

Product Name: Teveten HCT
Issued: Dec-31-2012

SAFETY DATA SHEET

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name: Teveten HCT
Synonyms: Teveten 600/12.5 mg Tablets; Teveten 600/25 mg Tablets; Eprosartan Mesylate/Hydrochlorothiazide Tablets; Teveten Plus; Teveten HCT
List Number: 3015; 3020

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended use: Pharmaceuticals

1.3 Details of the supplier of the safety data sheet

Supplier: Manufactured for:
AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
1-800-255-5162
+1-847-937-7433

Customer Service Telephone: 1-800-255-5162 (US and Canada only)
+1-847-937-7433

E-mail Address: AbbVie.SDS@abbvie.com

1.4 Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

General Note

Serious eye damage/eye irritation Category 1

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Indication of danger: Xi - Irritant

Risk Phrases: R41 - Risk of serious damage to eyes

2.2 Label elements

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Section 2. Hazards identification



Signal Word: Danger

Hazard Statements: H318 - Causes serious eye damage

P280 - Wear protective gloves/protective clothing/eye protection/face protection
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Eprosartan mesylate 144143-96-4	60-80	NA	Xi, R41	Eye Dam. 1 (H318)	No data available
Lactose 63-42-3	1-9.9	200-559-2		Not Hazardous*	No data available
Cellulose Microcrystalline 9004-34-6	1-9.9	232-674-9		Not Hazardous*	No data available
Starch 9005-25-8	1-9.9	232-679-6		Not Hazardous*	No data available
Povidone 9003-39-8	1-9.9	NA		Not Hazardous*	No data available
Hydrochlorothiazide 58-93-5	1-9.9	200-403-3		Not Hazardous*	No data available
Polyvinyl alcohol 9002-89-5	1-5	NA		Not Hazardous*	No data available
Titanium Dioxide 13463-67-7	1-5	236-675-5		Not Hazardous*	No data available

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

For the full text of the R-phrases mentioned in this Section, see Section 16

For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

4.1 Description of first aid measures

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Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms: None known from occupational exposure. Clinical data suggests the following: increased susceptibility to infections, abdominal pain, hyper-triglyceridemia, bone and joint pain, depression, coughing, muscle weakness, dizziness, low blood potassium, gastrointestinal upset, excessive urination. Reported to cause the following: incoordination, headaches, confusion, vertigo.

Medical Conditions Aggravated by Exposure: Medical conditions exacerbated due to exposure to the following organs: liver, kidneys.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: Not determined

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8

6.2. Environmental precautions

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Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Recover product and place in an appropriate container for disposal.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Eprosartan mesylate 144143-96-4	100 mcg/m ³ TWA	None
Lactose 63-42-3	Not Applicable	None
Cellulose Microcrystalline 9004-34-6	Not Applicable	None
Starch 9005-25-8	Not Applicable	None
Povidone 9003-39-8	Not Applicable	None
Hydrochlorothiazide 58-93-5	0.25 mg/m ³ for 8-hour TWA	None
Polyvinyl alcohol 9002-89-5	Not Applicable	None
Titanium Dioxide 13463-67-7	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Lactose 63-42-3	10 mg/m ³ total dust, 3 mg/m ³ respirable dust				
Cellulose Microcrystalline 9004-34-6	10 mg/m ³ total dust	TWA: 10 mg/m ³		20 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)	
Starch 9005-25-8	10 mg/m ³ total dust for Starch			10 mg/m ³ (TWA) 4 mg/m ³ (TWA) 10 mg/m ³ (TWA)	
Povidone 9003-39-8	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate				

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Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Titanium Dioxide 13463-67-7	10 mg/m ³ TWA	TWA: 10 mg/m ³		10 mg/m ³ (TWA) 4 mg/m ³ (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Cellulose Microcrystalline 9004-34-6		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	20 mg/m ³ (STEL) 12 mg/m ³ (STEL) 20 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)
Starch 9005-25-8		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	30 mg/m ³ (STEL) 12 mg/m ³ (STEL) 30 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)
Titanium Dioxide 13463-67-7		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	30 mg/m ³ (STEL) 12 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)

8.2. Exposure controls

Engineering Controls:	No special provisions are required under normal product use conditions. When handling bulk formulation, use in a well-ventilated area.
Respiratory Protection:	Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.
Eyes:	Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.
Gloves:	Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.
Other PPE Data:	Wear appropriate body coverings if contact may occur.
Environmental Exposure Controls:	Not determined

