SAFETY DATA SHEET

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Third Revised Edition UNITED NATIONS New York and Geneva, 2019

Atorvastatin Calcium Tablets USP (10 mg, 20 mg, 40 mg AND 80 mg)

1. IDENTIFICATION

GHS Product identifier: Atorvastatin Calcium
Product code: #

Chemical Description: calcium;(3R,5R)-7-[2-(4-fluorophenyl)-3-phenyl-4-(phenylcarbamoyl)-5-propan-2-ylpyrrol-1-yl]-3,5-dihydroxyheptanoate

Other means of identification:

Recommended use of the chemical: Used for lipid regulation.

Restrictions on use: The product should be used only for the above-mentioned use and may not be used for any other purpose than stated above.

Manufactured by:
Mankind Pharma Ltd.,
Unit III, Opp. Dental College, Rampur Ghat,
Teh. -Paonta Sahib (HP-173025), India.
CIN No.: U74899DL1991PLC044843

Emergency phone number: +91 1704227600

2. HAZARDS IDENTIFICATION

Classification
Globally Harmonized System, UN (GHS)

Classification	Category	Exposure Route
Skin irritation	2	
Reproductive toxicity	2	-

Labeling
Globally Harmonized System, UN (GHS)

Classification	
Signal Word	**Warning**
Hazard Statements:	H302: Harmful if swallowed. H315: Causes skin irritation H361: Suspected of damaging fertility or the unborn child
Precautionary Statements:	P261: Avoid breathing dust. P264: Wash hands thoroughly after handling. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection. P305 + P351 + P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P332+P313 If skin irritation occurs: Get medical advice/attention. P337+P313: If eye irritation persists: Get medical advice/attention. P311: Call a poison centre/physician P391: Collect spillage
Other hazards	Control formation and generating of dusts during use.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical nature: Mixture containing Atorvastatin Calcium

Hazardous ingredients	CAS	Content
Atorvastatin Calcium	344423-98-9	6.91%
Lactose Monohydrate	64044-51-5	<100%
Microcrystalline cellulose	9004-34-6	<100%
Precipitated Calcium carbonate	471-34-1	<100%
Croscarmellose Sodium	74811-65-7	<100%
Hydroxypropyl cellulose	9004-64-2	<100%
Polysorbate 80	9005-65-6	<100%
Magnesium Stearate	557-04-0	<100%
Opadry	Not applicable	-

4. FIRST-AID MEASURES

Inhalation

Move the person into fresh air. In case of respiratory symptoms, place the person in a semi-seated position and administer oxygen. If not breathing, give artificial respiration. Consult a physician.

Skin contact

Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Fire/explosion hazard

Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products

Formation of toxic gases is possible during heating or fire.

Personal protection

Self-contained breathing apparatus. Fire-fighters must wear self-contained breathing apparatus for firefighting if necessary.

Special exposure hazards

Do not release chemically contaminated water into drains, soil or surface water. Dispose of contaminated water and soil according to local regulations.

6. ACCIDENTAL RELEASE MEASURES

Personal protection

Goggles, gloves, protective clothing, respiratory protection.
Remove ignition sources and provide sufficient ventilation.

Environmental precautions

Prevent contamination of soil, drains and surface waters.

Spillage procedure

Take up mechanically and collect in suitable container (adequately labelled) for disposal.

7. HANDLING AND STORAGE

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. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Occupational hygiene

Avoid ingestion, inhalation, skin and eye contact. Handle in accordance with good industrial hygiene practice and any legal requirements.

Conditions for safe storage

Avoid dust formation and ignition sources. Ensure good local exhaust ventilation.
Keep away from heat/sparks/open flames/hot surfaces – No smoking.

Storage facilities

Store in a cool, dry area with adequate ventilation. Keep tightly closed.

Segregation

Store locked up.

Storage conditions

Keep containers closed.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits

CAS No	Name	OEL
344423-98-9	Atorvastatin calcium	Pfizer OEL TWA-8 Hr 50 µg/m^3
471-34-1	Calcium carbonate	Australia TWA 10 mg/m^3
9004-34-6	Microcrystalline cellulose	ACGIH TLV TWA 10 mg/m^3
557-04-0	Magnesium Stearate	TWA 10 mg/m^3

Occupational exposure controls

Appropriate engineering controls

Maintain air concentrations below occupational exposure standards. Prevent dust formation.

General Personal Protection

Goggles, gloves, protective clothing.

Respiratory protection

Not required for the normal use of this product. 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.

Hand protection

Protective gloves.

