Annora

SAFETY DATA SHEET

Section 1: Identification	
Product Name	Atorvastatin Calcium Tablets
Recommended use	Pharmaceutical product used as Lipid regulating agent
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sanga Reddy, Telangana 502313, India.
Distributor	**Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
GHS class	Not classified as hazardous
Signal Word	Not Classified
Hazard Statements	Not classified in accordance with international standards for workplace safety.
Other Hazards	An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).
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.

Section 3: Composition/Information on Ingredients	
Ingredients	**CAS**
Atorvastatin calcium	134523-03-8
Calcium carbonate	471-34-1
Magnesium stearate	557-04-0
Microcrystalline cellulose	9004-34-6
Hydroxypropyl Cellulose	9004-64-2

Lactose Monohydrate	10039-26-6
Croscarmellose Sodium	74811-65-7
Polysorbate 80	9005-65-6
OpadryWhite YS-1-7040	NA

Section 4: First-Aid Measures

Eye contact	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
Skin Contact	Remove contaminated clothing and shoes. Wash skin with soap and water. If irritation occurs or persists, get medical attention.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.
Ingestion	Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
Symptoms and Effects of Exposure	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.
Medical Conditions Aggravated by Exposure	None known
Notes to Physician	None

Section 5: Fire-Fighting Measures

Extinguishing Media	Extinguish fires with CO_2, extinguishing powder, foam, or water.
Hazardous Combustion Products	Formation of toxic gases is possible during heating or fire.
Fire / Explosion Hazards	Fine particles (such as dust and mists) may fuel fires/explosions
Advice for Fire-Fighters	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus

Section 6: Accidental Release Measures

Personal Precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure

Environmental precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Measures for Cleaning / Collecting	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Additional Consideration for Large Spills	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.
Section 7: Handling and Storage	
Precautions for Safe Handling	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Storage Conditions	Store as directed by product packaging.
Specific end use(s)	Pharmaceutical drug product
Section 8: Exposure Controls/Personal Protection	
Engineering Controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or

	safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Hands	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
Respiratory protection	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

Section 9: Physical and Chemical Properties

Physical State: Tablet

Description: Atorvastatin Calcium Tablets, USP are supplied as follows:

Strength	How Supplied	NDC	Tablet Description
10 mg of atorvastatin	bottles of 90	NDC 31722-424-90	white to off-white, oval, biconvex film coated tablets debossed with '10' on one side and 'A 53' on other side
	bottles of 500	NDC 31722-424-05	
	bottles of 1000	NDC 31722-424-10	
20 mg of atorvastatin	bottles of 90	NDC 31722-425-90	white to off-white, oval, biconvex film coated tablets debossed with '20' on one side
	bottles of 500	NDC 31722-425-05	

		bottles of 1000	NDC 31722-425-10	and 'A 54' on other side
	40 mg of atorvastatin	bottles of 90	NDC 31722-426-90	white to off-white, oval, biconvex film coated tablets debossed with '40' on one side and 'A 55' on other side
		bottles of 500	NDC 31722-426-05	
	80 mg of atorvastatin	bottles of 90	NDC 31722-427-90	white to off-white, oval, biconvex film coated tablets debossed with '80' on one side and 'A 56' on other side
		bottles of 500	NDC 31722-427-05	

Section 10: Stability and Reactivity

Reactivity	No data available
Chemical Stability	Stable under normal conditions of use.
Possibility of Hazardous Reactions Oxidizing Properties	No data available
Conditions to Avoid	Fine particles (such as dust and mists) may fuel fires/explosions..
Incompatible materials	As a precautionary measure, keep away from strong oxidizers.
Hazardous Decomposition Products	No data available

Section 11: Toxicological Information

Information on Toxicological Effects General Information	The information included in this section describes the potential hazards of the individual ingredients.
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.

Acute Toxicity: (Species, Route, End Point, Dose)

Atorvastatin calcium

Rat/Mouse Oral LD50 > 5000 mg/kg

Rabbit Dermal LD50 > 2000mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Atorvastatin calcium

Revision date: 25-May-2018

Skin Sensitization - Beuhler Guinea Pig Negative

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Atorvastatin calcium

104 Week(s) Dog Oral 10 mg/kg/day LOAEL Liver

13 Week(s) Mouse Oral 100 mg/kg/day LOAEL Liver

52 Week(s) Rat Oral 5 mg/kg/day NOAEL Liver

13 Week(s) Rat Oral 5 (male); 20 (female) mg/kg/day NOAEL Liver

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Atorvastatin calcium

Reproductive & Fertility Rat Oral 20 mg/kg/day NOAEL Negative

Fertility and Embryonic Development Rat Oral 100 mg/kg/day NOAEL Negative

Embryo / Fetal Development Rat Oral 100 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity

bryo / Fetal Development Rabbit Oral 10 mg/kg/day NOAEL Not Teratogenic, Maternal Toxicity, Fetotoxicity

Peri-/Postnatal Development Rat Oral 20 mg/kg/day NOAEL Fetotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Atorvastatin calcium

In Vitro Bacterial Mutagenicity (Ames) Salmonella , E. coli Negative

In Vivo Micronucleus Mouse Bone Marrow Negative

Mutagenicity No evidence of mutagenic or clastogenic activity in in vitro or in vivo tests.

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Atorvastatin calcium

104 Week(s) Mouse Oral 200 mg/kg/day NOAEL Not carcinogenic

104 Week(s) Rat Oral 100 mg/kg/day NOAEL Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA**.**

Section 12: Ecological Information

Environmental Overview	In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil . Not readily biodegradable. May have harmful effects on the aquatic environment. May persist in the aquatic environment. Releases to the environment should be avoided.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)
Atorvastatin calcium
In Vivo Micronucleus Mouse Bone Marrow Negative
Daphnia magna (Water Flea) EC50 48 Hours 200 mg/L
Atorvastatin calcium
Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours > 92 mg/L
Revision date: 25-May-2018
Pseudokirchneriella subcapitata (Green Alga) OECD EbC50 72 Hours 75 mg/L
Reproductive & Fertility Rat Oral 20 mg/kg/day NOAEL Negative
Daphnia magna (Water Flea) OECD NOEC 21 Days 0.14 mg/L
13 Week(s) Mouse Oral 100 mg/kg/day LOAEL Liver
Atorvastatin calcium
Pimephales promelas (Fathead Minnow) OECD NOEC 32 Days 0.45 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)
Atorvastatin calcium
Aspergillus niger (Fungus) MIC > 1000 mg/L
Trichoderma viride (Fungus) MIC > 1000 mg/L
Clostridium perfingens (Bacterium) MIC 100 mg/L
Activated sludge OECD EC50 >1000 mg/L

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)
Atorvastatin calcium
TAD Soil (various) Ultimate (CO2 Evolution) <10% After 28 Day(s) Not Ready
OECD Activated sludge Ultimate (CO2 Evolution) <10% After 28 Day(s) Not Ready

Photolysis: (Method, pH, Endpoint, Results)
Atorvastatin calcium
OECD 7 Half-Life 0.339 Day(s)
Bio-accumulative Potential: No data available
Mobility in Soil: No data available

Section 13: Disposal Considerations

Waste Treatment Methods	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the

	relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 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.

Section 15: Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture
Atorvastatin calcium

CERCLA/SARA 313 Emission	Not Listed
reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	

Section 16: Other Information

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Version : 00

Further information

Revision date: NA
Revision note: NA

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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