InvaGen Pharmaceuticals, Inc.

SAFETY DATA SHEET

Gemfibrozil Tablets, USP

1. IDENTIFICATION

Manufacturer:

InvaGen Pharmaceuticals Inc.
7, Oser Avenue
Hauppauge, NY 11788

Emergency Phone:

1-631-231-3233

Common Name: Gemfibrozil Tablets, USP

Chemical Family: A fibric acid derivative.

Synonym(s): No data available.

Chemical Name: 5-(2, 5-dimthylphenoxy)-2, 2-dimethylpentanoic acid.

Trade Name(s): Gemfibrozil Tablets, USP 600mg.

Therapeutic Category: Antihyperlipidemic.

Molecular formula: $C_{15}H_{22}O_3$ **Molecular Weight:** 250.35

2.HAZARDS IDENTIFICATION

Not considered hazardous when handled under normal conditions.

EMERGENCY OVERVIEW

Caution Statement:
Each Gemfibrozil Tablets intended for oral administration contains Gemfibrozil, USP and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Routes of Entry: Oral

Effects of Overexposure: Tablets are intended for human consumption under guidance of a physician. Intact Tablets are not considered hazardous under normal handling procedures.

Medical conditions Aggravated by Long Term Exposure: Primary biliary cirrhosis, impaired kidney function, impaired liver function, Gallbladder disease.

Carcinogenicity: Gemfibrozil - Not listed by IARC, NTP and OSHA.

3.COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS #	Concentration %
		600 mg
Gemfibrozil, USP	25812-30-0	≈ 63.8%
Excipients	NA	≈36.2%

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.
* All Concentrations are percent by weight.

4. FIRST AID MEASURES

Inhalation: Move in to fresh air and keep at rest. For breathing difficulties, Oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.

Skin Contact: Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.

Eye Contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Get medical attention.

Notes to the Physician:
The mechanism of action of Gemfibrozil has not been definitely established. In man, gemfibrozil has been shown to inhibit peripheral lipolysis and to decrease the hepatic extraction of free fatty acids, thus reducing hepatic triglyceride production. Gemfibrozil inhibits synthesis and increases clearance of VLDL carrier apolipoprotein B, leading to a decrease in VLDL production.

Overdose Treatment:
There have been reported cases of overdosage with gemfibrozil. In one case, a 7-year-old child recovered after ingesting up to 9 grams of gemfibrozil. Symptoms reported with overdosage were abdominal cramps, abnormal liver function tests, diarrhea, increased CPK, joint and muscle pain, nausea and vomiting. Symptomatic supportive measures should be taken, should an overdose occur.

5.FIRE-FIGHTING MEASURES

Extinguishing Media: Water spray, CO2, dry chemical or alcohol resistant foam.

Unusual Fire & Explosion Hazards: Emits toxic fumes under fire conditions.

Special Fire Fighting Procedures: Self-Contained breathing apparatus and full protective clothing must be worn in case of fire.

Protective Measures: Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

6.ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all firefighting procedures.

Environmental precautions: Do not release in to the environment.

Spill Cleanup methods: Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like. Collect in containers and seal securely. For waste disposal, see section 13 of the SDS.

7.HANDLING AND STORAGE

Handling: Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

Storage: Keep container tightly closed in a cool, well-ventilated place. Keep away from heat and direct sun light.

8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Tablets are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to the powder may occur.

Protective Measures: Minimize open handling. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas.

Respiratory Protection: Use a NIOSH approved respirator or an alternate approved dust mask should be used.

Hand Protection: Chemical resistant gloves.

Eye Protection: Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mist or aerosols, wear the appropriate goggles. Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and Body Protection: Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene Measures: Wash skin thoroughly with soap and water.

9.PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Physical State: Solid

Form: Tablets

Appearance:

600 mg Tablets	White film coated, capsule shaped, biconvex tablets de-bossed with **I** on the left side of bisect and **G** on the right side of bisect on one side and **225** on the other.

10. STABILITY AND REACTIVITY

Possibility of hazardous reactions: Stable under ordinary conditions of use and storage.

