SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, European Union CLP EC 1272/2008 and the Global Harmonization Standard

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

PRODUCT IDENTIFIER/TRADE/MATERIAL NAME: VALSARTAN TABLETS

Valsartan Tablets, 40 mg, 80 mg, 160 mg and 320 mg

DESCRIPTION: Valsartan Tablets
PRODUCT USE: Human Pharmaceutical
USES ADVISED AGAINST: Non-Pharmaceutical Use
CHEMICAL NAME: For Active Ingredient: N-(1-oxopentyl)-N-[[2'-(1H-tetrazol-5-yl) [1,1'-biphenyl]-4-yl]methyl]-L-valine
CHEMICAL FAMILY: For Active Ingredient: Biphenyltetrazoles Derivative
HOW SUPPLIED: 40 mg, 80 mg, 160 mg and 320 mg Tablets
FORMULA: For Active Ingredient: $C_{24}H_{29}N_5O_3$

SUPPLIER OF THE SAFETY DATA SHEET

RESPONSIBLE PARTY U.S.:	**ACTAVIS, INC.**
U.S. ADDRESS:	400 Interpace Parkway, Morris Corporate Center III Parsippany, NJ 07054, USA
U.S. BUSINESS PHONE/GENERAL SDS INFORMATION:	1-800-272-5525
RESPONSIBLE PARTY EUROPE:	
EUROPEAN ADDRESS:	
EUROPEAN BUSINESS PHONE:	
EMERGENCY PHONE (U.S./NORTH AMERICA):	CHEMTREC: 1-800-424-9300 (24 hours) U.S., Canada, Puerto Rico
EMERGENCY PHONE (OUTSIDE U.S.):	CHEMTREC: +1-703-527-3887 (24 hours) Outside North America
Email:	SafetyDataSheets@Actavis.com

NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, Canadian WHMIS [Controlled Products Regulations], EU Directives through EC 1907: 2006, and European Union CLP EC 1272/2008, required information is included in appropriate sections based on the U.S. ANSI Z400.1-2010 format. This product has been classified in accordance with the hazard criteria of the countries listed above.

DATE OF PREPARATION: June 24, 2012 **DATE OF REVISION:** September 23, 2013

2. HAZARDS IDENTIFICATION

EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

Classification: Not Applicable Signal Word: Not Applicable Hazard Statement Codes: Not Applicable

EU LABELING AND CLASSIFICATION 67/548/EEC: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

Classification: Not Applicable Risk Phrases: Not Applicable Safety Phrases: Not Applicable

See Section 16 for full EU classification information of product and components and full text of hazard and precautionary statements.

EMERGENCY OVERVIEW:

Product Description: This product is supplied as one side and oval with beveled edges (40 mg) and un-scored and almond-shaped with beveled edges (80, 160 and 320 mg). The tablets are yellow (40 mg), pale red (80 mg), grey-orange (160 mg) and dark grey-violet (320 mg).

Health Hazards: In the workplace, exposure to dusts from tablets via inhalation or eye contact may cause irritation. No information is available on possible effects from skin exposure. Non-therapeutic ingestion may be harmful The most common adverse effects from therapeutic use have been headache, dizziness, fatigue, abdominal pain and viral infection. May cause harm to fetus during therapeutic use. Additional adverse effects from therapeutic use are described in Section 11 (Toxicological Information).

Flammability Hazards: If heated to high temperatures for a prolonged period, the product may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon, titanium, magnesium, sodium and nitrogen oxides). Accumulation of dusts from this product has the potential to be ignited by static discharge and create an air/dust explosion hazard.

Reactivity Hazards: This product is not reactive.

Environmental Hazards: Large quantities of this product released to the aquatic and terrestrial environment may have an adverse effect.

