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

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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. 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 with long lasting effects.

Known Clinical Effects: Adverse effects associated with 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.

Australian Hazard Classification

(NOHSC):

Hazardous Substance. Non-Dangerous Goods.

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## 2. HAZARDS IDENTIFICATION

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**

TIGEGI GOGO					
Ingredient	CAS Number	<b>EU EINECS/ELINCS List</b>	<b>EU Classification</b>	%	
Calcium stearate	1592-23-0	216-472-8	Not Listed	*	
Gemfibrozil	25812-30-0	247-280-2	Xn;R22	69.8	
			Repr.Cat. 3,R62		
			Carc.Cat. 3,R40		
			N;R51/53		
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*	
Silicon dioxide, colloidal NF	7631-86-9	231-545-4	Not Listed	*	
Starch	9005-25-8	232-679-6	Not Listed	*	
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*	

Ingredient	CAS Number	<b>EU EINECS/ELINCS List</b>	<b>EU Classification</b>	%
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	*
Polysorbate 80	9005-65-6	Not Listed	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	*
Methylparaben	99-76-3	202-785-7	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*
Opadry white	NOT ASSIGNED	Not Listed	Not Listed	*

Additional Information: \* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace

safety.

For the full text of the R phrases mentioned in this Section, see Section 16

## 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.

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.

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## 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:** 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.

**Storage Conditions:** Store as directed by product packaging.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

**Calcium stearate** 

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Gemfibrozil

Pfizer OEL TWA-8 Hr: 1000µg/m<sup>3</sup>

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³

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## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Estonia OEL - TWA 10 mg/m<sup>3</sup> 10 mg/m<sup>3</sup> France OEL - TWA **Ireland OEL - TWAs** 10 ma/m<sup>3</sup> 4 mg/m<sup>3</sup> Latvia OEL - TWA  $2 \text{ mg/m}^3$ **OSHA - Final PELS - TWAs:** 15 mg/m<sup>3</sup> Portugal OEL - TWA 10 mg/m<sup>3</sup> 10 mg/m<sup>3</sup>

Silicon dioxide, colloidal NF

Spain OEL - TWA

Australia TWA 2 mg/m<sup>3</sup> Austria OEL - MAKs 4 mg/m<sup>3</sup>  $0.3 \text{ mg/m}^{3}$  $0.1 \text{ mg/m}^{3}$ Czech Republic OEL - TWA 4.0 mg/m<sup>3</sup> Estonia OEL - TWA 2 mg/m<sup>3</sup> **Finland OEL - TWA** 5 mg/m<sup>3</sup> Germany - TRGS 900 - TWAs 4 mg/m<sup>3</sup> Germany (DFG) - MAK 4 mg/m<sup>3</sup> Ireland OEL - TWAs 6 ma/m<sup>3</sup> 2.4 mg/m<sup>3</sup> Latvia OEL - TWA 1 mg/m<sup>3</sup> 20 mppcf **OSHA - Final PELs - Table Z-3 Mineral D:** Listed Slovakia OEL - TWA 4.0 mg/m<sup>3</sup>

#### Starch

**ACGIH Threshold Limit Value (TWA)** 10 mg/m<sup>3</sup> 10 mg/m<sup>3</sup> **Australia TWA Belgium OEL - TWA** 10 mg/m<sup>3</sup> **Bulgaria OEL - TWA** 10.0 mg/m<sup>3</sup> 4.0 mg/m<sup>3</sup> Czech Republic OEL - TWA  $10 \text{ mg/m}^3$ **Greece OEL - TWA** 5 mg/m<sup>3</sup> Ireland OEL - TWAs  $10 \text{ mg/m}^3$ 4 mg/m<sup>3</sup> **OSHA - Final PELS - TWAs:** 15 mg/m<sup>3</sup> 10 mg/m<sup>3</sup> Portugal OEL - TWA Slovakia OEL - TWA  $4 \text{ mg/m}^3$ 10 mg/m<sup>3</sup> Spain OEL - TWA

Polyethylene glycol

Austria OEL - MAKs 1000 ma/m<sup>3</sup> 1000 mg/m<sup>3</sup> Germany - TRGS 900 - TWAs

1000 mg/m³ average molecular weight 200-600 Germany (DFG) - MAK

Slovakia OEL - TWA 1000 ma/m<sup>3</sup> 1000 mg/m<sup>3</sup> Slovenia OEL - TWA

Engineering controls should be used as the primary means to control exposures. General **Engineering Controls:** 

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.

