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: ROSUVASTATIN CALCIUM TABLET

DESCRIPTION: Rosuvastatin Calcium Oral Tablets
PRODUCT USE: Human Pharmaceutical
USES ADVISED AGAINST: Non-Pharmaceutical Use
CHEMICAL NAME: For Active Ingredient: bis[(E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl (methylsulfonyl) amino] pyrimidin-5-yl](3R,5S)-3,5-dihydroxyheptan-6-enoic acid] calcium salt
CHEMICAL FAMILY: For Active Ingredients: Organic Methylsulfonyl Amino Salt
FORMULA: For Active Ingredient: $(C_{22}H_{27}FN_{306}S)2Ca$
HOW SUPPLIED: 5 mg, 10 mg, 20 mg and 40 mg Rosuvastatin Calcium Tablets
OTHER DESIGNATIONS:

5 mg: NDC 16252-0615-30 bottles of 30; NDC 16252-0615-90 bottles of 90; NDC 16252-0615-50 bottles of 500;
10 mg: NDC 16252-0616-30 bottles of 30; NDC 16252-0616-90 bottles of 90; NDC 16252-0616-50 bottles of 500;
20 mg: NDC 16252-0617-30 bottles of 30; NDC 16252-0617-90 bottles of 90; NDC 16252-0617-50 bottles of 500;
40 mg: NDC 16252-0618-30 bottles of 30; NDC 16252-0618-90 bottles of 90; NDC 16252-0618-50 bottles of 500

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:	
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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
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NOTE: ALL United States Occupational Safety and Health Administration (OSHA) Standard, 29 CFR Parts 1910, 1915, 1917, 1918 and 1926, and the U.S. OSHA Instruction CPL 02-02-079, July 9, 2015, U.S. State equivalent Standards, Canadian WHMIS [Controlled Products Regulations], and European Union CLP EC 1272/2008, required information is included in appropriate sections based on the UN Global Harmonization Standard format. This product has been classified in accordance with the hazard criteria of the countries listed above.

DATE OF PREPARATION: March 4, 2016 **DATE OF REVISION:** New

2. HAZARDS IDENTIFICATION

U.S. OSHA HAZARD COMMUNICATION STANDARD 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.

EMERGENCY OVERVIEW:

Product Description: This product is supplied as yellow, round convex shaped coated tablets (5 mg), pink, round convex shaped coated tablets (10 mg), pink, round convex shaped coated tablets (20 mg) or pink, oval shaped coated tablets (40 mg).

Health Hazards: Accidental ingestion may be harmful. In therapeutic use, the most common adverse effects reported have included muscle pain, abdominal pain, headache, lack or loss of strength and energy, weakness, nausea. Prolonged therapeutic use may cause serious adverse systemic effects to the liver and other organs. Limited evidence of potential carcinogenic effects, based on animal data. May cause harm to the fetus. Animal studies indicate potential adverse effects on fertility. May cause harm to breast fed babies. These effects may be possible as a result of workplace exposure. Refer to Section 11 (Toxicological Information) for additional information on adverse effects.

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 iron, titanium, calcium, carbon, magnesium, sodium and nitrogen oxides, small organic aldehydes, acrolein).

Reactivity Hazards: This product is not reactive.