Emergency Considerations: Emergency responders should wear appropriate protection for the situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements/Symbol
ACTIVE INGREDIENT:				
Valsartan	137862-53-4	Not Listed	Proprietary	SELF CLASSIFICATION: EU 67/548 Classification: Reproductive Toxicity Cat. 3 Risk Phrases: R22, R62, R63, R50 Hazard Symbol: Xn EU/GHS 1272/2008 Classification: Acute Oral Toxicity Cat. 5, Reproductive Toxicity Cat. 2 Hazard Statement Codes: H3032, H361df Hazard Symbol/Pictogram: GHS08
EXCIPIENTS:				
Colloidal Silicone Dioxide	112945-52-5	Not Listed	Proprietary	EU (67/548/EEC): No Classification Applicable EU/GHS 1272/2008: No Classification Applicable
Crospovidone	9003-39-8	Not Listed	Proprietary	EU (67/548/EEC): No Classification Applicable EU/GHS 1272/2008: No Classification Applicable
Hydroxyprolylmethyl Cellulose	9004-65-3	Not Listed	Proprietary	EU (67/548/EEC): No Classification Applicable EU/GHS 1272/2008: No Classification Applicable
Iron Oxide, Black	1317-61-9	215-277-5	Proprietary	EU (67/548/EEC): No Classification Applicable EU/GHS 1272/2008: No Classification Applicable
Iron Oxide, Red	1309-37-1	215-168-2	Proprietary	EU (67/548/EEC): No Classification Applicable EU/GHS 1272/2008: No Classification Applicable
Iron Oxide, Yellow	20344-49-4	Not Listed	Proprietary	EU (67/548/EEC): No Classification Applicable EU/GHS 1272/2008: No Classification Applicable
Magnesium Stearate	557-04-0	209-150-3	Proprietary	EU (67/548/EEC): No Classification Applicable EU/GHS 1272/2008: No Classification Applicable
Microcrystalline Cellulose	9004-34-6	232-674-9	Proprietary	EU (67/548/EEC): No Classification Applicable EU/GHS 1272/2008: No Classification Applicable
Polyethylene Glycol	25322-68-3	NLP # 500-038-2	Proprietary	EU (67/548/EEC): No Classification Applicable EU/GHS 1272/2008: No Classification Applicable
Titanium Dioxide	13463-67-7	236-675-5	Proprietary	EU (67/548/EEC): No Classification Applicable EU/GHS 1272/2008: No Classification Applicable

See Section 16 for full classification information of product and components.

4 FIRST-AID MEASURES

PROTECTION OF FIRST AID RESPONDERS: First-aid responders should not attempt to treat victims of exposure to this material without adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary.

DESCRIPTION OF FIRST AID MEASURES: Victim(s) must be taken for medical attention. Remove victim(s) to fresh air, as quickly as possible. Only trained personnel should administer supplemental oxygen and/or cardio-pulmonary resuscitation, when necessary. Take copy of label and SDS to physician or other health professional with victim(s).

INHALATION: If dusts or particulates from this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect occurs after removal to fresh air.

SKIN EXPOSURE: If the product contaminates the skin and adverse effect occurs, begin decontamination with running water. Minimum flushing is for 20 minutes. Do not interrupt flushing. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Seek medical attention if adverse effect occurs after flushing.

EYE EXPOSURE: If particulates from this product enter the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 20 minutes. Do not interrupt flushing. Seek immediate medical attention after flushing if adverse effect occurs.

INGESTION EXPOSURE: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Rinse mouth with water immediately. Victim should drink large quantities of water. If milk is available, victim should drink it after drinking water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

IMPORTANT SYMPTOMS AND EFFECTS: See Sections 2 (Hazard Identification) and 11 (Toxicological Information).

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing renal conditions, gastrointestinal problems, abnormalities of the esophagus which delay esophageal emptying such as stricture or achalasia, and hypercalcemia may be aggravated if ingested

IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED: Treat symptoms and eliminate exposure. No specific information is available on the treatment of overdosage of this product. However, based on knowledge of this class of compounds, oral overdosage may result in hypocalcemia, hypophosphatemia, and upper gastrointestinal adverse events, such as upset stomach, dyspepsia, esophagitis, gastritis, or ulcer. Milk or antacids should be given to bind the product. Due to the risk of esophageal irritation, vomiting should not be induced, and the patient should remain fully upright. Dialysis would not be beneficial.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not established.

AUTOIGNITION TEMPERATURE: Not established.

FLAMMABLE LIMITS & METHOD OF DETERMINATION (in air by volume, %): Not determined.

FIRE EXTINGUISHING MEDIA: Use extinguishing media appropriate for surrounding fire.

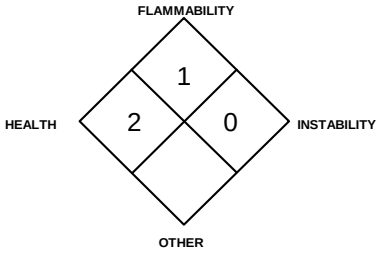
UNSUITABLE EXTINGUISHING MEDIA: None known.

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL: This product may ignite if highly heated for a prolonged period of time. When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon, titanium, magnesium, sodium and nitrogen oxides).

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

NFPA RATING



Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe

SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. Contaminated protective equipment should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: In the event of a spill, clear the area and protect people.

PROTECTIVE EQUIPMENT:

Small Spills: For incidental spills (e.g., 1 vial of tablets), wear double latex or nitrile disposable gloves and eye protection.

Large Spills: For large spills (e.g., a pallet of vials), protective apparel should be used with a respirator when there is any danger of airborne dusts being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit.

METHODS FOR CLEANUP AND CONTAINMENT:

Small Spills: Pick-up or sweep-up spilled tablets.

