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

Material Name: Gemfibrozil tablets, 600 mg

Material Name: Gemfibrozil tablets, 600 mg

Trade Name: Lopid; Lopid UD; Gevilon

Chemical Family: Mixture

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gemfibrozil</td>
<td>25812-30-0</td>
<td>247-280-2</td>
<td>69.8</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>*</td>
</tr>
<tr>
<td>Calcium stearate</td>
<td>1592-23-0</td>
<td>216-472-8</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>*</td>
</tr>
<tr>
<td>Silicon dioxide, colloidal NF</td>
<td>7631-86-9</td>
<td>231-545-4</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl cellulose</td>
<td>9004-64-2</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Polysorbate 80</td>
<td>9005-65-6</td>
<td>Not listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White tablet
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.
Suspected of causing cancer.
Suspected of damaging fertility.
Toxic to aquatic life.

Known Clinical Effects: Adverse effects associated with the therapeutic use include gastrointestinal disturbances such as nausea, dyspepsia, and vomiting and gastrointestinal irritation.
EU Indication of danger: Harmful
Toxic to Reproduction; Category 3
Carcinogenic: Category 3
Dangerous for the Environment

EU Hazard Symbols:

EU Risk Phrases:
R22 - Harmful if swallowed.
R40 - Limited evidence of a carcinogenic effect
R51 - Toxic to aquatic organisms.
R62 - Possible risk of impaired fertility.

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.

4. 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.

5. FIRE FIGHTING MEASURES

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

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

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

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

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. 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.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Gemfibrozil
Pfizer OEL TWA-8 Hr: 1.0 mg/m³

Starch
OSHA - Final PELs - TWAs:
= 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Calcium stearate
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

Microcrystalline cellulose
OSHA - Final PELs - TWAs:
= 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Silicon dioxide, colloidal NF
OSHA - Final PELs - Table Z-3 Mineral D: 
= (80)/(% SiO2) mg/m³ TWA
= 20 mppcf TWA
Australia TWA = 2 mg/m³ TWA
The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Local and general ventilation should be used as necessary, when handling this material in bulk.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: None required 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.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Tablet
Color: White
10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

Hazardous Decomposition Products: None known
Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Starch
Mouse  IP  LD50  6600 mg/kg

Polysorbate 80
Rat  Oral  LD50  25 g/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

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

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

Microcrystalline cellulose
Skin Irritation  Rabbit  Non-irritating
Eye Irritation  Rabbit  Non-irritating

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

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

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))
Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

**Gemfibrozil**

*Bacterial Inhibition* (Species, Method, End Point, Duration, Result)

<table>
<thead>
<tr>
<th>Organism</th>
<th>Method</th>
<th>End Point</th>
<th>Duration</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Salmonella</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Aspergillus Niger</em></td>
<td>OECD</td>
<td>MIC</td>
<td>72 Hours</td>
<td>1000 mg/L</td>
</tr>
</tbody>
</table>

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**

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>52 Week(s)</td>
<td>Dog</td>
<td>Oral</td>
<td>300 mg/kg/day</td>
<td>NOAEL</td>
<td>Not carcinogenic</td>
</tr>
<tr>
<td>52 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>150 mg/kg/day</td>
<td>LOAEL</td>
<td>Liver, Tumors</td>
</tr>
</tbody>
</table>

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

**Gemfibrozil**

IARC: Group 3

**Silicon dioxide, colloidal NF**

IARC: Group 3

12. ECOLOGICAL INFORMATION

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

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

**Gemfibrozil**

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>End Point</th>
<th>Duration</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia</td>
<td>OECD</td>
<td>EC50</td>
<td>48 Hours</td>
<td>21 mg/L</td>
</tr>
<tr>
<td>Rainbow Trout</td>
<td>OECD</td>
<td>LC50</td>
<td>96 Hours</td>
<td>22 mg/L</td>
</tr>
<tr>
<td>Green algae</td>
<td>OECD</td>
<td>EC50</td>
<td>72 Hours</td>
<td>6.2 mg/L</td>
</tr>
</tbody>
</table>

Bacterial Inhibition: (Species, Method, End Point, Duration, Result)

**Gemfibrozil**

*Nostoc sp.* (Freshwater Cyanobacteria) OECD MIC 6 Days 100 mg/L
*Aspergillus Niger* OECD MIC 72 Hours 1000 mg/L
13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: Xn, N
EU Indication of danger: Harmful
Toxic to Reproduction; Category 3
Carcinogenic: Category 3
Dangerous for the Environment

EU Risk Phrases:
- R22 - Harmful if swallowed.
- R40 - Limited evidence of a carcinogenic effect
- R51 - Toxic to aquatic organisms.
- R62 - Possible risk of impaired fertility.

EU Safety Phrases:
- S22 - Do not breathe dust.
- S36/37 - Wear suitable protective clothing and gloves.
- S53 - Avoid exposure - obtain special instructions before use.
- S57 - Use appropriate containment to avoid environmental contamination.

OSHA Label:
WARNING
Harmful if swallowed.
Suspected of causing cancer.
Suspected of damaging fertility.
Toxic to aquatic life.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 1, Subdivision A

Gemfibrozil
California Proposition 65
carcinogen, initial date 12/22/00
female reproductive toxicity, initial date 8/20/99
male reproductive toxicity, initial date 8/20/99
**MATERIAL SAFETY DATA SHEET**

**Material Name:** Gemfibrozil tablets, 600 mg  
**Revision date:** 19-Dec-2006  
**Page 7 of 7**  
**Version:** 2.0

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16. OTHER INFORMATION

**Prepared by:** Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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 a warranty of any kind, expressed or implied.

**End of Safety Data Sheet**