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

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

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	LABEL ELEMENTS GHS Under U.S. OSHA & EU Classification (1272/2008 EC) Hazard Statement Codes /Symbol
ACTIVE INGREDIENTS:				
Rosuvastatin Calcium bis[(E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino] pyrimidin-5-yl](3R,5S)-3,5-dihydroxyhept-6-enoic acid] calcium salt	147098-20-2	Not Listed	Proprietary	SELF-CLASSIFICATION GHS under U.S. OSHA & EU CLP 1272/2008: Classification: Reproductive Toxicity Cat. 1B, Carcinogenic Toxicity Cat. 2, Adverse Effects on or Via Lactation, Eye Irritation Cat. 2A, STOT (Ingestion-Liver, Musculoskeletal System) RE Cat. 2 Hazard Statement Codes: H360FD, H351, H362, H319, H373
EXCIPIENTS:				
Crospovidone	9003-39-8	Not Listed	Proprietary	GHS under U.S. OSHA & EU CLP 1272/2008: No Classification Applicable
FD&C Blue No. 2	860-22-0	212-728-8	Proprietary	SELF-CLASSIFICATION GHS under U.S. OSHA & EU CLP 1272/2008: Classification: Acute Oral Toxicity Cat. 4 Hazard Statement Codes: H302
FD&C Red No. 40	4548-53-2	224-909-9	Proprietary	SELF-CLASSIFICATION GHS under U.S. OSHA & EU CLP 1272/2008: Classification: Acute Oral Toxicity Cat. 5 Hazard Statement Codes: H303
Iron Oxide Red	1309-37-1	215-168-2	Proprietary	GHS under U.S. OSHA & EU CLP 1272/2008: No Classification Applicable
Iron Oxide Yellow	51274-00-1	257-098-5	Proprietary	GHS under U.S. OSHA & EU CLP 1272/2008: No Classification Applicable
Lactose Monohydrate	64044-51-5	For Anhydrous: 200-559-2	Proprietary	GHS under U.S. OSHA & EU CLP 1272/2008: No Classification Applicable
Magnesium Stearate	557-04-0	209-150-3	Proprietary	GHS under U.S. OSHA & EU CLP 1272/2008: No Classification Applicable
Microcrystalline Cellulose	9004-34-6	232-674-9	Proprietary	GHS under U.S. OSHA & EU CLP 1272/2008: No Classification Applicable
Polyethylene Glycol	25322-68-3	NLP # 500-038-2	Proprietary	GHS under U.S. OSHA & EU CLP 1272/2008: No Classification Applicable
Polyvinyl Alcohol	9002-89-5	209-183-3	Proprietary	GHS under U.S. OSHA & EU CLP 1272/2008: No Classification Applicable
Sodium Carbonate Monohydrate	5968-11-6	For Anhydrous: 207-838-8	Proprietary	SELF-CLASSIFICATION GHS under U.S. OSHA & EU CLP 1272/2008: Classification: Eye Irritation Cat. 2A Hazard Statement Codes: H319
Sodium Dodecyl Sulfate	151-21-3	205-788-1	Proprietary	SELF-CLASSIFICATION GHS under U.S. OSHA & EU CLP 1272/2008: Classification: Acute Oral Toxicity Cat. 4, Eye Irritation Cat. 2A Hazard Statement Codes: H302, H319
Talc	14807-96-6	238-877-9	Proprietary	GHS under U.S. OSHA & EU CLP 1272/2008: No Classification Applicable
Titanium Dioxide	13463-67-7	236-675-5	Proprietary	SELF-CLASSIFICATION GHS under U.S. OSHA & EU CLP 1272/2008: Classification: Carcinogenic Cat. 1B Hazard Statement Codes: H350i

See Section 16 for full classification information of 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: In therapeutic use, pre-existing uncontrolled hypothyroidism, and renal impairment or insufficiency usually as a consequence of long-standing diabetes mellitus, muscle conditions such as myopathy and rhabdomyolysis, active liver disease, or high levels of cholesterol and/or triglycerides may be aggravated. Workplace exposure may also aggravate these conditions. Persons who may have hypersensitivity reactions to any ingredient or other disorders described in Section 11 (Toxicological Information) may experience aggravation upon exposure.

4 FIRST-AID MEASURES (Continued)

IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED: Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive immediate medical attention. No specific antidote is known. Treatment should be symptomatic and supportive. Hemodialysis does not significantly enhance clearance of Rosuvastatin.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not established.

AUTOIGNITION TEMPERATURE: Not established.

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

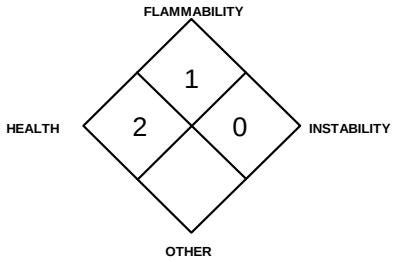
FIRE EXTINGUISHING MEDIA: Use extinguishing media appropriate for surrounding fire.