Large Spills: Trained personnel following pre-planned procedures should handle non-incidental releases. Access to the spill areas should be restricted. Sweep up spilled product carefully, avoiding the generation of airborne dusts.

All Spills: Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Do not mix with wastes from other materials. If necessary, discard contaminated response equipment or rinse with soapy water before returning such equipment to service. Dispose of in accordance with applicable international, national, state, and local procedures (see Section 13, Disposal Considerations).

ENVIRONMENTAL PRECAUTIONS: Prevent material from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

7. HANDLING and USE

PRECAUTIONS FOR SAFE HANDLING: Employees must be trained to properly use this product. As with all chemicals, avoid getting this material ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics in work areas where this product is handled or stored. Wash thoroughly after handling this product or equipment and containers of this product. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Use of this product should be performed in a designated area for working with drugs. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this compound, and during patient administration. If necessary, work areas must be regularly cleaned and decontaminated.

PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store this product in original container. Store at 20°C to 25°C (68°F to 77°F). (See USP Controlled Room Temperature.) Inspect bottles containing this product for leaks or damage. Store away from incompatible materials (see Section 10, Stability and Reactivity).

SPECIFIC END USE(S): This product human pharmaceutical. Follow all industry standards for use of this product.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS.

OCCUPATIONAL/WORKPLACE EXPOSURE LIMITS/GUIDELINES:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	IDLH mg/m^3	mg/m^3
Valsartan	137862-53-4	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established.

EXPOSURE LIMITS/CONTROL PARAMETERS (continued):

OCCUPATIONAL/WORKPLACE EXPOSURE LIMITS/GUIDELINES:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	IDLH mg/m^3	mg/m^3
Cellulose Compounds Exposure limits given are for cellulose CAS# 9004-34-6		10	NE	15 (total dust), 5 (respirable fraction)	NE	10 (total dust), 5 (respirable fraction)	NE	NE	NE
Colloidal Silicon Dioxide	112945-52-5	NE	NE	NE	NE	NE	NE	NE	NE
Crospovidone	9003-39-8	NE	NE	NE	NE	NE	NE	NE	Carcinogen: IARC-3
Iron Oxides Exposure limits given are for CAS# 1309-37-1	1309-37-1	3 (respirable fraction)	NE	10 (fume)	NE	5 (dust and fume)	NE	NE	Carcinogen: IARC-3, MAK-3B, TLV-A4
Magnesium Stearate Exposure limits given are for Stearates	557-04-0	10	NE	NE	NE	NE	NE	NE	Carcinogen: TLV-A4
Polyethylene Glycol	25322-68-3	NE	NE	NE	NE	NE	NE	NE	DFG MAKs: TWA = 1000 (inhalable fraction) PEAK = 8•MAK 15 min. average value, 1-hr interval, 4 per shift AIHA WEEL: TWA = 10 (aerosol only)
Titanium Dioxide	13463-67-7	10	NE	15 (total dust) 10 (vacated 1989 PEL)	NE	See Pocket Guide Appendix A		Ca; 5000	Carcinogen: IARC-2B, MAK-3A, NIOSH-Ca, TLV-A4

NE = Not Established.

INTERNATIONAL OCCUPATIONAL EXPOSURE LIMITS: In addition to the exposure limit values cited in this section, other exposure limits have been established by various countries for the components of this product. The exposure limits given may not be the most current; individual country authorities should be contacted to check on more current limits.