**Environmental Exposure Controls:** Refer to specific Member State legislation for requirements under Community environmental

legislation.

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal

protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk

processing operations.

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and

for bulk processing operations.

Respiratory protection: 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:TabletColor:WhiteMolecular Formula:MixtureMolecular Weight:Mixture

Polymerization: Will not occur

## 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable under normal conditions of use.

**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

## 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)

Polysorbate 80

Rat Oral LD50 25 g/kg

## Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg Rabbit Dermal LD50 > 2000 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

### Hydroxypropyl methylcellulose

Rat Oral LD50 > 10,000 mg/kg

#### Methylparaben

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### 11. TOXICOLOGICAL INFORMATION

Mouse LD50 > 8000 mg/kg Oral

Rat Oral LD50 2280 mg/kg

### Propylparaben

Mouse Oral LD 50 6332 mg/kg

Mouse Sub-tenon injection (eye) LD 50 200 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

## Polyethylene glycol

Eye Irritation Rabbit Mild Skin Irritation Rabbit Mild

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

#### Gemfibrozil

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

### Propylparaben

3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system

Male reproductive system 4 Week(s) Rat Oral 347.2 mg/kg LOAEL

#### 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 Oral **NOAEL** Not Teratogenic Rabbit 200 mg/kg Embryo / Fetal Development Rat Oral 281 mg/kg NOAEL Not Teratogenic Embryo / Fetal Development Rat Oral 300 ma/ka **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

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

500

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## 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)

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.

## 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 6 Days 100 mg/L

Aspergillus Niger OECD MIC 72 Hours 1000 mg/L

## 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, or IMDG regulations.

## 15. REGULATORY INFORMATION

EU Symbol: Xn, N

500

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## 15. REGULATORY INFORMATION

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. \$53 - 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 with long lasting effects.

## Canada - WHMIS: Classifications

## WHMIS hazard class:

Class D, Division 1, Subdivision A



Calcium stearate

Not Listed **California Proposition 65** Inventory - United States TSCA - Sect. 8(b) Present Australia (AICS): Present **EU EINECS/ELINCS List** 216-472-8

Gemfibrozil

**California Proposition 65** carcinogen initial date 12/22/00

female reproductive toxicity 8/20/99

male reproductive toxicity initial date 8/20/99

Standard for the Uniform Scheduling

for Drugs and Poisons:

**EU EINECS/ELINCS List** 247-280-2

Hydroxypropyl cellulose

**California Proposition 65** Not Listed Inventory - United States TSCA - Sect. 8(b) Present

Schedule 4

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15. REGULATORY INFORMATION	
Australia (AICS):	Present
Microcrystalline cellulose	
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9
EO EINEOG/EEINOO EISt	232-01-4-3
Polysorbate 80	
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
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Australia (AICS):	Present
Ciliaan diavida aallaidal NE	
Silicon dioxide, colloidal NF	Mark I Sara al
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-545-4
Starch	
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the	Present
obligations of Register:	
EU EINECS/ELINCS List	232-679-6
Propylparaben	
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-307-7
Methylparaben	
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7
EG EMEGG/EEMOG EIGE	202 100 1
Polyethylene glycol	
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
	Schedule 3
Standard for the Uniform Scheduling	Scriedule 3
for Drugs and Poisons:	
Hydroxypropyl methylcellulose	
California Proposition 65	Not Listed
•	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling	Schedule 4
for Drugs and Poisons:	

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## 15. REGULATORY INFORMATION

**Opadry white** 

California Proposition 65

Not Listed

## **16. OTHER INFORMATION**

## Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

R40 - Limited evidence of a carcinogenic effect

R62 - Possible risk of impaired fertility.

R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients. Updated Section 2 - Hazard

Identification. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 -

Regulatory Information.

Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

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** 

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