

**SAFETY DATA SHEET**

Date: 10/17/2017

Generic Name: Atorvastatin Calcium Tablets

 Brand Equivalent: Lipitor<sup>®</sup> Tablets

<b>SECTION 1: IDENTIFICATION</b>	
<b>Product Name</b>	Atorvastatin Calcium Tablets, 10 mg, 20 mg, 40 mg and 80 mg
<b>Active substance</b>	Atorvastatin Calcium
<b>Synonyms</b>	N/A
<b>Formula</b>	(C <sub>33</sub> H <sub>34</sub> FN <sub>2</sub> O <sub>5</sub> ) <sub>2</sub> Ca
<b>Intended Use</b>	competitive inhibitor of HMG-CoA reductase
<b>Chemical Name</b>	[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)
<b>How Supplied</b>	10 mg, 20 mg, 40 mg and 80 mg: Yellow , Oval shape, biconvex, film coated
<b>Manufacturer Name &amp; Address</b>	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
<b>Telephone No.</b>	631-434-2723

<b>2. HAZARDS IDENTIFICATION</b>	
<b>Statement of Hazard:</b>	Non-hazardous in accordance with international standards for workplace safety.
<b>Additional Hazard Information:</b>	<b>Short Term:</b> May cause eye irritation (based on components). <b>Long Term:</b> Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.
<b>Known Clinical Effects:</b>	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.
<b>EU Indication of danger:</b>	Not classified
<b>Australian Hazard Classification (NOHSC):</b>	Non-Hazardous Substance. Non-Dangerous Goods.
<b>Note</b>	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.

<b>3. Composition/Information on ingredients</b>		
<b>Components</b>	<b>CAS-No</b>	<b>Concentration (%w/w)</b>
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.

<b>4. FIRST AID MEASURES</b>	
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Inhalation</b>	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.
<b>Ingestion</b>	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.
<b>Indication of immediate medical attention and special treatment needed</b>	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.

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

<b>6. ACCIDENTAL RELEASE MEASURES</b>	
<b>Personal precautions, protective equipment and emergency procedures</b>	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.
<b>Environmental precautions</b>	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.
<b>Methods and materials for containment and cleaning up</b>	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.

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

<b>8. Exposure controls/Personal protection</b>	
<b>Engineering Controls and Ventilation</b>	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.
<b>Respiratory Protection</b>	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.
<b>Eye protection</b>	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
<b>Hand protection</b>	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.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	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.

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

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

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

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

<b>13. Disposal considerations</b>	
<b>Disposal instructions</b>	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.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	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.
<b>Contaminated packaging</b>	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.

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



<b>15. Regulatory Information</b>	
<b>US federal regulations</b>	
<b>TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)</b>	Not regulated.
<b>CERCLA Hazardous Substance List (40 CFR 302.4)</b>	Not listed.
<b>SARA 304 Emergency release notification</b>	Not regulated.
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>	Not listed.
<b>Superfund Amendments and Reauthorization Act of 1986 (SARA)</b>	
<b>SARA 302 Extremely hazardous substance</b>	Not listed.
<b>SARA 311/312 Hazardous chemical</b>	No
<b>SARA 313 (TRI reporting)</b>	Not regulated.
<b>Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List</b>	Not regulated
<b>Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)</b>	Not regulated.
<b>Safe Drinking Water Act (SDWA)</b>	Not regulated.
<b>US. California Proposition 65</b>	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.

<b>16. Other information</b>	
<b>Recommended Restrictions for Use:</b>	Not available
<b>Prepared on</b>	10/17/17
<b>Revision</b>	02
<b>Disclaimer</b>	The above information is believed to be correct but should only be used as a guide. ScieGen Pharmaceuticals, Inc. disclaims any express or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the above information.