COLLOIDAL SILICON DIOXIDE:
Australia: TWA = 2 mg/m^3 (respirable dust), JUL 2008

CROSPOVIDONE:
Russia: STEL = 10 mg/m^3, JUN 2003

HYDROXYPROPYLMETHYL CELLULOSE:
Russia: STEL = 10 mg/m^3, JUN 2003

IRON OXIDE, BLACK:
ARAB Republic of Egypt: TWA = 3 ppm (5 mg/m^3) (fume), JAN 1993
Australia: TWA = 0.1 mg(Fe)/m^3, JUL 2008
Australia: TWA = 5 mg(Fe)/m^3 (fume), JUL 2008
Belgium: TWA = 2 ppm (5 mg(Fe)/m^3) (fume), MAR 2002
Denmark: TWA = 3.5 mg(Fe)/m^3, OCT 2002
Finland: TWA = 5 mg(Fe)/m^3, fume, SEP 2009
France: VME = 5 mg(Fe)/m^3 (fume), FEB 2006
Germany: MAK = 1.5 mg(Fe)/m^3 (respirable), 2005
Hungary: TWA = 6 mg/m^3 (resp), SEP 2000
Japan: OEL = 1 mg/m^3 (respirable), 4 mg/m^3 (total), APR 2007
Korea: TWA = 10 mg/m^3, 2006
Korea: TWA = 5 mg/m^3, 2006
Mexico: TWA = 10 mg/m^3; STEL = 20 mg/m^3, 2004
The Netherlands: MAC-TGG = 10 mg/m^3, 2003
The Netherlands: MAC-TGG = 5 mg(Fe)/m^3, 2003
New Zealand: TWA = 5 mg(Fe)/m^3 (dust and fume), JAN 2002
New Zealand: TWA = 10 mg/m^3 (inspirable dust), JAN 2002
Norway: TWA = 3 mg/m^3, JAN 1999
The Philippines: TWA = 10 mg/m^3 (fume), JAN 1993
Poland: MAC(TWA) fume = 5 mg/m^3, MAC(STEL) = 10 mg/m^3, JAN 1999
Russia: TWA = 6 mg/m^3, JUN 2003
Sweden: TWA = 3.5 mg(Fe)/m^3 (resp. dust), JUN 2005
Switzerland: MAK-W = 3 mg/m^3, DEC 2006
Thailand: TWA = 10 mg/m^3 (fume), JAN 1993
Turkey: TWA = 10 mg/m^3 (fume), JAN1993
United Kingdom: TWA = 4 mg/m^3 (respirable), 2005
United Kingdom: TWA = 10 mg/m^3 (inhalable), 2005
United Kingdom: TWA = 5 mg(Fe)/m^3; STEL = 10 mg(Fe)/m^3, 2005
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

IRON OXIDE, RED:
ARAB Republic of Egypt: TWA = 3 ppm (5 mg/m^3) (fume), JAN 1993
Australia: TWA = 0.1 mg(Fe)/m^3, JUL 2008
Australia: TWA = 5 mg(Fe)/m^3 (fume), JUL 2008
Belgium: TWA = 2 ppm (5 mg(Fe)/m^3) (fume), MAR2002
Denmark: TWA = 3.5 mg(Fe)/m^3, OCT 2002
Finland: TWA = 5 mg(Fe)/m^3, fume, SEP 2009
France: VME = 5 mg(Fe)/m^3 (fume), FEB 2006
Germany: MAK = 1.5 mg(Fe)/m^3 (respirable), 2005
Hungary: TWA = 6 mg/m^3 (resp), SEP2000
Japan: OEL = 1 mg/m^3 (respirable), 4 mg/m^3 (total), APR 2007
Korea: TWA = 10 mg/m^3, 2006
Korea: TWA = 5 mg/m^3, 2006
Mexico: TWA = 10 mg/m^3; STEL = 20 mg/m^3, 2004

IRON OXIDE, RED (continued):
The Netherlands: MAC-TGG = 5 mg(Fe)/m^3, 2003
The Netherlands: MAC-TGG = 10 mg/m^3, 2003
New Zealand: TWA = 5 mg(Fe)/m^3 (dust and fume), JAN 2002
New Zealand: TWA = 10 mg/m^3 (inspirable dust), JAN 2002
Norway: TWA = 3 mg/m^3, JAN 1999
The Philippines: TWA = 10 mg/m^3 (fume), JAN 1993
Poland: MAC(TWA) fume = 5 mg/m^3, MAC(STEL) = 10 mg/m^3, JAN 1999
Russia: TWA = 6 mg/m^3, JUN 2003
Sweden: TWA = 3.5 mg(Fe)/m^3 (resp. dust), JUN 2005
Switzerland: MAK-W = 3 mg/m^3, DEC 2006
Thailand: TWA = 10 mg/m^3 (fume), JAN1993
Turkey: TWA = 10 mg/m^3 (fume), JAN 1993
United Kingdom: TWA = 4 mg/m^3 (respirable), 2005
United Kingdom: TWA = 10 mg/m^3 (inhalable), 2005
United Kingdom: TWA = 5 mg(Fe)/m^3;STEL = 10 mg(Fe)/m^3, 2005
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

MAGNESIUM STEARATE:
New Zealand: TWA = 10 mg/m^3 (inspirable dust), JAN 2002
Sweden: TWA = 5 mg/m^3, JUN 2005

MICROCRYSTALLINE CELLULOSE:
Belgium: TWA = 10 mg/m^3, MAR 2002
France: VME = 10 mg/m^3, FEB 2006
Korea: TWA = 10 mg/m^3, 2006
Mexico: TWA = 10 mg/m^3; STEL = 20 mg/m^3, 2004
The Netherlands: MAC-TGG = 2 mg/m^3, 2003
New Zealand: TWA = 10 mg/m^3 (inspirable dust), JAN 2002
Russia: STEL = 10 mg/m^3, JUN 2003
Switzerland: MAK-W = W 6 mg/m^3, DEC 2006
United Kingdom: TWA = 10 mg/m^3 (inhalable), 2005
United Kingdom: TWA = 4 mg/m^3; STEL = 20 mg/m^3 (respirable), 2005
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam, check ACGIH TLV

