

MSN Laboratories Private Limited R&D Center, Formulation Division
 FDQA Issue
 Sign: *Bheer*
 Date: 27/07/2017



MSN Laboratories Private Limited
 R&D Center, Formulation Division.

MATERIAL SAFETY DATA SHEET		Page 1 of 5
* Product Name	Atorvastatin Calcium Tablets/ Atorvastatin Calcium Film Coated Tablets 10/20/40/80 mg	

1. Product Information

Product Name: Atorvastatin Calcium Tablets/ Atorvastatin Calcium Film Coated Tablets 10/20/40/80 mg

2. Composition/Information on Ingredients

C.A.S. No : 134523-03-8
 Molecular Formula : $C_{66}H_{68}CaF_2N_4O_{10}$
 Formula Weight : 1155.34
 Chemical Name : [R-(E)]-1-[[[1-[3-[2-(7-chloro-2-quinolinyl)ethenyl]phenyl]-3-[2-(1hydroxy-1-methylethyl)phenyl]propyl]thio]methyl] cyclopropane acetic acid, monosodium salt.

3. Hazards Identification

- Eye:** Causes eye irritation.
- Skin:** Causes skin irritation.
- Ingestion:** May cause irritation of the digestive tract. Toxic if swallowed.
- Inhalation:** May be harmful if inhaled. Causes respiratory tract irritation

4. First Aid Measures

- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

5. Emergency Overview

Major Health Hazards: No major health hazards are known.

6. Fire Fighting Measures

- Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.
- Hazardous Combustion Products:** Carbon monoxide, carbon dioxide, oxides of nitrogen, oxides of sulfur, hydrochloride, and other chlorine-containing compounds

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Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

7. Accidental Release Measures

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

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.

Measures for Environmental Protections:

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

8. Handling and Storage

General 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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. Releases to the environment should be avoided.

Storage Conditions: Store as directed by product packaging.

9. Exposure Controls/Personal Protection

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: 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.

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10. Physical Properties

Appearance:

- 10 mg: White coloured, oval shaped, biconvex, film-coated tablets debossed with "MA" on one side and "1" on other side.
- 20 mg: White coloured, oval shaped, biconvex, film-coated tablets debossed with "MA" on one side and "2" on other side.
- 40 mg: White coloured, oval shaped, biconvex, film-coated tablets debossed with "MA" on one side and "3" on other side.
- 80 mg :White coloured, oval shaped, biconvex, film-coated tablets debossed with "MA" on one side and "4" on other side.

11. Stability and Reactivity

Stability: Stable under normal conditions of use.

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: None known

12. Toxicological Information

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

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

Rat Oral 3 mg/kg/day NOAEL Adrenal gland, Heart
Rabbit Dermal LD50 > 2000 mg/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):

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)

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

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

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					

Reproductive Effects:

atorvastatin calcium at doses up to 175 mg/kg/day in males or up to 225 mg/kg/day in females. Also, atorvastatin did not cause adverse effects on sperm or semen parameters, or on reproductive organ histology in dogs given doses of 10, 40, or 120 mg/kg/day for 2 years.

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

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

104 Week(s)	Mouse	Oral	200 mg/kg/day	NOAEL	Not carcinogenic
104 Week(s)	Rat	Oral	100 mg/kg/day	NOAEL	Not carcinogenic

13. Ecological Information

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Daphnia magna (Water Flea)	EC50	48 Hours	200 mg/L		
Oncorhynchus mykiss (Rainbow Trout)	OECD	LC50	96 Hours	> 92 mg/L	
Pseudokirchneriella subcapitata (Green Alga)	OECD	EbC50	72 Hours	75 mg/L	
Daphnia magna (Water Flea)	OECD	LOEC	21 Days	0.27 mg/L	
Pimephales promelas (Fathead Minnow)	OECD	LOEC	32 Days	0.92 mg/L	

Bacterial Inhibition: (Species, Method, End Point, Duration, Result)

Aspergillus niger (Fungus) MIC > 1000 mg/L
Trichoderma viride (Fungus) MIC > 1000 mg/L

14. Disposal Considerations

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.

15. Transport Information

IATA: This substance is considered to be non-hazardous for transport.

IMO: This substance is considered to be non-hazardous for transport.

RID/ADR: This substance is considered to be non-hazardous for transport.

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16. Regulatory Information

U.S. FEDERAL REGULATORY INFORMATION

This product does not contain any ingredients which are regulated on the U.S. EPA List of Toxic Chemicals (40 CFR 372), and is therefore not subject to release reporting under section 313 of EPCRA, (SARA Title III).

17. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.

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