



MATERIAL SAFETY DATA SHEET

Revision date: 02-Feb-2000

Version: 1.1

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

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Material Name: Lopid tablets (600 mg)

Trade Name:	Not determined
Synonyms:	Gemfibrozil tablets
Chemical Family:	Not determined
Intended Use:	Anti-hyperlipidemic

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Gemfibrozil	25812-30-0	247-280-2	69.8

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

3. HAZARDS IDENTIFICATION

Appearance: solid
Signal Word: CAUTION

Statement of Hazard: May cause eye, skin and respiratory tract irritation May be harmful if swallowed.

Eye Contact:	May cause eye irritation.
Skin Contact:	May cause skin irritation.
Inhalation:	May cause respiratory tract irritation. An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).
Ingestion:	May be harmful if swallowed
EU Indication of danger:	Harmful
EU Hazard Symbols:	

R22 - Harmful if swallowed.
R37/38 - Irritating to respiratory system and skin.

Additional Information: For a more detailed discussion of potential health hazards and toxicity see Section 11.
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.

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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 the affected area with soap and water. Seek medical attention if unusual symptoms occur. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder.

Ingestion: In the event of swallowing this material, dilute with large quantities of water or milk. Get medical attention.

Inhalation: Remove to fresh air. If discomfort persists, get medical attention.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: None known or expected.

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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: Wipe up with a damp cloth and place in container for disposal. 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: Contain the source of the spill or leak if it is safe to do so. Spills should be handled by vacuuming or wet mopping. Clean spill area thoroughly.

Additional Information: Review Sections 3, 8 and 12 before proceeding with clean up.

7. HANDLING AND STORAGE

General Handling: Avoid contact with eyes. Avoid contact with skin and clothing. Avoid breathing dust.

Storage Conditions: Store in a cool, dry place away from direct sunlight.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Gemfibrozil

Pfizer OEL TWA-8 Hr: 1.0 mg/m³

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Engineering Controls: Good general ventilation should be sufficient to control airborne levels.

Personal Protective Equipment:

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Hands: Chemical protective gloves
Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin: None required for normal use of this material. Wear protective clothing with long sleeves when working with large quantities. Wash hands and arms thoroughly after handling this material.
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
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: Avoid direct sunlight, conditions that might generate heat, and sources of ignition.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.
Hazardous Decomposition Products: None known
Polymerization: No data available

11. TOXICOLOGICAL INFORMATION

IARC: 3 - Not classifiable as to its carcinogenicity to humans
Acute Toxicity: (Species, Route, End Point, Dose)

Gemfibrozil

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

Inhalation Acute Toxicity May cause respiratory tract irritation
Ingestion Acute Toxicity See Acute toxicity table.
Eye Irritation / Sensitization Possible eye irritant.
Skin Irritation / Sensitization May cause skin irritation

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

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

Reproductive Effects Reproductive toxicity studies are equivocal and inconclusive.

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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

Mutagenicity This material was non-mutagenic in bacterial and mammalian cells.

Gemfibrozil

52 Week(s)	Dog	Oral	300	NOAEL	Not carcinogenic
52 Week(s)	Rat	Oral	150	LOAEL	Liver, Tumors

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

Gemfibrozil

IARC: Group 3

Additional Information: Effects reported during consumer use include gastrointestinal disturbances and abdominal pain.

12. ECOLOGICAL INFORMATION

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

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

Gemfibrozil

Nostoc	OECD	MIC	6 Days	100 mg/L
Aspergillus Niger	OECD	MIC	72 Hours	1000 mg/L

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Labeling:	Xn
EU Indication of danger:	Harmful

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EU Risk Phrases:

R22 - Harmful if swallowed.
R37/38 - Irritating to respiratory system and skin.

EU Safety Phrases:

S2 - Keep out of reach of children.
S24 - Avoid contact with skin.
S36 - Wear suitable protective clothing.

OSHA Label:

CAUTION

May cause eye, skin and respiratory tract irritation May be harmful if swallowed.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision B

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
247-280-2

EU EINECS List

16. OTHER INFORMATION

Prepared by:

Corporate Occupational Toxicology & Hazard Assessment

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