

# MATERIAL SAFETY DATA SHEET

## SECTION: 1 - IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY

### COMPANY ADDRESS EMERGENCY TELEPHONE NUMBERS:

**Manufacturer address:**

**GRAVITI PHARMACEUTICALS PVT. LTD**

Plot No. 621/E, 621/EE, Isnapur village  
Patancheru Mandal, Sangareddy (District)  
Telangana- 502302

Emergency Telephone number: +91 9885017112

**Distributor address**

**Laurus Generics Inc**

400 Connell Drive Suite 5200  
Berkeley Heights, NJ 07922

**PRODUCT**

**Fenofibric acid Delayed Release Capsules 45 mg and 135 mg**

**NAME:****CHEMICAL****NAME:**

Choline Fenofibrate

**PRODUCT USE:**

As monotherapy to reduce TG in patients with severe hypertriglyceridemia.

In combination with a statin to reduce TG and increase HDL-C in patients with mixed dyslipidemia and CHD or a CHD risk

equivalent who are on optimal statin therapy to achieve their LDL-C goal.

## SECTION-2 HAZARDS IDENTIFICATION

**Appearance:**

45 mg: Opaque reddish brown color cap and opaque yellow color body

135 mg: Opaque Blue color cap and opaque yellow color body

**Explosion:**

Not determined

**Health:**

Fenofibric acid Delayed Release Capsules is contraindicated in:

- Patients with severe renal impairment, including those receiving dialysis.
- Patients with active liver disease, including those with primary biliary cirrhosis and unexplained
- persistent liver function abnormalities.
- Patients with preexisting gallbladder disease.
- Nursing mothers.
- Patients with hypersensitivity to fenofibric acid, choline fenofibrate or fenofibrate

# MATERIAL SAFETY DATA SHEET

## SECTION-3: COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name	CAS NO.
Choline Fenofibrate	856676-23-8
Hydroxy propyl methyl cellulose (Methocel K15 M Premium CR)	9904-65-3
Povidone (Kollidon®30)	9003-39-08
Hydroxy propyl cellulose (Klucel EXF)	9004-64-2
Methacrylic acid copolymer (Eudragit L 30-D55)	25212-88-8
Talc	14807-96-6
Colloidal silicon dioxide ( Aerosil®200 Pharma)	7631-86-9
Sodium Stearyl Fumarate ( PRUV®)	4070-80-8
Triethyl citrate	77-93-0

## SECTION-4: FIRST AID MEASURES

<b>Eye Contact:</b>	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Skin Contact:</b>	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Ingestion:</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Inhalation:</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Protection of First-aiders:</b>	Use personal protective equipment

## SECTION-5: FIRE FIGHTING MEASURES

<b>Special Exposure Hazards:</b>	Not determined
<b>Extinguishing Media:</b>	Use extinguishing agent suitable for type of surrounding fire

# MATERIAL SAFETY DATA SHEET

## Advice for

### firefighters

Protective Equipment  
and Precautions for  
Firefighters:

As in any fire, wear self-contained breathing apparatus and full protective gear

## SECTION-6: ACCIDENTAL RELEASE MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited however; the following guidance may be used as needed.

### Personal Precautions:

**Protective equipment:** Use appropriate personal protection equipment (PPE)

**Methods for Cleaning Up:** Recover product and place in an appropriate container for disposal

**Environmental Precautions:** Contain material and prevent release to waterways or soil

## SECTION-7: HANDLING AND STORAGE

**Precautions for safe handling** Handle in accordance with good industrial hygiene and safety practice.

**Conditions for safe storage, including any incompatibilities:** Store according to label instructions.

**Specific end use(s)** Pharmaceuticals

**Recommended use:**

## SECTION-8: EXPOSURES AND CONTROLS

### Exposure Controls

**Engineering controls:** No special provisions are required under normal product use conditions. When handling bulk formulation, use in a well-ventilated area.

**Respiratory Protection:** Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

**Eyes protection:** Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.

# MATERIAL SAFETY DATA SHEET

**Gloves:** Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.

**Environmental Exposure Controls:** Not determined

## SECTION-9: PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b> Capsule	<b>Odour Threshold:</b> No data available
<b>Odour:</b> Not determined	<b>Vapor Pressure (mm Hg):</b> Not determined
<b>Melting/Freezing Point (°C):</b> Not determined	<b>Vapor Density (Air = 1):</b> Not determined
<b>Lower Explosive Limit:</b> Not determined	<b>Specific Gravity:</b> Not determined
<b>Upper Explosive Limit:</b> Not determined	<b>Partition coefficient: n-octanol/water:</b> Not determined
<b>Molecular Formula:</b> No data available	<b>Autoignition Temp. (°C):</b> Not determined
<b>Solvent Solubility:</b> Not determined	<b>Decomposition temperature (°C):</b> Not determined
<b>Water Solubility:</b> Not determined	<b>Viscosity (centipoise):</b> Not determined
<b>pH:</b> Not determined	<b>Explosion Severity:</b> Not determined
<b>Boiling Point (°C):</b> Not determined	<b>Oxidizer Properties:</b> Not determined

## SECTION-10: STABILITY AND REACTIVITY

<b>Reactivity:</b>	Not determined
<b>Chemical stability:</b>	Stable under normal conditions
<b>Possibility of hazardous reactions:</b>	Not determined
<b>Conditions to avoid:</b>	Not determined
<b>Incompatible materials:</b>	Not determined
<b>Hazardous decomposition products:</b>	Carbon oxides, Nitrogen oxides (NOx)

## SECTION-11: TOXICOLOGICAL INFORMATION

**Routes of Exposure:** **Oral:** Clinical Route, **Dermal:** Unlikely, **Inhalation:** Unlikely

Acute toxicity: Not classified

LD50 and LC50 data: Not available

Skin corrosion/irritation: Not classified

Serious eye damage/irritation: Not classified

Respiratory or skin sensitization: Not classified

Germ cell mutagenicity: Not classified

Teratogenicity: Not available

Carcinogenicity: Not classified

Specific target organ toxicity (single exposure): Not classified

# MATERIAL SAFETY DATA SHEET

Specific target organ toxicity (repeated exposure): Not classified  
Reproductive toxicity: Not classified  
Aspiration hazard: Not classified  
Information on toxicological effects - ingredient(s)

## SECTION-12: ECOLOGICAL INFORMATION

No relevant studies identified.

## SECTION-13: DISPOSAL CONSIDERATIONS

**Waste disposal recommendations:** Disposal should be made in accordance with country, federal, state and local regulations.

## SECTION-14: TRANSPORTATION INFORMATION

IATA/ICAO - Not Regulated

IMDG - Not Regulated

DOT - Not Regulated

IMO - Not Regulated

## SECTION-15: REGULATORY INFORMATION


This Section Contains Information relevant to compliance with other Federal and/or state laws.

## SECTION-16: OTHER INFORMATION

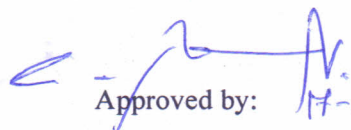
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Prepared & Reviewed by:

  
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