UNSUITABLE EXTINGUISHING MEDIA: None known.

SPECIFIC HAZARDS ARISING FROM THE PRODUCT: 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., iron, titanium, calcium, carbon, magnesium, sodium and nitrogen oxides, small organic aldehydes, acrolein).

Explosion Sensitivity to Mechanical Impact or 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. Move to a secure area. 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. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of pharmaceutical preparations, and during patient administration. As with all chemicals, avoid getting this product 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. 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.

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
Rosuvastatin Calcium	147098-20-2	NE	NE	NE	NE	NE	NE	NE	Actavis OEL: 10 µg/m^3
Crospovidone	9003-39-3	NE	NE	NE	NE	NE	NE	NE	Carcinogen: IARC-3
FD&C Blue No. 2	860-22-0	NE	NE	NE	NE	NE	NE	NE	NE
FD&C Blue No. 40	4548-53-2	NE	NE	NE	NE	NE	NE	NE	Carcinogen: IARC-3
Iron Oxide Yellow Iron Oxide Red Exposure limits given are for CAS# 1309-37-1 (Fe2O3)	51274-00-1 1309-37-1	5 (resp. fract.)	NE	10 (fume)	NE	5 (dusts & fume, as Fe)	NE	2500 (dust & fume, as Fe)	Carcinogen: IARC-3, MAK-3B, TLV-A4
Microcrystalline Cellulose Exposure limits are for cellulose	9004-34-6	10	NE	15 (total dust), 5 (resp. fract.)	NE	10 (total dust), 5 (resp. fract.)	NE	NE	NE
Lactose Monohydrate	64044-51-5	NE	NE	NE	NE	NE	NE	NE	NE
Magnesium Stearate	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 DFG MAK Pregnancy Risk Classification: C AIHA WEEL: TWA = 10 (aerosol only)
Polyvinyl Alcohol	9002-89-5	NE	NE	NE	NE	NE	NE	NE	Carcinogen: IARC-3
Sodium Carbonate Monohydrate	5968-11-6	NE	NE	NE	NE	NE	NE	NE	NE
Sodium Dodecyl Sulfate	151-21-3	NE	NE	NE	NE	NE	NE	NE	NE
Talc	14807-96-6	2 (resp. fract.)	NE	20 mppcf (containing < 1% quartz)	NE	2 (resp. dust) and < 1% quartz	NE	NE	Carcinogen: IARC-3, MAK-3B (respirable fraction), TLV-A4
Titanium Dioxide	13463-67-7	10	NE	15 (total dust) 10 (vacated 1989 PEL)	NE	See NIOSH Pocket Guide Appendix A		Ca, 5000	Carcinogen: IARC-2B, MAK-3A, NIOSH-Ca, TLV-A4

NE = Not Established. mppcf = Millions of Particles per Cubic Foot

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.

IRON OXIDES:
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 = 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
Belgium: TWA = 10 mg/m^3, MAR 2002

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 PEG:
Denmark: TWA = 1000 mg/m^3, MAY 2011
Germany: MAK = 1000 mg/m^3 (inhalable), 2011
The Netherlands: MAC-TGG = 1000 mg/m^3, 2003

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

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

TALC:
Australia: TWA = 2.5 mg/m^3, JUL 2008
Belgium: TWA = 2 mg/m^3, MAR 2002
Finland: TWA = 0.5 f/cc, fibrous, SEP 2009
Finland: TWA = 5 mg/m^3, granulated, SEP 2009
Japan: OEL = 0.5 mg/m^3 (respirable), 2 mg/m^3 (total), MAY 2009
Korea: TWA = 2 mg/m^3, 2006
Mexico: TWA = 2 mg/m^3 (respirable), 2004
The Netherlands: MAC-TGG = 1 mg/m^3, 2003
New Zealand: TWA = 2 mg/m^3 (respirable dust), JAN 2002
Sweden: TWA = 2 mg/cm^3 (total dust); TWA = 1 mg/cm^3 (resp. dust), JUN 2005
Switzerland: MAK-W = 2 mg/m^3, DEC 2006
United Kingdom: TWA = 1 mg/m^3 (resp. dust), OCT 2007
In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/CONTROL PARAMETERS (continued):

International Occupational Exposure Limits (continued):

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

TITANIUM DIOXIDE (continued):
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
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
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 tablets.
COLOR: As described in Section 2.
ODOR: Odorless.
ODOR THRESHOLD: Not applicable.
HOW TO DETECT THIS SUBSTANCE (identification properties): The appearance of this product is a distinguishing characteristic.

