



MATERIAL SAFETY DATA SHEET

Revision date: 19-Dec-2006

Version: 2.0

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

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

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Gemfibrozil	25812-30-0	247-280-2	69.8
Starch	9005-25-8	232-679-6	*
Calcium stearate	1592-23-0	216-472-8	*
Microcrystalline cellulose	9004-34-6	232-674-9	*
Silicon dioxide, colloidal NF	7631-86-9	231-545-4	*

Ingredient	CAS Number	EU EINECS List	%
Hydroxypropyl cellulose	9004-64-2	Not listed	*
Polysorbate 80	9005-65-6	Not listed	*

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.

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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.

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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

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Molecular Formula: Mixture Molecular Weight: Mixture

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))

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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)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Sister Chromatid Exchange	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> Mammalian Cell Mutagenicity	Chinese Hamster Ovary (CHO) cells HGPRT	Negative
<i>In Vivo</i> 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

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

Daphnia	OECD	EC50	48 Hours	21 mg/L
Rainbow Trout	OECD	LC50	96 Hours	22 mg/L
Green algae	OECD	EC50	72 Hours	6.2 mg/L

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

Gemfibrozil

<i>Nostoc</i> sp. (Freshwater Cyanobacteria)	OECD	MIC	6 Days	100 mg/L
<i>Aspergillus Niger</i>	OECD	MIC	72 Hours	1000 mg/L

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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

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Standard for the Uniform Scheduling for Drugs and Poisons: EU EINECS List	Schedule 4 247-280-2
Starch Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS List	XU Present 232-679-6
Calcium stearate Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS List	Present Present 216-472-8
Hydroxypropyl cellulose Inventory - United States TSCA - Sect. 8(b) Australia (AICS):	XU Present
Polysorbate 80 Inventory - United States TSCA - Sect. 8(b) Australia (AICS):	XU Present
Microcrystalline cellulose Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS List	XU Present 232-674-9
Silicon dioxide, colloidal NF Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS List	Present Present 231-545-4

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