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	Tablet
Odor:	Not determined.
Odor Threshold:	Not determined
pH:	Not determined.
Boiling Pt. @ 760 mm Hg (°C):	Not determined.
Melting/Freezing Point (°C):	Not determined
Flash Point (°C):	Not determined.
Evaporation Rate at 20°C:	Not determined.
Flammability (Solid):	Not determined.
Lower Explosive Limit:	Not determined.
Upper Explosive Limit:	Not determined.
Vapor Pressure (mm Hg):	Not determined.

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Vapor Density (Air = 1): Not determined.
Specific Gravity: Not determined.
Solubility(ies): Not determined.
Partition coefficient: n-octanol/water Not determined.
Autoignition Temp. (°C): Not determined.
Decomposition temperature (°C): Not determined.
Viscosity (centipoise): Not determined.
Explosion Severity: Not determined.
Oxidizer Properties: Not determined.

9.2. Other information

Not determined

Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined.

10.4. Conditions to avoid

Not determined.

10.5 Incompatible materials

Not determined

10.6 Hazardous decomposition products

Carbon oxides, Nitrogen oxides (NOx), Hydrogen chloride

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Clinical Route
Dermal: Yes
Inhalation: Unlikely

Acute Toxicity - Oral: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Eprosartan mesylate 144143-96-4	LD50 >	2,000	mg/kg	Rats
Lactose 63-42-3	LD50 >	10000	mg/kg	Rats

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Chemical Name	Acute Test	Value	Units	Species
Cellulose Microcrystalline 9004-34-6	LD50 >	5000	mg/kg	Rats
Povidone 9003-39-8	LD50 =	100000 1040	mg/kg	Rats Rabbits
Hydrochlorothiazide 58-93-5	LD50 >	40000		Mice
	LD50 =	2750	mg/kg	Rats

Acute Toxicity - Dermal: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Cellulose Microcrystalline 9004-34-6	LD50 >	2000	mg/kg	Rabbits

Acute Toxicity - Inhalation: Data for component (s) given below.

Chemical Name	Test	Value	Units	Species
Cellulose Microcrystalline 9004-34-6	LC 50 >	5800	mg/m ³ , 4 hour	Rats

Other Toxicology Data: Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Eprosartan mesylate 144143-96-4	LD 50 (iv) >	300 100	mg/kg	Rats Dogs	

Corrosivity: Not determined.

Dermal Irritation: Active Ingredient : Did not produce skin irritation in rabbits.

Eye Irritation: Active Ingredient : Produced severe eye irritation in rabbits.

Sensitization: Active Ingredient : Negative in the maximization assay in guinea pigs at challenge concentrations.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Data for component (s) given below.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Titanium Dioxide 13463-67-7	Lungs	Rats	10,000	mg/L	Inhalation	2 years

Reproductive Effects: Active Ingredient : In animals adverse reproductive effects include: maternal toxicity, fetal toxicity. Based on these experimental results, protection against maternal toxicity will provide adequate protection against potential embryo-fetal toxicity and teratogenicity

Data for component (s) given below.

Chemical Name	Species	Dosage	Units	Route	Duration
Eprosartan mesylate 144143-96-4	Rabbits	>= 10	mg/kg	Oral	During Gestation

Carcinogenicity: Data for component(s) given below.

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Eprosartan mesylate 144143-96-4	No increase in tumors	Mice Rats	2000 600	Oral	mg/kg/day	2 years

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Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Titanium Dioxide 13463-67-7	Lungs	Rats	250,000	Inhalation	mg/L	2 years

Mutagenicity: Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Eprosartan mesylate 144143-96-4	Negative	Negative	Negative	Equivocal results

Aspiration hazard: Not determined

Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

Section 12. Ecological information

12.1. Toxicity

Data for component (s) given below.

Chemical Name	Percent	LC 50 (mg/l)	Species	Duration
Eprosartan mesylate 144143-96-4	60-80	110 mg/l	Lepomis macrochirus	96 Hours

Chemical Name	Percent	EC 50 (mg/l)	Species	Duration
Eprosartan mesylate 144143-96-4	60-80	150 mg/l	Daphnia magna	48 Hours

Chemical Name	Percent	EB 50/ErC 50 (mg/l)	Species	Duration
Eprosartan mesylate 144143-96-4	60-80	> 100 mg/l	Selenastrum Capricornutum	72 Hours

12.2. Persistence and degradability

Not readily biodegradable. Data for component (s) given below.