The following information is for the Rosuvastatin Calcium active ingredient.

FORM: Amorphous powdered solid.
COLOR: White.
MOLECULAR WEIGHT: 1001.14
MOLECULAR FORMULA: $(C_{22}H_{27}FN_{306}S)2Ca$
ODOR: Odorless.
ODOR THRESHOLD: Odorless.
BOILING POINT @ 760 mmHg: 745.6°C (1374.1°F) [predict.]
MELTING POINT: Not available.
VAPOR PRESSURE (air = 1) @ 25°C: 0 mmHg
SPECIFIC GRAVITY (water = 1): 1.369 g/cm^3
EVAPORATION RATE (nBuAc = 1): Not applicable.
FLASH POINT: 404.7°C (760.5°F) [predict.]
SOLUBILITY IN WATER @ 25°C: Sparingly soluble.
OTHER SOLUBILITIES: Sparingly soluble in methanol, and slightly soluble in ethanol.
COEFFICIENT WATER/OIL DISTRIBUTION: Log Kow = 1.57 (est.); Log P = 0.422
PARTITION COEFFICIENT (OCTANOL/WATER) @ pH of 7.0: 0.13

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. iron, titanium, calcium, carbon, magnesium, sodium and nitrogen oxides, small organic aldehydes, acrolein). **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 EXPOSURE 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 from the drug product may slightly irritate the nose, throat, and lungs. Inhalation of large amounts may also cause under 'Other Potential Health Effects'.

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). The Butylated Hydroxyanisole component has been shown to cause contact dermatitis by skin patch testing. 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 available.

Ingestion: Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product caused by poor hygiene practices may be harmful. Symptoms of prolonged or repeated ingestion, as may occur when poor industrial hygiene is practiced, may include those described for 'Other Potential Health Effects'.

Injection: Injection is not a likely route of exposure for the form of this product.

11. TOXICOLOGICAL INFORMATION (Continued)

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: In therapeutic use, the most common adverse effects reported have included muscle pain, abdominal pain, headache, lack or loss of strength and energy, weakness, nausea. Prolonged therapeutic use may cause serious adverse systemic effects to the liver and other organs. Limited evidence of potential carcinogenic effects, based on animal data. May cause harm to the fetus. Animal studies indicate potential adverse effects on fertility. May cause harm to breast fed babies. These effects may be possible as a result of workplace exposure. The actual risk in the workplace is not known. In therapeutic use the following additional adverse effects described by body system have included:

- ***Body as a Whole:*** Lack or loss of strength and energy, weakness.
- ***Central Nervous System:*** Headache, dizziness.
- ***Cognitive Disorders:*** Rare post-marketing reports of cognitive impairment (e.g., memory loss, forgetfulness, amnesia, memory impairment, confusion) associated with statin use. These cognitive issues have been reported for all statins. The reports are generally non-serious, and reversible upon statin discontinuation, with variable times to symptom onset (1 day to years) and symptom resolution (median of 3 weeks).
- ***Endocrine System:*** Increases in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, leading to diabetes mellitus.
- ***Gastrointestinal System:*** Abdominal pain, constipation, nausea.
- ***Hypersensitivity Reactions:*** Rash, itching, hives, swelling of face and throat.
- ***Liver:*** Increases in serum transaminases [AST (SGOT) or ALT (SGPT)] have been reported with HMG-CoA reductase inhibitors.
- ***Musculoskeletal System:*** Muscle pain, breakdown of muscle tissue. Rare reports of immune-mediated necrotizing myopathy associated with statin use.
- ***Renal System:*** Acute renal failure.
- ***Reproductive System:*** Harm to fetus during pregnancy, adverse effects on fertility.
- ***Skin:*** Itching, rash.
- ***Urinary System:*** Dipstick-positive proteinuria (excess protein in urine) and microscopic hematuria (blood in urine).