POLYETHYLENE GLYCOL:
The Netherlands: MAC-TGG = 1000 mg/m^3, 2003
Russia: STEL = 10 mg/m^3, JUN 2003
Denmark: TWA = 1000 mg/m^3, OCT 2002
Germany: MAK = 1000 mg/m^3 (inhalable), 2005

TITANIUM DIOXIDE:
ARAB Republic of Egypt: TWA = 15 mg/m^3, JAN 1993
Belgium: TWA = 10 mg/m^3, MAR 2002
Denmark: TWA = 6 mg(Ti)/m^3, OCT 2002
France: VME = 10 mg/m^3, FEB 2006
Germany: MAK = 1.5 mg/m^3 (respirable), 2005
Japan: OEL = 1 mg/m^3 (respirable), 4 mg/m^3 (total), APR 2007
Korea: TWA = 10 mg/m^3, 2006
Mexico: TWA = 10 mg(Ti)/m^3; STEL = 20 mg(Ti)/m^3, 2004
The Netherlands: MAC-TGG = 10 mg/m^3, 2003
New Zealand: TWA = 10 mg/m^3 (inspirable dust), JAN 2002
Norway: TWA = 5 mg/m^3, JAN 1999
Poland: MAC(TWA) = 10 mg(Ti)/m^3, MAC(STEL) = 30 mg(Ti)/m^3, JAN 1999

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/CONTROL PARAMETERS (continued):

INTERNATIONAL OCCUPATIONAL EXPOSURE LIMITS (continued):

TITANIUM DIOXIDE (continued):
Russia: TWA = 10 mg/m^3, JUN 2003
Sweden: TWA = 5 mg/m^3 (total dust), JUN 2005
Switzerland: MAK-W = 3 mg/m^3, DEC 2006

TITANIUM DIOXIDE (continued):
Turkey: TWA = 15 mg/m^3, JAN 1993
United Kingdom: TWA = 10 mg/m^3 (inhalable), 2005
United Kingdom: TWA = TWA 4 mg/m^3 (respirable), 2005
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

PERSONAL PROTECTIVE EQUIPMENT: Use of personal protective equipment must be in compliance with U.S. OSHA 29 CFR Subpart I (beginning at 1910.132), Canadian CSA Standards Z94.4-02 and Z94.3-02, EU EN 529:2005, CEN/TR 15419:2006, and CR 13464:1999. Please reference applicable regulations and standards for relevant details.

RESPIRATORY PROTECTION: Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

EYE PROTECTION: No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, splash goggles or safety glasses should be considered.

HAND PROTECTION: During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS.

BODY PROTECTION: Use appropriate protective clothing for the task (e.g., lab coat, etc.).

9. PHYSICAL and CHEMICAL PROPERTIES

The following information is for the product.

FORM: Oval or almond-shaped tablets.
COLOR: Yellow, pale red, grey-orange, dark grey-violet.
ODOR: Odorless.
ODOR THRESHOLD: Not applicable.
HOW TO DETECT THIS SUBSTANCE (identification properties): The appearance of this product is a distinguishing characteristic.

The following values are available for the active ingredient, Valsartan:

FORM: Crystalline solid.
COLOR: White to tan.
MOLECULAR WEIGHT: 435.5
MOLECULAR FORMULA: $C_{24}H_{29}N_5O_3$
ODOR: Odorless.
ODOR THRESHOLD: Not applicable.
BOILING POINT @ 760 mmHg: 684.9°C (1264.8°F) [predict.]
MELTING POINT: 116-117°C (240.8-242.5°F)
VAPOR PRESSURE (air = 1) @ 25°C: 0.0 mmHg
SPECIFIC GRAVITY (water = 1): 1.213 g/cm^3
pH: Not established.
VAPOR DENSITY: Not available.
FLASH POINT: 368°C (694.4°F) [predicted]
FLAMMABILITY: Combustible.
SOLUBILITY IN WATER: Slightly soluble in water: 2.34e-02 g/L
OTHER SOLUBILITIES: Freely soluble in sodium hydroxide solution, in n-butylamine, and in dimethylformamide; sparingly soluble in methanol; insoluble in ether, in chloroform, and in dilute mineral acids.
COEFFICIENT WATER/OIL DISTRIBUTION: Log P = 4.26 (predicted); Log Pow = 3.993

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: This product is not reactive.
DECOMPOSITION PRODUCTS: *Combustion:* If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g. carbon, titanium, magnesium, sodium and nitrogen oxides). *Hydrolysis:* None known.
MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. Acids and alkalies, and other chemicals that could affect its performance should be avoided.
POSSIBILITY HAZARDOUS REACTION/POLYMERIZATION: Will not occur.
CONDITIONS TO AVOID: Avoid heat, light, and contact with incompatible chemicals.