Conditions to avoid: Excessive heat & Moisture.

Incompatible materials: Strong oxidizers, Strong Bases and Strong Acids.

Hazardous Decomposition products: Thermal decomposition or combustion may liberate irritating gases or vapors.

11.TOXICOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients (Gemfibrozil, USP), and not to the mixture(s) or final formulations.

Inhalation: No data available.

Ingestion: Harmful if swallowed.

Skin Corrosion/ irritation: No data available.

Serious eye damage/eye irritation: No data available.

Respiratory sensitizer/Skin sensitizer: No data available.

Carcinogenesis:
Long-term studies have been conducted in rats at 0.2 and 1.3 times the human exposure (based on AUC). The incidence of benign liver nodules and liver carcinomas was significantly increased in high dose male rats. The incidence of liver carcinomas increased also in low dose males, but this increase was not statistically significant (p=0.1). Male rats had a dose-related and statistically significant increase of benign Leydig cell tumors. The higher dose female rats had a significant increase in the combined incidence of benign and malignant liver neoplasms.
Long-term studies have been conducted in mice at 0.1 and 0.7 times the human exposure (based on AUC). There were no statistically significant differences from controls in the incidence of liver tumors, but the doses tested were lower than those shown to be carcinogenic with other fibrates.

Mutagenesis:
Electron microscopy studies have demonstrated a florid hepatic peroxisome proliferation following gemfibrozil administration to the male rat. An adequate study to test for peroxisome proliferation has not been done in humans but changes in peroxisome morphology have been observed. Peroxisome proliferation has been shown to occur in humans with either of two other drugs of the fibrate class when liver biopsies were compared before and after treatment in the same individual.

Impairment of Fertility:
Administration of approximately 2 times the human dose (based on surface area) to male rats for 10 weeks resulted in a dose-related decrease of fertility. Subsequent studies demonstrated that this effect was reversed after a drug-free period of about eight weeks, and it was not transmitted to the offspring.

Other information:
Medically less serious adverse effects reported with Gemfibrozil include: upset stomach, mild stomach pain, nausea, vomiting, diarrhea, headache, dizziness, drowsiness, mild joint or muscle pain, loss of interest in sex, impotence, difficulty having an orgasm, numbness or tingly feeling, cold symptoms such as stuffy nose, sneezing, sore throat.

12.ECOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients (Gemfibrozil, USP), and not to the mixture(s) or final formulations.

Ecotoxicity Effects:
Acute toxicity to Fish: No data available.
Acute toxicity to Aquatic Invertebrates: No data available.
Toxicity to Aquatic Plants: No data available.
Bioaccumulation: No data available.
Mobility: No data available.

13.DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of waste must be in accordance with all applicable Federal, State and local laws.

Measures for Avoidance and Recovery: Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

14.TRANSPORT INFORMATION

DOT: Not Regulated

IMDG: Not regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

15.REGULATORY INFORMATION

Stated regulatory information chosen primarily for possible usage of InvaGen Pharmaceutical, Inc. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

CERLA Hazardous Substance List (40 CFR 302.4): None
TSCA : None
SARA Title III
Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): None
Section 313 Toxic Release Inventory (40 CFR 372): None

16.OTHER INFORMATION

SDS Sections Revised:
Revision 01: Section 3 revised.
Revision 02: Sections 1 to 16 contain revisions to comply with 29 CFR 1910.1200(g) and Appendix D**.**

GLOSSARY:

SDS	Safety Data Sheet
NA	Not Applicable
CAS Number	Chemical Abstract Service Registry Number
NTP	National Toxicology Program
NIOSH	National Institute for Occupational Safety and Health
DOT	Department of Transportation
IMDG	International Maritime Dangerous Goods Code
ICAO	International Civil Aviation Organization
IATA	International Air Transport Association
IMO	International Maritime Organization
TSCA	Toxic Substances Control Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
SARA	Superfund Amendments and Reauthorization Act
OSHA	Occupational Safety and Health Administration

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