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: Accidental ingestion may be harmful. Eye contact with dusts may cause mechanical irritation. Inhalation of dusts from product may also cause effects described under 'Other Potential Health Effects'.

Chronic: Harm to fetus, based on animal data. Repeated workplace exposure to the skin contact may cause dermatitis (dry, red skin). Chronic therapeutic use or workplace exposure may cause effects described under 'Other Potential Health Effects'.

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

Acute: Accidental ingestion may be harmful. Eye contact with dusts may cause mechanical irritation. Inhalation of dusts from product may also cause effects described under 'Other Potential Health Effects'.

Chronic: Repeated workplace exposure to the skin contact may cause dermatitis (dry, red skin). Chronic therapeutic use or workplace exposure may cause effects described under 'Other Potential Health Effects'.

TARGET ORGANS: Acute: *Industrial Exposure*: Skin, eyes, respiratory system (dusts from product). *Therapeutic Doses*: Reproductive system. **Chronic:** *Industrial Exposure*: Skin. *Therapeutic Doses*: Body systems as given under 'Other Potential Health Effects'.

IRRITANCY OF PRODUCT: Dusts from this product may irritate contaminated tissue.

SENSITIZATION TO THE PRODUCT: In therapeutic use, itching, rash, hives, swelling of the face and throat have been reported.

TOXICITY DATA: Currently the following toxicity data are available for the active component. Data for excipients are also available but are not presented in this SDS. Contact Actavis for more information.

ROSUVASTATIN CALCIUM:

TDLo (Oral-Human) 5.88 mg/kg/12 weeks-intermittent: Musculoskeletal: other changes, Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: transaminases, other Enzymes

TDLo (Oral-Human) 47.9 mg/kg/12 weeks-intermittent: Kidney/Ureter/Bladder: proteinuria

TDLo (Oral-Human) 4.275 mg/kg/30 days-intermittent: Musculoskeletal: other changes Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: other Enzymes

TDLo (Oral-Human) 8 mg/kg/8 weeks-intermittent: Musculoskeletal: other changes; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: multiple enzyme effects; Biochemical: Metabolism (Intermediary): lipids including transport

ROSUVASTATIN CALCIUM (continued):

TDLo (Oral-Human) 4 mg/kg/8 weeks-intermittent: Behavioral: headache; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: multiple enzyme effects; Biochemical: Metabolism (Intermediary): lipids including transport

TDLo (Unreported-Human-Man) 16.016 mg/kg/8 weeks-intermittent: Blood: normocytic anemia, changes in platelet count

TDLo (Oral-Rat) 210 mg/kg/3 weeks-intermittent: Sense Organs and Special Senses (Eye): retinal changes (pigmentary depositions, retinitis, other); Vascular: BP lowering not characterized in autonomic section; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: other oxidoreductases

TOXICITY DATA (continued):

ROSUVASTATIN CALCIUM (continued):

TDLo (Oral-Rat) 3360 mg/kg/24 weeks-intermittent: Cardiac: other changes; Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol); Biochemical: Metabolism (Intermediary): other proteins

TDLo (Oral-Rat) 3360 mg/kg/24 weeks-intermittent: Cardiac: other changes

TDLo (Oral-Rat) 900 mg/kg/10 days-intermittent: Musculoskeletal: other changes

TDLo (Oral-Rat) 1650 mg/kg/16 days-intermittent: Musculoskeletal: other changes

TDLo (Oral-Rat) 1050 mg/kg/12 days-intermittent: Musculoskeletal: other changes

TDLo (Oral-Rat) 1320 mg/kg/15 days-intermittent: Musculoskeletal: other changes

TDLo (Oral-Rat) 1120 mg/kg/13 days-intermittent: Musculoskeletal: other changes

TDLo (Oral-Mouse) 4480 mg/kg/32 weeks-continuous: Vascular: other changes; Biochemical: Metabolism (Intermediary): other proteins, effect on inflammation or mediation of inflammation

