



MSN LABORATORIES PRIVATE LIMITED
FORMULATION DIVISION - III
PASHAMYLARAM
MATERIAL SAFETY DATA SHEET

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Product Name Rosuvastatin Calcium Tablets 5/10/20/40 mg

1. Product Information

Product Name: Rosuvastatin Calcium Tablets 5/10/20/40 mg

2. Composition/Information on Ingredients

C.A.S. No : : 147098-20-2
Molecular Formula : $(C_{22}H_{27}FN_3O_6S)_2Ca$
Molecular Weight : 1001.14.
Chemical Name : bis[(E)-7-[4- (4-fluorophenyl)-6-isopropyl-2- [methyl(methylsulfonyl)amino] pyrimidin-5- yl](3R,5S)-3,5-dihydroxyhept-6-enoic acid] calcium salt.

3. Hazards Identification

Eye: Causes eye irritation.

Skin: Causes skin irritation. Harmful if absorbed through the skin.

Ingestion: May cause irritation of the digestive tract.

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.

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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.

10. Physical Properties

5 mg : Yellow, round shaped, biconvex, film coated tablets debossed with "R5" on one side and plain on other side.

10 mg: Pink, round shaped, biconvex, film coated tablets debossed with "R10" on one side and plain on other side.

20 mg: Pink, round shaped, biconvex, film coated tablets debossed with "R20" on one side and plain on other side.

40 mg: Pink, oval shaped, biconvex, film coated tablets debossed with "R" on one side and "40" 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

Rosuvastatin: Acute toxicity: no data available Skin corrosion/irritation: no data available Serious eye damage/eye irritation: no data available Respiratory or skin sensitization: no data available Germ cell mutagenicity: no data available Carcinogenicity: IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH. NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP. MATERIAL SAFETY DATA SHEET Cat# 1955-5, -25, Rosuvastatin MSDS DATE: Mar 30, 2012 PAGE 3 OF 3 OSHA: 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: no data available Teratogenicity: no data available Specific target organ toxicity – single exposure (GHS): no data available Specific target organ toxicity – repeated exposure (GHS): no data available Aspiration hazard: no data available Potential Health Effects Inhalation: May be harmful if inhaled. May cause respiratory tract irritation. Skin: May be harmful if absorbed through skin. May cause skin irritation. Eyes: May cause eye irritation. Ingestion: May be harmful if swallowed. Signs and Symptoms of Exposure: To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. Synergistic effects: no data available Additional information: RTECS: not available.

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13. Ecological Information

Rosuvastatin: Persistence and degradability: no data available Toxicity: no data available Bioaccumulative potential: no data available Mobility in soil: no data available PBT and vPvB assessment: no data available Other adverse effects: no data available

14. Disposal Considerations

Product: Observe all federal, state, and local environmental regulations. Contaminated packaging: Dispose of as unused product.

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.

16. Regulatory Information

OSHA Hazards: No known OSHA hazards
SARA 302 Components: SARA 302: No chemical in this material are subject to the reporting requirements of SARA Title III, Section 302.
SARA 313 Components: SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title II, Section 313.
SARA 311/312 Hazards: No SARA hazards
Massachusetts Right To Know Components: No components are subject to the Massachusetts Right to Know Act.
Pennsylvania Right To Know Components: No components are subject to the Pennsylvania Right to Know Act.
New Jersey Right To Know Components: No components are subject to the New Jersey Right to Know Act.
California Prop. 65 Components: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

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.