



SAFETY DATA SHEET

Atorvaliq (Atorvastatin Calcium) Oral Suspension, 20 mg/5 mL

SDS DATE: 21-Feb-2023

SECTION 1: IDENTIFICATION

PRODUCT NAME: Atorvaliq (Atorvastatin Calcium) Oral Suspension, 20 mg/5 mL

SYNONYMS: Atorvastatin Calcium Oral Suspension, 20 mg/5 mL

NDC Number: 46287-030-01

MANUFACTURER: CMP Pharma, Inc.

ADDRESS: PO Box 147

8026 East Marlboro Road

Farmville, NC 27828

CHEMTREC PHONE: 1-800-424-9300

OTHER CALLS: 1-252-753-7111

CHEMICAL NAME (for active ingredient): (β R, δ R)-2-(4-fluorophenyl)- β , δ -dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid, calcium salt (2:1)

CHEMICAL FORMULA (for active ingredient): $2(C_{33}H_{34}FN_2O_5).Ca$

PHARMACOLOGICAL PROPERTIES (for active ingredient): Lipid regulating agent

PRODUCT USE: Lowers cholesterol and triglyceride (fats) levels in the blood

SECTION 2: HAZARD(S) IDENTIFICATION

HEALTH HAZARDS: May cause damage to organs through prolonged or repeated exposure if swallowed (Liver, muscle).

SIGNAL WORD: Warning

HAZARD SYMBOLS:



PRECAUTIONARY STATEMENTS:

Harmful to aquatic life with long lasting effects. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Wash hands and face thoroughly after handling. Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Immediately call a poison control center or doctor/physician.

HAZARDS NOT OTHERWISE CLASSIFIED: None classified.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

<u>INGREDIENT:</u>	<u>CAS NO.</u>	<u>Amount</u>
Atorvastatin Calcium	134523-03-8	0.4%

*Product also contains Methyl para hydroxy benzoate, Ethyl para hydroxy benzoate, Propyl para hydroxy benzoate, Sodium carboxy methyl cellulose, magnesium aluminum silicate. Sucralose, Acesulfame potassium, Orange flavor, Purified water



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SECTION 4: FIRST AID MEASURES

EYE CONTACT: Flush with copious amounts of water for at least 15 minutes. Hold eyelids away from eyeball to ensure thorough rinsing. Irrigate each eye continuously with normal saline during transport. Seek medical attention immediately.

SKIN CONTACT: Wash the affected area with plenty of warm water and soap. If irritation, redness, or rash persists, seek medical attention.

INGESTION: Do not induce vomiting. Wash out mouth with copious amounts of water. Seek medical attention immediately.

INHALATION: Remove affected person to fresh air and keep patient at rest. Seek medical attention immediately.

MOST IMPORTANT SYMPTOMS/EFFECTS

May cause eye irritation, abdominal pain, dizziness, flushing, heart palpitations, and swelling. Antihypertensive drug; has blood pressure-lowering properties.

NOTES TO PHYSICIANS OR FIRST AID PROVIDERS:

First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists.

SECTION 5: FIRE-FIGHTING MEASURES

SUITABLE EXTINGUISHING

MEDIA: Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

UNSUITABLE EXTINGUISHING

MEDIA: None known.

UNUSUAL FIRE AND EXPLOSION

HAZARDS: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides, hydrogen chloride and other chlorine- and sulfur-containing compounds.

SPECIAL FIRE FIGHTING

PROCEDURES: Evacuate personnel to a safe area. Wear self-contained breathing apparatus and personal protective equipment to prevent contact with skin and eyes.

PROTECTIVE MEASURES:

Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

MEASURES FOR ENVIRONMENTAL

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

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:

Non-essential personnel should be evacuated from the affected area. Spills should be cleaned up in a manner that minimizes exposure to personnel. Personnel involved in the cleanup of spills should wear the appropriate respiratory protection, gloves, eye protection, and protective coveralls. Minimize exposure.

METHODS/MATERIALS USED

FOR CONTAINMENT & CLEANING: 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. Clean spill area thoroughly.

Environmental Precautions:

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



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SECTION 7: HANDLING AND STORAGE

HANDLING PRECAUTIONS: Minimize dust generation and accumulation. Clean equipment and work surfaces with suitable detergent or solvent after use. Wash hands and exposed skin thoroughly with soap and water after use. Remove any contaminated clothing and clean before reuse.

STORAGE PRECAUTIONS: Store as directed by product packaging that is labeled in accordance with OSHA's Hazard Communication Standard [29CFR 1910.1200]. Keep this drug out of the reach of children.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

EXPOSURE LIMITS/GUIDELINES:

Component Name	WEEL (TWA)	OSHA PEL (TWA)	ACGIH TLV (TWA)	HSE WEL (TWA)
Atorvastatin Calcium	N/A	N/A	50 µg/m ³	N/A

ENGINEERING CONTROLS: In a manufacturing setting, local exhaust ventilation may be necessary to control air contaminants. The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces. If user operations generate aerosols, use ventilation to keep exposure to airborne contaminants below the exposure limit.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

EYE PROTECTION: Wear appropriate chemical safety goggles, safety glasses, or face shield as described by OSHA's eye and face protection regulations in 29 CFR 1910.133. Have eyewash stations available where eye contact can occur.

