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

**COMPANY ADDRESS EMERGENCY TELEPHONE NUMBERS:**

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| --- | --- |
| **Manufacturer address:**  | **Distributor address** |
| **GRAVITI PHARMACEUTICALS PVT. LTD** | Laurus Generics Inc, |
| Plot No. 621/E, 621/EE, Isnapur village  | Integrated commercialization |
| Patancheru Mandal, Sangareddy (District) | Solutions, LLC |
| Telangana- 502302 | 420 International Blyd Suite 500 |
| Emergency Telephone number: +91 9885017112 | Brooks KY 40109 |

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| **PRODUCT NAME:** | **Fenofibrate Tablets USP 48 mg and 145 mg** |
| **CHEMICAL NAME:** | Fenofibrate USP |
| **PRODUCT USE:** | Fenofibrate tablets are indicated as adjunctive therapy to diet to reduce elevated low-density lipoprotein cholesterol (LDL-C), total cholesterol (Total-C), Triglycerides and apolipoprotein B (Apo B), and to increase high-density lipoprotein cholesterol (HDL-C) in adult patients with primary hypercholesterolemia or mixed dyslipidemia. |

**SECTION- 2 HAZARDS IDENTIFICATION**

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| **Appearance:** | Fenofibrate Tablets 48 mg: Oval shape, yellow colour Fenofibrate Tablets 148 mg: Oval shape, white colour |
| **Fire and Explosion:**  | Expected to be non-combustible  |
| **Health:** | Fenofibrate is contraindicated in patients who exhibit hypersensitivity tofenofibrate.Fenofibrate is contraindicated in patients with hepatic or severe renaldysfunction, including primary biliary cirrhosis, and patients withunexplained persistent liver function abnormality.Fenofibrate is contraindicated in patients with preexisting gallbladderdisease*.* |

**SECTION-3: COMPOSITION/INFORMATION ON INGREDIENTS**

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| **Ingredient Name** | **CAS NO.** |
| Fenofibrate USP | 49562-28-9 |
| Lactose Monohydrate USP-NF (Super Tab 11 SD) | 64044-51-5 |
| Sucrose, USP-NF | 57-50-1 |
| Hypromellose2910, USP (Methocel E3 Premium LV) | 9004-65-3 |
| Microcrystalline cellulose USP-NF (Avicel PH 102) | 9004-34-6 |
| Sodium Lauryl Sulfate (Kolliphor SLS fine) | 151-21-3 |
| Crospovidone USP-NF (Type A- kollidon CL -F) | 9003-39-8 |
| Colloidal silicon dioxide USP-NF (Aerosil 200 Pharma) | 7631-86-9 |
| Magnesium stearate  |  |

**SECTION-4: FIRST AID MEASURES**

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| **Eye Contact:** | Flush eyes with plenty of water. Get medical attention. |
| **Skin Contact:** | Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs. |
| **Ingestion:**  | If conscious, give water to drink and induce vomiting. Do not attempt give any solid or liquid by mouth if the exposed subject is unconscious orsemi-conscious. Wash out the mouth with water. Obtain medical attention. |
| **Inhalation:**  | Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance. |

**SECTION-5: FIRE FIGHTING MEASURES**

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| **Fire and Explosion Hazards:** | Assume that this product is capable of sustaining combustion |
| **Extinguishing Media:** | Water spray, carbon dioxide, dry chemical powder or appropriate foam |
| **Fire Fighting Procedures:** | For single units (packages): No special requirements needed |
| For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires evolved from fires involving this product and associated packaging self-contained breathing apparatus and full protective equipment are recommended for firefighters  |
| **Hazardous Combustion Products:** | Hazardous combustion or decomposition products the product is expected when the product is exposed to fire. |

**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.

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| **Personal Precautions:** | Wear protective clothing and equipment consistent with the degree ofhazard. |
| **Environmental Precautions:** | For large spills, take precautions to prevent entry into waterways sewers, or surface drainage systems. |
| **Clean-up Methods:** | Collect and place it in a suitable, properly labeled container for recovery or disposal. |

**SECTION-7: HANDLING AND STORAGE**

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| **Handling:** | No special control measures required for the normal handling of thisproduct. Normal room ventilation is expected to be adequate for routinehandling of this product. |
| **Storage Conditions:** | Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Protect from moisture. Keep out of reach of children |

**SECTION-8: EXPOSURES AND CONTROLS**

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| **Exposure Controls** |  |
| Appropriate engineering controls: | Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits |
| **Personal protective equipment:** | Not generally required. The use of personal protective equipment may be necessary as conditions warrant.  |
| **Hand protection:** | Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR. |
|  **Eye protection:** | In laboratory, medical or industrial settings, or operations in which airborne particulates may be generated, safety glasses with side shields are recommended. |
| **Skin and body protection:**  | In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible  |

**SECTION-9: PHYSICAL AND CHEMICAL PROPERTIES**

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| **Physical State:** Tablets | **Appearance**  |
| **Odour:** No data available | **Fenofibrate Tablet 48 mg:** Yellow, oval shaped, biconvex, film coated tablets debossed with "158" on one side and plain on other side |
| **Molecular Formula:** No data available |
| **Solubility:** No data available |
| **Molecular Formula:** No data available | **Fenofibrate Tablet 145 mg:** White, oval shaped, biconvex, film coated tablets debossed with "159" on one side and plain on other side |
| **Solubility:** No data available |
| **Solvent Solubility:** No data available |
| **Water Solubility:** No data available | **Odour Threshold:** No data available |
| **PH:** No data available. |  |
| **Melting/Freezing Point (°C):** No data available |  |
| **Boiling Point (°C):** No data available |  |

**SECTION-10: STABILITY AND REACTIVITY**

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| Stable under recommended storage conditions. |

**SECTION-11: TOXICOLOGICAL INFORMATION**

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| **Information on toxicological effects - product** |
| 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  |
| Specific target organ toxicity (repeated exposure): Not classified  |
| Reproductive toxicity: Not classified |
| Aspiration hazard: Not classified |
| **Information on toxicological effects - ingredient(s)**  |
| LD50 and LC50 data: Not available |

**SECTION-12: ECOLOGICAL INFORMATION**

 No relevant studies identified.

**SECTION-13: DISPOSAL CONSIDERATIONS**

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| **Waste disposal recommendations**: | Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations. Do not dispose of waste into sewer. |

**SECTION-14: TRANSPOSRATION INFORMATION**

IATA/ICAO - Not Regulated

IMDG - Not Regulated

DOT – Not Regulated

**SECTION-15: REGULATORY INFORMATION**

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

**SECTION-16: OTHER INFORMATION**

Graviti Pharmaceuticals Pvt Ltd believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

Graviti shall not be held liable for any damage resulting from handling or from contact with the above product. Graviti reserves the right to revise this MSDS.

Prepared & Reviewed by: Approved by: