SAFETY DATA SHEET

OSHA's Hazard Communication Standard 2012

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

GHS product identifier	
Product name	**TELMISARTAN HCT TABLETS**
Other means of identification	**Not available**
Synonym(s)	Formulated Product TELMISARTAN HCT Tablets, 40/12.5 mg TELMISARTAN HCT Tablets, 80/12.5 mg TELMISARTAN HCT Tablets, 80/25 mg
UN-Number	n/a
Recommended use	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.
Recommended restrictions	No other uses are advised.
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	Zhejiang Huahai Pharmaceutical Co Ltd
	Xunqiao, Linhai, Zhejiang 317024, China
Normal business hour **Beijing time 8:00AM-5:00PM**	Phone no 008657685016474
Email Address	liwangxing@huahaipharm.com
Emergency telephone number	008657685016474

2. Hazards Identification

Classified hazards

Physical hazards:	Not classified.	
Health hazards:	Acute toxicity, oral	Category 4
OSHA defined hazards:	Not classified.	
Environment hazards:	Not classified.	

Label elements

INDICATIONS AND USAGE

TELMISARTAN HCT fixed dose combination (40 mg telmisartan/12.5 mg hydrochlorothiazide)/(80 mg telmisartan/12.5 mg hydrochlorothiazide) is indicated in adults whose blood pressure is not adequately controlled on telmisartan alone.
TELMISARTAN HCT fixed dose combination (80 mg telmisartan/25 mg hydrochlorothiazide) is indicated in adults whose blood pressure is not adequately controlled on TELMISARTAN HCT 80 mg/12.5 mg (80 mg telmisartan/12.5 mg hydrochlorothiazide) or adults who have been previously stabilised on telmisartan and hydrochlorothiazide given separately.

WARNINGS AND PRECAUTIONS

TELMISARTAN HCT should be kept in the sealed blister due to the hygroscopic property of the tablets. Tablets should be taken out of the blister shortly before administration.

Hazard(s) not otherwise classified (HNOC)

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

Pictogram: 

Signal word:	Warning
Hazard statement(s)	
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation
H335	May cause respiratory irritation.
Precautionary statement(s)	none
Supplemental Hazard Statements	none

Storage: Store in the original package in order to protect from moisture.

Disposal: Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

OTHER INFORMATION: No additional information

3. Composition/Information on ingredients

Mixtures

Hazardous components Chemical name	Common name and synonyms	CAS number	%
HYDROCHLORCTHIAZIDE		58-93-5	<10
TELMISARTAN		144701-48-4	10-20
MICROCRYSTALLINE CELLULOSE		9004-34-6	10-30
CARBOXYMETHYL CELLULOSE CALCIUM		9050-4-8	5-20
STARCH		9005-25-8	20-40
MANNITOL		69-65-8	<15
POVIDONE		9003-39-8	<10
Other components below reportable levels			<10

4. First aid measures

Eye contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Inhalation	If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
Ingestion:	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
Most important symptoms/effects, acute and delayed	Lowered blood pressure, Nausea, Dizziness, Headache, Vomiting, Diarrhoea, Muscle cramps/spasms., To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.
Indication of immediate medical attention and special treatment needed	No data available.
General information	Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

5. Fire-fighting measures

Suitable extinguishing media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Carbon oxides, nitrogen oxides (NOx), Sulphur oxides, Hydrogen chloride gas.
Special protective equipment and precautions for firefighters	Wear self contained breathing apparatus for fire fighting if necessary.
Fire-fighting equipment /instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures:	Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Avoid breathing dust.
Methods and materials for containment and cleaning up	Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

Decontamination Procedures	No specific decontamination or detoxification procedures have been identified for this product.
Environmental precautions	Do not let product enter drains.

7. Handling and storage

Precautions for safe handling

Precautions for safe handling	Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.
Conditions for safe storage, including any incompatibilities	Store in the original package in order to protect from moisture.

8. Exposure controls/personal protection

Occupational exposure limits			
Chemical name	Type	values	Note/Form
Industrial Use			
Hydrochlorothiazide (CAS 58-93-5)	TWA-8 Hr	250µg/m3	
US. ACGIH Threshold Limit Values			
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3	
US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)			
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
US. NIOSH: Pocket Guide to Chemical Hazards			
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	REL	5 mg/m3	Respirable.
		10 mg/m3	Total
Australia/ACGIH Threshold Limit Value			
STARCH(CAS 9005-25-8)	TWA	10 mg/m3	

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Hand protection	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
Body Protection	Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Respiratory protection	Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. 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. When using, do not eat, drink or smoke.

9. Physical and chemical properties

Physical state	Solid.
Form	Tablet.
Color	**Strengths(mg)** / **Color** 40/12.5 / White to off-white 80/12.5 / White to off-white 80/25 / 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**
40/12.5	Biconvex two-layered, oblong-shaped, uncoated tablets, the hydrochlorothiazide layer is pink and unmarked; the telmisartan layer is white to off-white but may contain pink specks, and debossed with “S591”.
80/12.5	Biconvex two-layered, oblong-shaped, uncoated tablets, the hydrochlorothiazide layer is pink and unmarked; the telmisartan layer is white to off-white but may contain pink specks, and debossed with “S592”
80/25	Biconvex two-layered, oblong-shaped, uncoated tablets, the hydrochlorothiazide layer is yellow and unmarked; the telmisartan layer is white to off-white but may contain yellow specks, and debossed with “S593”.

10. Stability and reactivity

Reactivity	No data available.
Chemical stability	No data available.
Possibility of hazardous reaction	No data available.
Conditions to avoid	No data available.
Incompatible material	Strong oxidizing agents.
Hazardous decomposition products	No data available.
Other decomposition products - no data available	

11. Toxicological information

Information on likely routes of exposure	
Ingestion	May be harmful if swallowed.
Inhalation	May be harmful if inhaled. May cause respiratory tract irritation.
Skin contact	May be harmful if absorbed through skin. May cause skin irritation.
Eye contact	May cause eye irritation.
Symptoms related to the physical, chemical and toxicological characteristics	To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Acute toxicity

Components	**Species**	**Test Results**

Hydrochlorothiazide(CAS 58-93-5)		
Acute Oral LD50	Rat	2750mg/kg
Microcrystalline cellulose (CAS 9004-34-6)		
Acute Oral LD50	Rat	> 50,000 mg/kg
Acute Dermal LD50	Rabbit	>2000 mg/kg
Povidone(CAS 9003-39-8)		
Acute Oral LD50	Rat	100000 mg/kg

Skin corrosion/irritation	No data available.
Serious eye damage/eye irritation	No data available.
Respiratory sensitization	No data available.
Skin sensitization	No data available.
Germ cell mutagenicity	No data available.
Carcinogenicity	IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity	No data available.
Specific target organ toxicity - single exposure	No data available.
Specific target organ toxicity - repeated exposure	No data available.
Aspiration hazard	No data available.
Additional Information	RTECS: : Not available

12. Ecological information

Ecotoxicity	No information is available about the potential of this product to produce adverse environmental effects. Contains a substance which causes risk of hazardous effects to the environment.
Toxicity	No data available
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 for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	No data available
Waste from residues / unused products	Offer surplus and non-recyclable solutions to a licensed disposal company.
Contaminated packaging	Dispose of as unused product.

14. Transport information

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

Regulatory information	This Section Contains Information relevant to compliance with other Federal and/or state laws.

16. Other information

Issue date 16.12.2017

Revision date 16.12.2017

Version # 019b

Reference

1) SIGMA-ALDRICH TELMISARTAN SDS
2) SIGMA-ALDRICH HYDROCHLOROTHIAZIDE 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