ROSUVASTATIN CALCIUM (continued):

TDLo (Oral-Rat) 750 mg/kg/5 days-intermittent: Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: other Enzymes

TDLo (Oral-Mouse) 700 mg/kg/20 weeks-intermittent: Vascular: structural changes in vessels; Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol); Biochemical: Metabolism (Intermediary): lipids including transport

TDLo (Oral- Mammal-Dog) 42 mg/kg/3 weeks-intermittent: Blood; changes in serum composition (e.g. TP, bilirubin, cholesterol)

TDLo (Subcutaneous-Mouse) 70 mg/kg/2 weeks-intermittent: Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol); Biochemical: Metabolism (Intermediary): lipids including transport

TDLo (Subcutaneous-Mouse) 280 mg/kg/2 weeks-intermittent: Biochemical: Metabolism (Intermediary): effect on inflammation or mediation of inflammation

TDLo (Subcutaneous-Mouse) 840 mg/kg/12 weeks-intermittent: Endocrine: hypoglycemia; Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: other oxidoreductases, Biochemical: Metabolism (Intermediary): lipids including transport

OTHER ANIMAL TOXICITY DATA: Central nervous system vascular lesions, characterized by peri-vascular hemorrhages, edema, and mononuclear cell infiltration of peri-vascular spaces, have been observed in dogs treated with several other members of this drug class.

A chemically similar drug in this class produced dose-dependent optic nerve degeneration (Wallerian degeneration of retinogeniculate fibers) in dogs, at a dose that produced plasma drug levels about 30 times higher than the mean drug level in humans taking the highest recommended dose. Edema, hemorrhage, and partial necrosis in the interstitium of the choroid plexus was observed in a female dog sacrificed moribund at day 24 at 90 mg/kg/day by oral gavage (systemic exposures 100 times the human exposure at 40 mg/day based on AUC). Corneal opacity was seen in dogs treated for 52 weeks at 6 mg/kg/day by oral gavage (systemic exposures 20 times the human exposure at 40 mg/day based on AUC). Cataracts were seen in dogs treated for 12 weeks by oral gavage at 30 mg/kg/day (systemic exposures 60 times the human exposure at 40 mg/day based on AUC). Retinal dysplasia and retinal loss were seen in dogs treated for 4 weeks by oral gavage at 90 mg/kg/day (systemic exposures 100 times the human exposure at 40 mg/day based on AUC). Doses ≤ 30 mg/kg/day (systemic exposures ≤ 60 times the human exposure at 40 mg/day based on AUC) did not reveal retinal findings during treatment for up to one year.

CARCINOGENIC POTENTIAL OF COMPONENTS: The following information is available for the active ingredient.

In a 104-week carcinogenicity study in rats at dose levels of 2, 20, 60, or 80 mg/kg/day by oral gavage, the incidence of uterine stromal polyps was significantly increased in females at 80 mg/kg/day at systemic exposure 20 times the human exposure at 40 mg/day based on AUC. Increased incidence of polyps was not seen at lower doses. In a 107-week carcinogenicity study in mice given 10, 60, 200 mg/kg/day by oral gavage, an increased incidence of hepatocellular adenoma/carcinoma was observed at 200 mg/kg/day at systemic exposures 20 times the human exposure at 40 mg/day based on AUC. An increased incidence of hepatocellular tumors was not seen at lower doses.

The following excipient ingredients are listed:

IRON OXIDES (based on CAS# 1309-37-1): ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); IARC-3 (Unclassifiable as to Carcinogenicity in Humans); MAK-3B [respirable fraction] (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.)

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

FD&C RED No. 40, CROSPOVIDONE, POLYVINYL ALCOHOL: IARC-3 (Unclassifiable as to Carcinogenicity in Humans)

TALC: ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); IARC-3 (Unclassifiable as to Carcinogenicity in Humans); MAK-3B [respirable fraction] (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.)