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees using this product in an occupational setting. The following paragraphs describe the symptoms of exposure by route of exposure.
INHALATION: Inhalation of airborne dusts generated by damaged tablets of this product may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.
CONTACT WITH SKIN or EYES: Acute skin contact is not expected to cause adverse effect. Prolonged or repeated skin contact may cause dermatitis (dry, red skin). Contact with the eyes of airborne dusts generated by damaged tablets of this product may cause mild to moderate irritation, redness, and tearing.
SKIN ABSORPTION: No information is available on potential skin absorption.
INGESTION: Ingestion is not a significant route of occupational overexposure. Symptoms of acute ingestion may include nausea and vomiting. Symptoms of chronic ingestion caused by poor hygiene practices may include those described for "Other Potential Health Effects".
INJECTION: Local pain and inflammation may result from subcutaneous injection.
OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: Employees handling this product should not experience adverse effects if handled properly. The most common adverse effects from therapeutic use have been headache, dizziness, fatigue, abdominal pain and viral infection.

11. TOXICOLOGICAL INFORMATION (Continued)

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses (continued): Additional effects from therapeutic use of this product, listed by body system, can include:

- ***Body as a Whole:*** Allergic reaction and asthenia
- ***Cardiovascular:*** Palpitations
- ***Dermatologic:*** Pruritus and rash, alopecia.
- ***Digestive:*** Constipation, dry mouth, dyspepsia, and flatulence, elevated liver enzymes and very rare reports of hepatitis
- ***Musculoskeletal:*** Back pain, muscle cramps, and myalgia
- ***Neurologic and Psychiatric:*** Anxiety, insomnia, paresthesia, and somnolence.
- ***Hypersensitivity:*** There are rare reports of angioedema.
- ***Blood and Lymphatic:*** There are very rare reports of thrombocytopenia.
- ***Renal:*** Impaired renal function
- ***Respiratory:*** Dyspnea
- ***Special Senses:*** Vertigo
- ***Urogenital:*** Impotence.
- **Vascular:** Vasculitis.
- ***Other Effects:*** Chest pain, syncope, anorexia, vomiting, hyperkalemia and angioedema. Rare cases of rhabdomyolysis have been reported in patients receiving angiotensin II receptor blockers.

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2*
FLAMMABILITY HAZARD	(RED)	1
PHYSICAL HAZARD	(YELLOW)	0

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe * = Chronic hazard

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Exposure to this product may cause the following health effects:

Acute: Exposure to dusts from this product may cause irritation by inhalation, skin or eye contact. Accidental ingestion may be harmful.

Chronic: Not information is available on effects from chronic occupational exposure. Refer to 'Other Health Effects' for possible effects from chronic therapeutic exposure.

TARGET ORGANS:

Acute: *Industrial Exposure*: Skin, eyes, respiratory system. *Therapeutic Doses*: Refer to information given under 'Other Health Effects'.

Chronic: *Industrial Exposure*: Skin. *Therapeutic Doses*: Refer to 'Other Potential Health Effects'.

IRRITANCY OF PRODUCT: This product may irritate contaminated tissue.

SENSITIZATION TO THE PRODUCT: Allergic reactions including anaphylaxis, angioedema, bronchospasm and rash have been reported.

TOXICITY DATA: The following data are for the active ingredient. Additional data for excipients are available but are not presented in this SDS. Contact Watson Pharmaceuticals for more information.

VALSARTAN:

TDLo (Oral-Human) 48 mg/kg/6 weeks-intermittent:Vascular: BP lowering not characterized in autonomic section

TDLo (Oral-Human) 48 mg/kg/12 weeks-intermittent: Vascular: BP lowering not characterized in autonomic section

TDLo (Oral-Human) 1144 mg/kg: female 79 week(s) pre-mating 1-24 week(s) after conception: Reproductive: Effects on Embryo or Fetus: fetotoxicity (except death, e.g., stunted fetus); Specific Developmental Abnormalities: urogenital system; Effects on Newborn: delayed effects

TDLo (Unreported-Woman) 6.4 mg/kg: Immunological Including Allergic: other immediate (humoral): urticaria, allergic rhinitis, serum sickness

TDLo (Unreported-Woman) 2656 mg/kg/2 years-intermittent: Vascular: other changes

TDLo (Oral-Rat) 112 mg/kg/2 weeks-intermittent: Vascular: BP elevation not characterized in autonomic section

