mg/kg
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Serious eye damage/eye irritation	Dust may irritate the eyes.	
Respiratory sensitization	Not a respiratory sensitizer.	
Skin sensitization	This product may cause a serious allergic reaction with swelling of the face, lips, tongue and/or throat which may cause difficulty in swallowing and/or breathing.	
Germ cell mutagenicity	This product is not expected to be mutagenic.	
Carcinogenicity	There is no evidence of carcinogenic effects for this product.	
Reproductive toxicity	This product has been rated Pregnancy Category D-POSITIVE EVIDENCE OR RISK, There is a risk to fetus after drug is administered, but under certain circumstances (e.g., treatment of life threatening illnesses) the benefits can	



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	outweigh the risk. Animal reproduction studies have not been conducted with product It is not known if this product is excreted in human milk. Because many drugs are excreted in human milk and because of the tumorigenicity of this product shown in animal studies, the decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother
Specific target organ toxicity - single exposure	No data available.
Specific target organ toxicity - repeated exposure	No data available.
Aspiration hazard	Due to the physical form of the product it is not an aspiration hazard.
Additional Information	No data available.

## 12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.	
Components	Species	Test Results
Telmisartan (CAS 144701-48-4)		
Other NOAEL	Activated sludge	1000 mg/l, 3 h Method: OECD 209
Acute Fish LC50	Oncorhynchus mykiss	3.74 mg/l, 96 h Method: OECD 203
Chronic Algae EC50	Desmodesmus subspicatus	9.87 mg/l, 72 h Method: OECD 201 1.75 mg/l, 72 h Method: OECD 201
Other EC50	Daphnia sp.	18 mg/l, 48 h
Persistence and degradability	No data available	
Bioaccumulative potential	No data available	
Mobility in soil	No data available	
Results of PBT and vPvB assessment	No data available	
Other adverse effects	No data available	

## 13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).



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<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.
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### 14. Transport information

<b>DOT - Not Regulated</b>	
DOT Proper shipping Name	Not dangerous goods
DOT UN/ID No	N/A
DOT Hazard Class	N/A
DOT Packing Group	N/A
DOT Label	N/A
<b>IATA/ICAO - Not Regulated</b>	
IATA Proper shipping Name	Not dangerous goods
IATA UN/ID No	N/A
IATA Hazard Class	N/A
IATA Packaging Group	N/A
IATA Label	N/A
<b>IMDG - Not Regulated</b>	
IMDG Proper shipping Name	Not dangerous goods
IMDG UN/ID No	N/A
IMDG Hazard Class	N/A
IMDG Flash Point	N/A
IMDG Label	N/A

### 15. Regulatory information

This Section Contains Information relevant to compliance with other Federal and/or state laws.	
<b>US federal regulations</b>	<p>This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&amp;D or drug use.</p> <p>Over-the-counter drugs in their solid final form (e.g. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.</p> <p>OSHA GHS: GHS symbols in consumer packaged form are not required per OSHA 29 CFR 1910.1200(b)(5) and OSHA 29 CFR 1910.1200(b)(5)(iii).</p>
<b>TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)</b>	Not regulated.
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>	Not listed.
<b>CERCLA Hazardous Substance List (40 CFR 302.4)</b>	Not listed.



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Superfund Amendments and Reauthorization Act of 1986 (SARA)		
<b>Hazard categories</b>	Immediate Hazard	No
	Delayed Hazard	No
	Fire Hazard	No
	Pressure Hazard	No
	Reactivity Hazard	No
<b>SARA 302 Extremely hazardous substance</b>		Not listed.
<b>SARA 311/312 Hazardous chemical</b>		No
<b>SARA 313 (TRI reporting)</b>		Not regulated.
<b>Other federal regulations</b>		
<b>Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List</b>		Not regulated.
<b>Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)</b>		Not regulated.
<b>Safe Drinking Water Act</b>		Not regulated.
<b>US state regulations</b>		
<b>US. Massachusetts RTK - Substance List</b>		Not regulated.
<b>US. New Jersey Worker and Community Right-to-Know Act</b>		Not listed.
<b>US. Pennsylvania Worker and Community Right-to-Know Law</b>		Not listed.
<b>US. Rhode Island RTK</b>		Not regulated.
<b>US. California Proposition 65</b>		California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.
<b>International Inventories</b>		
<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No



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Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).  
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

### 16. Other information

Issue date 15.10.2021  
Revision date 15.10.2021  
Version # 027B  
Reference  
1) WEST-WARD TELMISARTAN TABLETS SDS  
2) SIGMA-ALDRICH TELMISARTAN SDS  
3) HUAHAI TELMISARTAN SDS

#### General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet

Signature: 张伟明