Chemical Name	Percent	% Degradation	Duration
Eprosartan mesylate 144143-96-4	60-80	0	28 days

12.3. Bioaccumulative potential

Data for components given below.

Chemical Name	Percent	Log Po/w
Eprosartan mesylate 144143-96-4	60-80	< 3

12.4. Mobility in soil

Not determined.

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12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

Section 13. Disposal considerations

13.1 Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

Section 14. Transport information

ADR, DOT, ICAO/IATA, IMDG/IMO

Status: Not regulated

- 14.1. UN Number:** Not applicable
14.2. Proper shipping name: Not applicable
14.3. Hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazard: Not applicable
14.6. Special Provisions: Not applicable
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

Section 15. Regulatory Information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Eprosartan mesylate 144143-96-4	-	-	-	Not listed.	-
Lactose 63-42-3	200-559-2	X	X	Not listed.	X
Cellulose Microcrystalline 9004-34-6	232-674-9	X	X	Not listed.	X
Starch 9005-25-8	232-679-6	X	X	Not listed.	X
Povidone 9003-39-8	-	X	X	Not listed.	X
Hydrochlorothiazide 58-93-5	200-403-3	X	X	Not listed.	X

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Polyvinyl alcohol 9002-89-5	-	X	X	Not listed.	X
Titanium Dioxide 13463-67-7	236-675-5	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Eprosartan mesylate 144143-96-4	-	-	-	-	-	
Lactose 63-42-3	-	8-(4)-389	X	X	KE-17416	
Cellulose Microcrystalline 9004-34-6	Present	-	X	X	KE-05339	
Starch 9005-25-8	Present	-	X	X	KE-32128	
Povidone 9003-39-8	Present	-	X	X	KE-13324	
Hydrochlorothiazide 58-93-5	-	8-(7)-769	-	X	-	HSR007104
Polyvinyl alcohol 9002-89-5	Present	-	X	X	KE-29060	
Titanium Dioxide 13463-67-7	Present	-	X	X	KE-33900	

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances

ENCS - Japan Existing and New Chemical Substances

ISHL - Japan Industrial Safety and Health Law

IECSC - China Inventory of Existing Chemical Substances

AICS - Australian Inventory of Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Eprosartan mesylate	60-80	Not Listed	Not Listed	Not Listed
Lactose	1-9.9	Not Listed	Not Listed	Not Listed
Cellulose Microcrystalline	1-9.9	Not Listed	Not Listed	Not Listed
Starch	1-9.9	Not Listed	Not Listed	Not Listed
Povidone	1-9.9	Not Listed	Not Listed	Not Listed
Hydrochlorothiazide	1-9.9	Not Listed	Not Listed	Not Listed
Polyvinyl alcohol	1-5	Not Listed	Not Listed	Not Listed
Titanium Dioxide	1-5	Not Listed	Not Listed	Not Listed

SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Eprosartan mesylate	60-80	No	Not Applicable	Not applicable
Lactose	1-9.9	No	Not Applicable	Not applicable
Cellulose Microcrystalline	1-9.9	No	Not Applicable	Not applicable
Starch	1-9.9	No	Not Applicable	Not applicable
Povidone	1-9.9	No	Not Applicable	Not applicable
Hydrochlorothiazide	1-9.9	No	Not Applicable	Not applicable
Polyvinyl alcohol	1-5	No	Not Applicable	Not applicable
Titanium Dioxide	1-5	No	Not Applicable	Not applicable

Immediate Health: Yes
Delayed Health: No
Fire: No
Sudden Pressure: No
Reactivity: No

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RCRA Status: Not determined.

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

WHMIS Hazard Class: Not determined.

NFPA Rating:
Health: 1
Fire: 1
Reactivity: 0

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

Section 16. Other information

Risk Phrases: R41 - Risk of serious damage to eyes

Full text of H-Statements referred to under sections 2 and 3

H318 - Causes serious eye damage

Document Authored By: Global Occupational Toxicology (D-03QC)

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Supersedes the SDS dated: Sep-30-2008

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