TDLo (Oral-Rat) 448 mg/kg/8 weeks-intermittent: Cardiac: other changes: Blood: other changes; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: other Enzymes

TDLo (Oral-Rat) 450 mg/kg/15 days-intermittent: Cardiac: changes in heart weight; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: phosphatases, Metabolism (Intermediary): effect on Sodium-Potassium pump

VALSARTAN (continued):

TDLo (Oral-Rat) 175 mg/kg/5 weeks-intermittent: Cardiac: changes in heart weight; Vascular; BP lowering not characterized in autonomic section

TDLo (Oral-Rat) 350 mg/kg/5 weeks-intermittent: Cardiac: changes in heart weight; Vascular: BP lowering not characterized in autonomic section; Nutritional and Gross Metabolic: weight loss or decreased weight gain

TDLo (Oral-Rat) 784 mg/kg/8 weeks-intermittent: Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: dehydrogenases

TDLo (Oral-Rat) 210 mg/kg/1 weeks-intermittent: Vascular: BP lowering not characterized in autonomic section

TDLo (Oral-Rat) 840 mg/kg/4 weeks-intermittent: Brain and Coverings: other degenerative changes; Vascular: BP lowering not characterized in autonomic section

TDLo (Oral-Mouse) 6000 mg/kg/150 days-intermittent: Behavioral: alteration of classical conditioning; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: other; Enzymes Biochemical: Metabolism (Intermediary): other proteins

TDLo (Intravenous-Rat) 10 mg/kg: Vascular: BP lowering not characterized in autonomic section

TDLo (Unreported-Rat) 560 mg/kg/8 weeks-intermittent: Gastrointestinal: changes in structure or function of endocrine pancreas; Endocrine: hypoglycemia

CARCINOGENIC POTENTIAL OF COMPONENTS: There was no evidence of carcinogenicity when Valsartan was administered in the diet to mice and rats for up to 2 years at doses up to 160 and 200 mg/kg/day, respectively. These doses in mice and rats are about 2.6 and 6 times, respectively, the maximum recommended human dose on a mg/m² basis. (Calculations assume an oral dose of 320 mg/day and a 60-kg patient.)

The excipient components are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

CROSPOVIDONE: IARC-3 (Unclassifiable as to Carcinogenicity in Humans)

IRON OXIDES: ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); IARC-3 (Unclassifiable as to Carcinogenicity in Humans); MAK-3B (Substances for which in vitro tests or animal studies have yielded evidence of carcinogenic effects that is not sufficient for classification of the substance in one of the other categories. Further studies are required before a final classification can be made.)

MAGNESIUM STEARATE (as a stearate compound): ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen)

TITANIUM DIOXIDE: IARC-2B (Possibly Carcinogenic to Humans); MAK-3A (Substances for which the criteria for classification in Category 4 or 5 are fulfilled for which the database in insufficient for the establishment of a MAK value); NIOSH-Ca (Potential Occupational Carcinogen with no Further Classification)

11. TOXICOLOGICAL INFORMATION (Continued)

CARCINOGENIC POTENTIAL OF COMPONENTS (continued): The remaining components of this product are not found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.
oral dose of 320 mg/day and a 60-kg patient.)

REPRODUCTIVE TOXICITY INFORMATION: In therapeutic use, during the first trimester of pregnancy, this product is rated during the first trimester Pregnancy Category C (Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks) and during second and third trimesters, D (There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks). Reports of fetal and neonatal toxicity in babies born to women treated with Candesartan Cilexetil during pregnancy. There are, however, no adequate and well-controlled studies in pregnant women.

Mutagenicity: Mutagenicity assays did not reveal any Valsartan-related effects at either the gene or chromosome level. These assays included bacterial mutagenicity tests with Salmonella (Ames) and E coli; a gene mutation test with Chinese hamster V79 cells; a cytogenetic test with Chinese hamster ovary cells; and a rat micronucleus test.

Embryotoxicity: ACE inhibitors can cause fetal and neonatal morbidity and mortality when administered to pregnant women. Several dozen cases have been reported in the world literature.

Teratogenicity: The use of ACE inhibitors during the second and third trimesters of pregnancy has been associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios has also been reported, presumably resulting from decreased fetal renal function; oligohydramnios in this setting has been associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patent ductus arteriosus have also been reported, although it is not clear whether these occurrences were due to the ACE inhibitor exposure. These adverse effects do not appear to have resulted from intrauterine ACE-inhibitor exposure that has been limited to the first trimester.

Reproductive Toxicity: Valsartan had no adverse effects on the reproductive performance of male or female rats at oral doses up to 200 mg/kg/day. This dose is 6 times the maximum recommended human dose on a mg/m² basis. (Calculations assume an oral dose of 320 mg/day and a 60-kg patient.)

