



## GLENMARK PHARMACEUTICALS LIMITED

### SAFETY DATA SHEET

**PRODUCT: ROSUVASTATIN CALCIUM**  
**TABLETS, 5 mg, 10 mg, 20 mg and 40**  
**mg**

**SDS NO. : SDSGHS.039.00**

**EFFECTIVE DATE :08/01/2016**

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#### Section 1. Identification

**1.1 Substance Name:** Rosuvastatin Calcium Tablets, 5 mg, 10 mg, 20 mg and 40 mg

**1.2 Chemical Name:** Not Known

**1.3 Relevant identified uses of the substance or mixture and uses advised against:**  
Lipid lowering agent

**1.4 Company Identification:** Glenmark Pharmaceuticals Inc., USA  
750 Corporate Drive  
Mahwah, NJ 07430

**1.6 Emergency Contact details:** (201) 684-8000

#### Section 2. Hazard Identification

**2.1 Classification of the substance or mixture**

**Classification according to Regulation GHS**

**Emergency Overview**

**2.2 Risk Phrase:** Not Known

**2.3 Label elements:** Not Known

**2.4 Safety Advice:**

**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.

**Ingestion:** Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.



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**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

**2.5 Other hazards:** Not Known

### Section 3- Composition/Information on Ingredients

#### 3.1 Substances

COMPONENTS	CAS	CONCENTRATION (WT %)	EXPOSURE
Rosuvastatin calcium	147098-20-2	Proprietary	N/E

### Section 4. First aid Measures

#### 4.1 Inhalation:

- If fumes, aerosols or combustion products are inhaled remove from contaminated area.
- Other measures are usually unnecessary.

#### 4.2 Skin:

If skin or hair contact occurs:

- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

#### 4.3 Eyes: If this product comes in contact with the eyes:

- Wash out immediately with fresh running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Seek medical attention without delay; if pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

#### 4.4 Ingestion:

- If swallowed do NOT induce vomiting.
- If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.



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- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.
- Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
- Seek medical advice.

#### **4.5 Most important symptoms and effects, both acute and delayed**

For statin overdose:

Treatment of statin overdose should be symptomatic and supportive and may include the following:

- Administer activated charcoal as an aqueous slurry.
- For rhabdomyolysis, administer 0.9% saline to maintain urine output of 2 - 3 milliliters/kg/hour. Monitor fluid. balance, serum electrolytes, CPK, liver enzymes, and renal function. Administer diuretics if needed to maintain urine output. Urinary alkalisation is not recommended.
- Haemodialysis is not expected to enhance clearance.

[Poisindex 2009]

Treat symptomatically.

### **Section 5. Fire-fighting Measures**

#### **5.1 General Information:**

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use water delivered as a fine spray to control fire and cool adjacent area.

#### **5.2 Extinguishing Media:**

- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.

#### **5.3 Fire/Explosion Hazard:**

- Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under



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which the combustion process occurs, such materials may cause fires and / or dust explosions.

- Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions).
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>), hydrogen fluoride, nitrogen oxides (NO<sub>x</sub>), sulfur oxides (SO<sub>x</sub>), other pyrolysis products typical of burning organic material. May emit poisonous fumes.

**5.4 Fire Incompatibility:** Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result

**5.5 NFPA Rating:** Not Known

## Section 6. Accidental Release Measures

**6.1 General Information:** Personal Protective Equipment advice is contained in Section 8 of the SDS.

**6.2 Major Spills:** Moderate hazard.

- CAUTION: Advise personnel in area.
- Alert Emergency Services and tell them location and nature of hazard.
- Control personal contact by wearing protective clothing.

**6.3 Minor Spills:**

- Remove all ignition sources.
- Clean up all spills immediately.
- Avoid contact with skin and eyes.
- Control personal contact with the substance, by using protective equipment.



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## Section 7. Handling and Storage

### 7.1 Handling:

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.
- Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions)
- Minimize airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame.
- Establish good housekeeping practices.
- Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.

### 7.2 Storage:

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry area protected from environmental extremes.
- Store away from incompatible materials and foodstuff containers.

**7.3 Storage Incompatibility:** Avoid reaction with oxidizing agents

## Section 8. Exposure Controls/Personal Protection

### 8.1 Occupational Exposure Limits (OEL):

Components	CAS No.	Type	Value
Rosuvastatin Calcium	147098-20-2	8 HR TWA	Not Known

### 8.2 Exposure controls:

#### **Appropriate engineering**

Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly

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**controls**

effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.  
The basic types of engineering controls are:  
Process controls which involve changing the way a job activity or process is done to reduce the risk.  
Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment.