SKIN PROTECTION: Avoid unintended skin contact. Wear gloves impervious to conditions of use. Additional protection may be necessary to prevent skin contact including the use of an apron, face shield, boots, or full body protection. A safety shower should be located in the work area.

RESPIRATORY PROTECTION: If exposure limits are exceeded, approved respiratory protection should be worn. Seek professional assistance for proper selection of respiratory protection.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/ODOR: This product is a white to off-white liquid with an orange odor.
ODOR THRESHOLD: No data available.

FLASH POINT:	Not established.	% VOLATILE:	Not established.
AUTOIGNITION TEMP:	Not established.	VISCOSITY:	Not established.
BOILING POINT:	Not established.	UPPER FLAMMABILITY LIMIT:	Not established.
MELTING POINT:	Not established.	Octanol/H₂O PART. COEFFICIENT:	Not established.
VAPOR PRESSURE (mmHg):	Not established.	POUR POINT:	Not established.
EVAPORATION RATE (H₂O = 1):	Not established.	% SOLUBILITY IN WATER:	Not established.
VAPOR DENSITY (AIR = 1):	Not established.	pH:	6.5 – 8.5
LOWER FLAMMABILITY LIMIT:	Not established.		

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY: No available data.



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- POSSIBILITY OF HAZARDOUS REACTIONS:** Material is stable under normal conditions and storage.
- CONDITIONS TO AVOID:** Fine particles (such as dust and mist) may fuel fires/explosions.
- INCOMPATIBLE MATERIALS:** Strong oxidizing agents.
- HAZARDOUS DECOMPOSITION PRODUCTS:** No data available.

SECTION 11: TOXICOLOGICAL INFORMATION

INFORMATION ON LIKELY ROUTES OF EXPOSURE:

- INGESTION:** May be harmful if swallowed. May cause eye irritation (based on components). Antihypertensive drug; has blood pressure-lowering properties.
- INHALATION:** No data available.
- SKIN CONTACT:** No data available
- EYE CONTACT:** Avoid contact with eyes. May cause irritation of the eyes.

SIGNS AND SYMPTOMS OF OVEREXPOSURE:

Eye irritation, abdominal pain, dizziness, flushing, heart palpitations, and swelling.

- ACUTE TOXICITY VALUES:** LD 50 for active ingredient (oral, rat) = >5000 mg/kg

SECTION 12: ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION:

This product has not been tested for persistence, biodegradability, bioconcentration, soil absorption, or mobility. Care should be taken to avoid environmental release.

ECOTOXICITY INFORMATION:

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD:

It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed of. Waste disposal must be in accordance with all local, state, and federal regulations. Wear proper protective equipment when handling waste materials.

WASTE DISPOSAL CONTAINERS:

Waste materials must be placed in and shipped in appropriate poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers is done in accordance with all applicable regulations.

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION SHIPPING REGULATIONS:

This product is not regulated.

SECTION 15: REGULATORY INFORMATION



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U.S. FEDERAL REGULATIONS

TOXIC SUBSTANCE CONTROL ACT (TSCA):

All components of this product are included on the TSCA inventory.

CLEAN WATER ACT (CWA):

There are no ingredients in this mixture listed in the Clean Water Act.

CLEAN AIR ACT (CAA):

There are no ingredients in this mixture listed under the Clean Air Act.

SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT):

There are no ingredients in this mixture listed under SARA.

STATE REGULATIONS:

Complies with OSHA standards. 29CFR1910.

INTERNATIONAL REGULATIONS:

CANADIAN ENVIRONMENTAL PROTECTION ACT:

Listed

CANADIAN WORKPLACE HAZARDOUS MATERIALS INFORMATION SYSTEMS (WHMIS):

Listed

EUROPEAN INVENTORY OF EXISTING CHEMICALS (EINECS):

Listed

EU CLASSIFICATION:

European labeling in accordance with EC directives.

EU RISK (R) AND SAFETY (S) PHRASES (OCCUPATIONAL EXPOSURE):

R38 Irritating to skin
R43 May cause sensitization by skin contact
R61 May cause harm to unborn child
S2 Keep out of the reach of children
S36/27 Wear suitable protective clothing and gloves

SECTION 16: OTHER INFORMATION

CREATION DATE: 17Feb2023

REVISION DATE: 21Feb2023

DISCLAIMER: CMP Pharma, Inc. believes that the information contained in this Safety Data Sheet (SDS) is accurate, and while it is provided in good faith, it is without warranty of any kind, express or implied.

The information contained herein is designated only as guidance for safe handling and storage of the substance and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment, should handle all chemicals. CMP Pharma, Inc. shall not be held liable for any loss, injury, or damage from contact with the product.