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, ACGIH Biological Exposure Indices (BEIs) have not been determined for the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

MOBILITY: This product has not been tested for mobility in soil. Information is available some components, but is not presented in this SDS. Contact Watson Pharmaceutical for more information.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability. It is expected that the components will slowly degrade in the environment and form a variety of organic and inorganic materials; however, no specific information is known. Information is available some components, but is not presented in this SDS. Contact Watson Pharmaceutical for more information.

BIO-ACCUMULATION POTENTIAL: This product has not been tested for bio-accumulation potential. Information is available some components, but is not presented in this SDS. Contact Watson Pharmaceutical for more information.

ECOTOXICITY: All releases to terrestrial, atmospheric and aquatic environments should be avoided. No aquatic toxicity data are available for the active component. Data may be available for the excipient components, but are not presented in this SDS. Contact Watson Pharmaceutical for more information.

OTHER ADVERSE EFFECTS: This product does not contain any component with known ozone depletion potential.

RESULTS OF PBT AND vPvB ASSESSMENT: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

ENVIRONMENTAL EXPOSURE CONTROLS: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT/DISPOSAL METHODS: Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING: Wear proper protective equipment when handling waste materials.

U.S. EPA WASTE NUMBER: Not applicable to wastes consisting only of this product.

EUROPEAN WASTE CODES: Wastes from Human or Animal Health Care or Related Research: 18 01 06: Chemicals consisting of or containing dangerous substances.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION REGULATIONS: This product is not classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA, TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not classified as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product is not classified as Dangerous Goods, by rules of IATA.

14. TRANSPORTATION INFORMATION (Continued)

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is not classified as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is not classified by the United Nations Economic Commission for Europe to be dangerous goods.

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: Not applicable.

ENVIRONMENTAL HAZARDS: This product is neither environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) nor a marine pollutant according to the IMDG Code and is not listed in Annex III under MARPOL 73/78.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for any component of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA REPORTABLE QUANTITIES (RQ): Not applicable.

U.S. TSCA INVENTORY STATUS: This product is regulated under Food and Drug Administration standards; it is not subject to requirements under TSCA.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): No component of this product is on the California Proposition 65 Lists.

CANADIAN REGULATIONS:

CANADIAN DSL INVENTORY STATUS: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it excepted from requirements of the DSL/NDSL Inventory.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: The components of this product are not on the CEPA Priorities Substances Lists.

CANADIAN WHMIS CLASSIFICATION AND SYMBOL: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

EUROPEAN REGULATIONS:

SAFETY, HEALTH, AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE PRODUCT: When formulated in a finished medicinal product for human use, this material is subject to Directive 2001/83/EC and subsequent amendments to the directive.

CHEMICAL SAFETY ASSESSMENT: No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

16. OTHER INFORMATION

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): CAUTION! MAY BE HARMFUL IF ACCIDENTALLY SWALLOWED. DUSTS MAY CAUSE RESPIRATORY, SKIN AND EYE IRRITATION. THIS PRODUCT CONTAINS A COMPOUND THAT MAY CAUSE HARM TO FETUS. Do not take internally without prescription. Avoid unnecessary contact with skin, eyes, and clothing. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. FIRST-AID: In case of contact, flush skin or eyes with plenty of water. If adverse respiratory reaction occurs, give oxygen and seek immediate medical attention. If ingested, DO NOT induce vomiting-seek immediate medical attention. IN CASE OF FIRE: Use water fog, dry chemical, CO_2, or "alcohol" foam. IN CASE OF SPILL: Pick up or sweep up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Safety Data Sheet for additional information.

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU LABELING AND CLASSIFICATION 67/548/EEC: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

CLASSIFICATION OF COMPONENTS:

CLP Regulation (EC) 1272/2008

Valsartan: Self-Classification

Classification: Reproductive Toxicity Category 2, Acute Toxicity Oral Category 5

Signal Word: Warning

Hazard Statements: H303: May be harmful if swallowed. H361d: Suspected of damaging the unborn child.

All Remaining Components:

An official classification for these substances has not been published in the CLP 1272: 2008 and a self-classification is not applicable.

16. OTHER INFORMATION (Continued)

CLASSIFICATION OF COMPONENTS (continued):

67/548/EEC:

Valsartan: Self-Classification

Classification: Harmful

Risk Phrases: R63: Possible risk of harm to the unborn child.

All Remaining Components:

Classification: An official classification for these substances has not been published in Commission Directives and a self-classification is not applicable.

REFERENCES AND DATA SOURCES: Contact the supplier for information.

METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

REVISION DETAILS: New

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc. • PO Box 1961, Hilo, HI 96721 • 800/441-3365 • 808/969-4846

DATE OF PRINTING: September 23, 2013