TITANIUM DIOXIDE: ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); IARC-2B (Possibly Carcinogenic to Humans); MAK-3A (Substances Which Cause Concern that They Could Be Carcinogenic for Man But Cannot Be Assessed Conclusively Because of Lack of Data. Substances for which the criteria for classification in Category 4 or 5 are fulfilled, but for which the database is insufficient for the establishment of a MAK value.); NIOSH-Ca (Potential Occupational Carcinogen with No Further Categorization); Notice of Intended Change: ACGIH TLV-A3 (Confirmed Animal Carcinogen with Unknown Relevance to Humans)

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.

REPRODUCTIVE TOXICITY INFORMATION: There are no adequate and well-controlled studies of Rosuvastatin Calcium in pregnant women; however, this drug can cause fetal harm when administered to a pregnant woman. This drug is contraindicated in women who are or may become pregnant. Lipid lowering drugs offer no benefit during pregnancy, because cholesterol and cholesterol derivatives are needed for normal fetal development. In the workplace, the risk to the fetus should be communicated and the appropriate action should be taken to prevent exposure in accordance with company policy and regulatory requirements. This product is rated by the FDA for therapeutic risk as Pregnancy Risk Category X (Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits).

Mutagenicity: Rosuvastatin was not mutagenic or clastogenic with or without metabolic activation in the Ames test with *Salmonella typhimurium* and *Escherichia coli*, the mouse lymphoma assay, and the chromosomal aberration assay in Chinese hamster lung cells. Rosuvastatin was negative in the *in vivo* mouse micronucleus test.

Embryotoxicity/Teratogenicity:

Human Information: There have been rare reports of congenital anomalies following intrauterine exposure to HMG-CoA reductase inhibitors. In a review of about 100 prospectively followed pregnancies in women exposed to other HMG-CoA reductase inhibitors, the incidences of congenital anomalies, spontaneous abortions, and fetal deaths/stillbirths did not exceed the rate expected in the general population.

11. TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION (continued):

Embryotoxicity/Teratogenicity (continued):

Human Information (continued): However, this study was only able to exclude a three-to-fourfold increased risk of congenital anomalies over background incidence. In 89% of these cases, drug treatment started before pregnancy and stopped during the first trimester when pregnancy was identified.

Animal Data: Rosuvastatin crosses the placenta and is found in fetal tissue and amniotic fluid at 3% and 20%, respectively, of the maternal plasma concentration following a single 25 mg/kg oral gavage dose on gestation day 16 in rats. A higher fetal tissue distribution (25% maternal plasma concentration) was observed in rabbits after a single oral gavage dose of 1 mg/kg on gestation day 18. In female rats given oral gavage doses of 5, 15, 50 mg/kg/day Rosuvastatin before mating and continuing through day 7 post-coitus results in decreased fetal body weight (female pups) and delayed ossification at the high dose (systemic exposures 10 times the human exposure at 40 mg/day based on AUC). In pregnant rats given oral gavage doses of 2, 10, 50 mg/kg/day from gestation day 7 through lactation day 21 (weaning), decreased pup survival occurred in groups given 50 mg/kg/day, systemic exposures ≥ 12 times the human exposure at 40 mg/day based on body surface area. In pregnant rabbits given oral gavage doses of 0.3, 1, 3 mg/kg/day from gestation day 6 to lactation day 18 (weaning), exposures equivalent to the human exposure at 40 mg/day based on body surface area, decreased fetal viability and maternal mortality was observed. Rosuvastatin was not teratogenic in rats at ≤ 25 mg/kg/day or in rabbits ≤ 3 mg/kg/day (systemic exposures equivalent to the human exposure at 40 mg/day based on AUC or body surface area, respectively).

