

SAFETY DATA SHEET

Date: 10/17/2017

Generic Name: Atorvastatin Calcium Tablets

 Brand Equivalent: Lipitor[®] Tablets

SECTION 1: IDENTIFICATION	
Product Name	Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg
Active substance	Atorvastatin Calcium
Synonyms	N/A
Formula	(C ₃₃ H ₃₄ FN ₂ O ₅) ₂ Ca
Intended Use	competitive inhibitor of HMG-CoA reductase
Chemical Name	[R-(R* , R*)]-2-(4-fluoro phenyl)-β, δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid, calcium salt (2:1)
How Supplied	10 mg, 20 mg, 40 mg and 80 mg: Yellow , Oval shape, biconvex, film coated
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723

2. HAZARDS IDENTIFICATION	
Statement of Hazard:	Non-hazardous in accordance with international standards for workplace safety.
Additional Hazard Information:	Short Term: May cause eye irritation (based on components). Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.
Known Clinical Effects:	Adverse effects associated with therapeutic use of atorvastatin include constipation, flatulence, upset stomach, and abdominal pain. Clinical use of this drug has caused changes in liver function, muscle pain, weakness.
EU Indication of danger:	Not classified
Australian Hazard Classification (NOHSC):	Non-Hazardous Substance. Non-Dangerous Goods.
Note	This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. Composition/Information on ingredients		
Components	CAS-No	Concentration (%w/w)
Atorvastatin calcium	134523-03-8	6.671
Anhydrous Lactose, NF (Super Tab 21AN)	63423	*
Sodium Carbonate Anhydrous, NF fine Powder	497198	*
Sodium Bicarbonate , USP #1	144-55-8	*
Sodium Lauryl Sulfate, NF (Texapon K 12 P PH)	151-21-3	*
Copovidone, NF (Plasdone S-630)	25086899	*
Silicified Microcrystalline Cellulose , NF (Prosolv SMCC 90)	9004-34-6	*
Mannitol, USP (Pearlitol 200 SD)	69658	*
Croscarmellose Sodium , NF (VIVASOL GF)	74811657	*
Colloidal Silicon Dioxide, NF (Aerosil 200)	7631-86-9	*
Magnesium Stearate, NF	557-04-0	*
Opadry Yellow AMB (80W120004)	Mixture	*

* Proprietary, In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES	
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Inhalation	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

5. FIRE-FIGHTING MEASURES	
Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. ACCIDENTAL RELEASE MEASURES	
Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Environmental precautions	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.

7. HANDLING AND STORAGE	
Precautions for safe handling	Avoid breaking or crushing tablets. Avoid prolonged exposure. Avoid release to the environment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).
Specific use(s)	Human pharmaceutical use

8. Exposure controls/Personal protection	
Engineering Controls and Ventilation	General ventilation normally adequate. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.
Respiratory Protection	No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Eye protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
Hand protection	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves. Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
<i>Appearance</i>	
Physical State	Solid.
Color	Refer section 1
Form	Tablet.
<i>Odour</i>	
Odour	Not available
Odor Threshold	Not available
pH	Not available
<i>Other information</i>	
Bulk density	Not available
Evaporation rate	Not available
Molecular formula	Not applicable
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Molecular Weight	Not applicable
Log Octanol/Water Partition	
Coeff [log Kow]	Not available
Surface Tension	Not available
pKa	Not available
Particle Size	Not available
Solubility, Water	Not available
Specific Gravity/ Relative Density	Not available
Viscosity, dynamic	Not available
Viscosity, kinematic	Not available
% Volatile	Not available
<i>Thermal/Stability properties</i>	
Autoignition temperature	Not available
Boiling Point	Not available
Thermal decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, UEL	Not available
Explosiveness	Not available
Flammability	Not available
Flash point	Not available
Melting Point	Not Available
Oxidizing Potential	Not available
<i>Vapor Properties</i>	
Vapor Density	Not available
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

10. Stability and Reactivity	
Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability	Stable under normal conditions
Conditions to Avoid	Contact with incompatible materials
Incompatible products	Strong oxidizing agents
Hazardous Decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.
Hazardous Reactions	No dangerous reaction known under conditions of normal use.

11. Toxicological Information	
Routes of Entry	Ingestion, Inhalation, Eye contact, Skin contact
Eye Irritation	Not irritating to eyes
Skin Irritation	Not irritating to eyes
Respiratory Irritation	Respiratory Irritant
Acute Toxicity Study	Due to lack of data the classification is not possible
Repeated Dose Toxicity	Due to lack of data the classification is not possible
Genetic Toxicity	Due to lack of data the classification is not possible
Carcinogenicity	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA
Reproductive Toxicity	Due to lack of data the classification is not possible
Developmental Toxicity	Due to lack of data the classification is not possible
Pharmacokinetics/Toxicokinetics	Due to lack of data the classification is not possible
Other Toxicity Information	Due to lack of data the classification is not possible

12. Ecological Information	
Ecotoxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available
Mobility in soil	Not available
Other adverse effects	Not available

13. Disposal considerations	
Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport Information
The following refers to all modes of transportation unless specified below.
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. Regulatory Information	
US federal regulations	
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)	Not regulated.
CERCLA Hazardous Substance List (40 CFR 302.4)	Not listed.
SARA 304 Emergency release notification	Not regulated.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	Not listed.
Superfund Amendments and Reauthorization Act of 1986 (SARA)	
SARA 302 Extremely hazardous substance	Not listed.
SARA 311/312 Hazardous chemical	No
SARA 313 (TRI reporting)	Not regulated.
Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List	Not regulated
Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)	Not regulated.
Safe Drinking Water Act (SDWA)	Not regulated.
US. California Proposition 65	California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

16. Other information	
Recommended Restrictions for Use:	Not available
Prepared on	10/17/17
Revision	02
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