1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Gemfibrozil tablets, 450 and 600 mg
Trade Name: Lopid; Lopid UD; Gevilon; LIPUR; GD-Gemfibrozil
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product for the treatment of high cholesterol (hyperlipidemia)

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Global Manufacturing
38-42 Wharf Road
West Ryde, New South Wales 2114
Australia
(02) 9850 3333
Ask for Environmental Health & Safety Manager

Emergency telephone number (North America):
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number (Australia):
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Acute Oral Toxicity: Category 4
Reproductive Toxicity: Category 2
Carcinogenicity: Category 2
Acute aquatic toxicity: Category 2
Chronic aquatic toxicity: Category 2

Label Elements

Signal Word: Warning
Hazard Statements:
H302 - Harmful if swallowed
H351 - Suspected of causing cancer
H361f - Suspected of damaging fertility
H401 - Toxic to aquatic life
H411 - Toxic to aquatic life with long lasting effects
**Precautionary Statements:**

- P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P270 - Do not eat, drink or smoke when using this product
- P273 - Avoid release to the environment
- P281 - Use personal protective equipment as required
- P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
- P308 + P313 - IF exposed or concerned: Get medical attention/advice
- P330 - Rinse mouth
- P405 - Store locked up
- P501 - Dispose of contents/container in accordance with all local and national regulations

**Other Hazards**

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

**Note:**

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### Hazardous

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<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS</th>
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4. FIRST AID MEASURES

Description of First Aid Measures

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 wash exposed area with soap and water. Obtain medical assistance if irritation occurs.

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.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up
Measures for Cleaning / Collecting: 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.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe 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 thoroughly after handling. Releases to the environment should be avoided. 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.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Refer to available public information for specific member state Occupational Exposure Limits.

Gemfibrozil
Pfizer OEL TWA-8 Hr: 1000µg/m³

Silicon dioxide, colloidal NF
Australia TWA 2 mg/m³
Austria OEL - MAKs 4 mg/m³
Czech Republic OEL - TWA 0.1 mg/m³

Estonia OEL - TWA 2 mg/m³
Finland OEL - TWA 5 mg/m³
Germany - TRGS 900 - TWAs 4 mg/m³
Germany (DFG) - MAK 4 mg/m³
Ireland OEL - TWAs 6 mg/m³

Latvia OEL - TWA 1 mg/m³
OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf Listed

Slovakia OEL - TWA 4.0 mg/m³
Slovenia OEL - TWA 0.3 mg/m³
Switzerland OEL -TWAs 4 mg/m³

Starch
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Exposure Controls**

Engineering Controls:

- Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

**Personal Protective Equipment:**

- Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

**Hands:**

- Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Eyes:** Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

**Respiratory protection:** Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

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</table>
SAFETY DATA SHEET

Material Name: Gemfibrozil tablets, 450 and 600 mg
Revision date: 30-Apr-2018

Flammability:
- Autoignition Temperature (Solid) (°C): No data available
- Flammability (Solids): No data available
- Flash Point (Liquid) (°C): No data available
- Upper Explosive Limits (Liquid) (% by Vol.): No data available
- Lower Explosive Limits (Liquid) (% by Vol.): No data available

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions
- Oxidizing Properties: No data available
- 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: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
Known Clinical Effects: Adverse effects associated with therapeutic use include gastrointestinal disturbances such as nausea, dyspepsia, and vomiting and gastrointestinal irritation.

Acute Toxicity: (Species, Route, End Point, Dose)

Polysorbate 80
- Rat Oral LD50 25 g/kg

Microcrystalline cellulose
- Rat Oral LD50 > 5000 mg/kg
- Rabbit Dermal LD50 > 2000 mg/kg

Hydroxypropyl methylcellulose
- Rat Oral LD50 > 10,000 mg/kg

Propylparaben
- Mouse Oral LD50 6332 mg/kg
- Mouse Sub-tenon injection (eye) LD 50 200 mg/kg

Gemfibrozil
- Mouse Oral LD50 2188 mg/kg
- Rat Oral LD50 1831 mg/kg
- Rat IP LD50 445 mg/kg
- Mouse IV LD50 > 60 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.
11. TOXICOLOGICAL INFORMATION

Irritation / Sensitization: (Study Type, Species, Severity)