Reproductive Toxicity: In rat fertility studies with oral gavage doses of 5, 15, 50 mg/kg/day, males were treated for 9 weeks prior to and throughout mating and females were treated 2 weeks prior to mating and throughout mating until gestation day 7. No adverse effect on fertility was observed at 50 mg/kg/day (systemic exposures up to 10 times the human exposure at 40 mg/day based on AUC). In testicles of dogs treated with Rosuvastatin at 30 mg/kg/day for one month, spermatidic giant cells were seen. Spermatidic giant cells were observed in monkeys after 6-month treatment at 30 mg/kg/day in addition to vacuolation of seminiferous tubular epithelium. Exposures in the dog were 20 times and in the monkey 10 times the human exposure at 40 mg/day based on body surface area. Similar findings have been seen with other drugs in this class. It is not known whether Rosuvastatin is excreted in human milk, but a small amount of another drug in this class does pass into breast milk. In rats, breast milk concentrations of Rosuvastatin are three times higher than plasma levels; however, animal breast milk drug levels may not accurately reflect human breast milk levels. Because another drug in this class passes into human milk and because HMG-CoA reductase inhibitors have a potential to cause serious adverse reactions in nursing infants. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

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.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability.

BIO-ACCUMULATION POTENTIAL: This product has not been tested for bio-accumulation potential.

ECOTOXICITY: The active ingredient can cause chronic toxicity to aquatic organisms. This product may be harmful to aquatic and terrestrial organisms; all releases to terrestrial, atmospheric and aquatic environments should be avoided. No aquatic toxicity data are available for the active ingredient.

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 08: Medicines Other Than Those Mentioned in 18 01 07.

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.

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

14. TRANSPORTATION INFORMATION (Continued)

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 does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and not component is specifically 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 (TPQ): 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.

Other U.S. Federal Regulations: Regulations of the FDA under the Federal Food, Drug and Cosmetic Act are applicable when this material is used in pharmaceutical preparations. Under the Hazard Communication Standard (HCS), Section (b)(5)(ii) drugs are subject to labeling requirements by the FDA under the Federal Food, Drug and Cosmetic Act and are exempt from labeling provisions of the HCS; this section of the HCS exempts only labeling requirements and not requirements for a Safety Data Sheet for drugs.

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): WARNING! MAY BE HARMFUL IF ACCIDENTALLY INGESTED. MAY CAUSE HARM TO FETUS AND BREAST-FED BABIES DURING PREGNANCY. LIMITED EVIDENCE OF CARCINOGENIC EFFECTS, BASED ON ANIMAL DATA. COMBUSTIBLE IF EXPOSED TO HIGH TEMPERATURES. 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.

CLASSIFICATION FOR COMPONENTS:

Full Text Global Harmonization, U.S. OSHA and EU CLP Regulation (EC) 1272/2008:

Rosuvastatin Calcium: This is a self-classification.

Classification: Reproductive Toxicity Category 1B, Carcinogenic Category 2, Adverse Effects on or Via Lactation, Eye Irritation Category 2A, Specific Target Organ Toxicity (Ingestion-Liver, Musculoskeletal System) Repeated Exposure Category 2

Hazard Statements: H360FD: May damage the unborn child. H351: Suspected of causing cancer. H362: May cause harm to breast-fed children. H319: Causes serious eye irritation. H373: May cause damage to organs through prolonged or repeated exposure.

FD&C Blue No. 2: This is a self-classification.

Classification: Acute Oral Toxicity Category 4

Hazard Statements: H302: Harmful if swallowed.

16. OTHER INFORMATION (Continued)

CLASSIFICATION FOR COMPONENTS (continued):

Full Text Global Harmonization, U.S. OSHA and EU CLP Regulation (EC) 1272/2008 (continued):

FD&C Red No. 40: This is a self classification.

Classification: Acute Oral Toxicity Category 5

Hazard Statements: H303: May be harmful if swallowed.

Sodium Carbonate Monohydrate: This is a self-classification.

Classification: Eye Irritation Category 2A

Hazard Statements: H319: Causes serious eye irritation.

Sodium Dodecyl Sulfate: This is a self-classification.

Classification: Acute Oral Toxicity Category 4, Eye Irritation Category 2A

Hazard Statements: H302: Harmful if swallowed. H319: Causes serious eye irritation.

Titanium Dioxide: The following is a Self-Classification.

Classification: Carcinogenic Category 1B

Hazard Statements: H350i: May cause cancer by inhalation.

All Other Components: No classification has been published or is 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.

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