Eye protection

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance & Colour: White, Oval shaped, film coated tablet with LS debossed on one site and ‘247, 248, 249 and 250 debossed on the other side for 10 mg, 20 mg, 40 mg and 80 mg strengths respectively.
Form: Tablets
Odour: Not specific
pH: Not available
Melting point: 176 °C
Boiling point: Not applicable
Flash point: Not applicable
Flammability (solid):
Burning test: Class 3 Localized combustion or glowing without flame.
Vapour pressure: Not applicable
Auto-ignition temperature: Not available
Decomposition temperature: Not available
Density: Not available
Solubility in solvents: Very slightly soluble in distilled water, slightly soluble in ethanol, and freely soluble in methanol.

n-Octanol/Water Partition Coefficient: 6.36
Viscosity: Not applicable
Oxidizing properties: Not applicable
Explosivity:
Dust Explosion Test: Class St_{2H} Violent explosion
Minimum Ignition Energy: 1.4 mJ

10. STABILITY AND REACTIVITY

Conditions to avoid
No decomposition under normal conditions

Materials to avoid
Keep away from strong oxidizing agents.

Hazardous decomposition products
calcium oxides; carbon dioxide; carbon monoxide; hydrogen fluoride; nitrogen oxides

11. TOXICOLOGICAL INFORMATION

Acute toxicity
Atorvastatin calcium 100% active ingredient has been tested for acute toxicity and belongs to category 4.

Atorvastatin calcium
Rat/Mouse Oral LD_{50} > 5000 mg/kg
Rabbit Dermal LD_{50} > 2000 mg/kg

Calcium carbonate
Rat Oral LD_{50} 6450 mg/kg

Microcrystalline cellulose

Rat Oral LD_{50} > 5000 mg/kg
Rabbit Dermal LD_{50} > 2000 mg/kg

Polysorbate 80
Rat Oral LD_{50} 25 g/kg
Rat Dermal LD_{50} > 2000

Magnesium stearate
Rat Oral LD_{50} > 2000 mg/kg
Rat Inhalation LC_{50} > 2000 mg/m^3

Atorvastatin calcium tablets are not classified for acute toxicity.

Primary Irritation

Skin irritation

Atorvastatin Calcium– category 2
Calcium carbonate, Magnesium stearate - category 2

Based on the sum of concentrations of ingredients, mixture falls in category 3 for skin.

Eye irritation

Atorvastatin Calcium– category 2
Calcium carbonate, Magnesium stearate - category 2

Based on the sum of concentrations of ingredients, mixture is not classifiable for eye irritation.

Respiratory or Skin sensitization

Not classified for respiratory or skin sensitization

CMR consideration:

Germ cell mutagenicity:
Data not sufficient for classification.

GHS Classification is not possible.

Carcinogenicity

104 Week(s) Mouse- Oral - 200 mg/kg/day NOAEL Not carcinogenic
No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA

Reproductive toxicity

Active ingredients belong to category 2. Since all the strengths of Atorvastatin calcium Tablets contain > 0.1% of the active ingredient, mixture falls under category 2.

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

Specific target organ toxicity single exposure: (STOT SE)

Active ingredient is classified in category 3. Mixture is not classified for STOT SE

Specific target organ toxicity repeated exposure:

Active ingredient is classified in category 2. Inadequate data for classification of mixture.

Aspiration hazard:
Data is not available.

Additional information: None

12. ECOLOGICAL INFORMATION

Ecotoxicity

Acute/chronic aquatic toxicity data

Atorvastatin calcium
Daphnia magna EC_{50} 48 Hours 200 mg/L
Daphnia magna NOEC 48 Hours 81 mg/L
Aspergillus niger MIC > 1000 mg/L

Based on the available data, mixture is not classified for ecotoxicity.

Persistence and degradability
Persistance – May persist
Degradation - Contains small amount of substance known to be hazardous to the environment or not degradable in waste water treatment plants

Bioaccumulation
Long-term adverse effects to aquatic organisms are possible.

Mobility in soil
Is not likely to be mobile in the environment due its low water solubility and propensity to bind to soil particles.

Behaviour in treatment plants
Data not available.

Additional information
This formulation has not been tested as a whole, the following apply to component substance(s): Long-term adverse effects to aquatic organisms are possible. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Product disposal
Product residues should be considered as hazardous waste. incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material. Disposal must be done through authorised waste disposal firms in compliance with local regulations. Waste should not be released to sewers.

Contaminated packaging
Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

This substance is not classified as dangerous for transport.
Not regulated for transport of dangerous goods: DOT, IATA, IMDG

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING
Compliance with following regulations:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), UNECE 2021 as amended.
- UN Recommendations on the Transport of Dangerous Goods, UNECE 2019
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16. OTHER INFORMATION

Recommended restrictions on use
This product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with any legal regulation. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

MSDS Changes
Prepared on 07/08/23