**Microcrystalline cellulose**
- Skin Irritation: Rabbit, Non-irritating
- Eye Irritation: Rabbit, Non-irritating

**Polyethylene glycol**
- Eye Irritation: Rabbit, Mild
- Skin Irritation: Rabbit, Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

**Propylparaben**
- 3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system
- 4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

**Gemfibrozil**
- 2 Week(s) Dog Intravenous 45 mg/kg LOAEL Male reproductive system
- 2 Week(s) Rat Intravenous 60 mg/kg NOAEL No effects at maximum dose
- 13 Week(s) Dog Oral 300 mg/kg LOAEL No effects at maximum dose
- 13 Week(s) Rat Oral 300 mg/kg NOAEL No effects at maximum dose

**Magnesium Stearate**
- 13 Week(s) Rat Oral 1092 g/kg LOAEL Liver

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

**Gemfibrozil**
- Reproductive & Fertility-Males: Rat Oral 300 mg/kg LOAEL Fertility
- Embryo / Fetal Development Rabbit Oral 200 mg/kg NOAEL Not Teratogenic
- Embryo / Fetal Development Rat Oral 281 mg/kg NOAEL Not Teratogenic
- Embryo / Fetal Development Rat Oral 300 mg/kg NOAEL Not Teratogenic
- Peri-/Postnatal Development Rat Oral 331 mg/kg LOAEL Fetotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

**Gemfibrozil**
- Bacterial Mutagenicity (Ames) *Salmonella* Negative
- In Vitro Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Negative
- In Vitro Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells HGPRT Negative
- In Vivo Chromosome Aberration Rat Bone Marrow Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

**Gemfibrozil**
- 52 Week(s) Dog Oral 300 mg/kg/day NOAEL Not carcinogenic
- 52 Week(s) Rat Oral 150 mg/kg/day LOAEL Liver, Tumors
11. TOXICOLOGICAL INFORMATION

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Silicon dioxide, colloidal NF
- IARC: Group 3 (Not Classifiable)
- NTP: Reasonably Anticipated To Be A Human Carcinogen

Gemfibrozil
- IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Gemfibrozil
- *Daphnia magna* (Water Flea) OECD EC50 48 Hours 21 mg/L
- *Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours 22 mg/L
- Green algae OECD EC50 72 Hours 6.2 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Gemfibrozil
- *Nostoc* sp. (Freshwater Cyanobacteria) OECD MIC 100 mg/L
- *Aspergillus Niger* OECD MIC 1000 mg/L

Persistence and Degradability:

Gemfibrozil
- OECD Activated sludge Ultimate (CO2 Evolution) 38% After 28 Day(s) Not Ready

Bio-accumulative Potential:

Gemfibrozil
- Predicted 7.4 Log D 2.7

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, ADG or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Gemfibrozil
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Carcinogen 12/22/2000
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS/ELINCS List: 247-280-2

Silicon dioxide, colloidal NF
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: 231-545-4

Hydroxypropyl cellulose
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: Not Listed

Methylparaben
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: 202-785-7

Opadry white
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed
15. REGULATORY INFORMATION

**Starch**
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **REACH - Annex IV - Exemptions from the obligations of Register**: Present
- **EU EINECS/ELINCS List**: 232-679-6

**Magnesium Stearate**
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **EU EINECS/ELINCS List**: 209-150-3

**Propylparaben**
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **EU EINECS/ELINCS List**: 202-307-7

**Polysorbate 80**
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **EU EINECS/ELINCS List**: Not Listed

**Microcrystalline cellulose**
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **EU EINECS/ELINCS List**: 232-674-9

**Hydroxypropyl methylcellulose**
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
- **Standard for the Uniform Scheduling for Drugs and Poisons**: Schedule 4
- **EU EINECS/ELINCS List**: Not Listed

**Polyethylene glycol**
- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **Inventory - United States TSCA - Sect. 8(b)**: Present
- **Australia (AICS)**: Present
15. REGULATORY INFORMATION

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<tbody>
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16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

- Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
- Carcinogenicity-Cat.2; H351 - Suspected of causing cancer
- Reproductive toxicity-Cat.2; H361f - Suspected of damaging fertility
- Hazardous to the aquatic environment, acute toxicity-Cat.2; H401 - Toxic to aquatic life
- Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects

Data Sources: Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 30-Apr-2018


Pfizer Inc 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.

End of Safety Data Sheet