**Personal protection**





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<b>Eye and face protection</b>	<ul style="list-style-type: none"> <li>• Safety glasses with side shields</li> <li>• Chemical goggles.</li> <li>• Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience.</li> </ul>
<b>Skin protection</b>	See Hand protection below
<b>Hands/feet protection</b>	<p>The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.</p> <p>The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.</p> <p>Suitability and durability of glove type is dependent on usage.</p> <p>Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.</p> <ul style="list-style-type: none"> <li>• polychloroprene.</li> <li>• nitrile rubber.</li> <li>• butyl rubber.</li> </ul>
<b>Body protection</b>	See Other protection below
<b>Other protection</b>	<ul style="list-style-type: none"> <li>• Overalls.</li> <li>• P.V.C. apron.</li> <li>• Barrier cream.</li> </ul>
<b>Thermal hazards</b>	Not Available



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**Section 9. Physical and Chemical Properties**

**9.1 Information on basic physical and chemical properties**

Physical State	:	Solid Tablet
Appearance	:	Tablet
Colour	:	Pink
pH Value	:	Not Known
Vapour Pressure	:	Not Known
Vapour Density	:	Not Known
Evaporation Rate	:	Not Known
<i>Other information</i>		
Flash point	:	Not Known
Molecular Weight	:	Not Known
Melting point/range	:	Not Known
Boiling point/boiling range	:	Not Known
Density	:	Not Known
Viscosity	:	Not Known
Water solubility	:	Not Known
Solubility in other solvents	:	Not Known
Minimum ignition energy (MIE)	:	Not Known
Minimum ignition temperature (MIT)	:	Not Known
Layer ignition temperature (LIT)	:	Not Known
Flammability/explosivity	:	Not Known
Reactivity/exotherms	:	Not Known
Electrostatic nature	:	Not Known





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Highly dusty material	:	Not Known
Any other properties which cause handling or processing difficulties	:	Not Known
Average PSD (particle size distribution (micron))	:	Not Known

**9.2 Other Information:** Not Known

### Section 10. Stability and Reactivity

**10.1 Reactivity:** The product is stable and non-reactive under normal conditions of use, storage and transport

**10.2 Chemical stability:** Stable at recommended storage conditions.

**10.3 Conditions to Avoid:** Contact with incompatible materials. Heat, flames and sparks

**10.4 Incompatibilities with Other Materials:** Not Known

**10.5 Hazardous Decomposition Products:** Irritating and/or toxic fumes and gases may be emitted upon the products decomposition

**10.6 Hazardous Polymerization:** Will not occur

### Section 11. Toxicological Information

#### 11.1 Information on toxicological effects

**Rosuvastatin calcium:**

**Acute Toxicity: Oral Mice: LD50 = >200 mg/kg**



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#### **Section 12. Ecological Information**

**12.1 Toxicity:** DO NOT discharge into sewer or waterways.

**12.2 Persistence and degradability:** Not Known

**12.3 Bioaccumulative potential:** Not Known

**12.4 Mobility in soil:** Not Known

**12.5 Other:** Not Known.

#### **Section 13. Disposal Considerations**

##### **13.1 Waste treatment methods**

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use.

- DO NOT allow wash water from cleaning or process equipment to enter drains.
- It may be necessary to collect all wash water for treatment before disposal.
- In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
- Where in doubt contact the responsible authority.
- Recycle wherever possible.
- Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.



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- Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or Incineration in a licensed apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

#### Section 14. Transport Information

##### 14. 1 Special precautions for user:

##### Labels Required

<b>Marine Pollutant</b>	NO
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**Land transport (UN):** NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

**Air transport (ICAO-IATA / DGR):** NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

**Sea transport (IMDG-Code / GGVSee):** NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

#### Section 15. Regulatory Information

##### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

Classified as non-hazardous.



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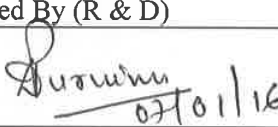
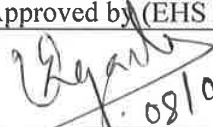
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#### Section 16. Additional Information

##### Disclaimer:

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Compiled By (R & D)	Approved by (EHS Head)
 07/01/16	 08/01/2016
Signature /Date	Signature /Date