



# SAFETY DATA SHEET

Revision date: 30-Apr-2018

Version: 3.2

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## 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 (Australia):  
International CHEMTREC (24 hours): +1-703-527-3887

Emergency telephone number (North America):

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

## 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

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**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
- P391 - Collect spillage
- 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**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Gemfibrozil	25812-30-0	247-280-2	Acute Tox.4 (H302) Carc.2 (H351) Repr.2 (H361f) Aquatic Acute 2 (H401) Aquatic Chronic 2 (H411)	70-73
Silicon dioxide, colloidal NF	7631-86-9	231-545-4	Not Listed	*
Starch	9005-25-8	232-679-6	Not Listed	*
Magnesium Stearate	557-04-0	209-150-3	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*

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

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Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*
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**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.  
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 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

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<b>Measures for Cleaning / Collecting:</b>	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.
<b>Additional Consideration for Large Spills:</b>	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

<b>Storage Conditions:</b>	Store as directed by product packaging.
<b>Specific end use(s):</b>	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/m <sup>3</sup>
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#### Silicon dioxide, colloidal NF

Australia TWA	2 mg/m <sup>3</sup>
Austria OEL - MAKs	4 mg/m <sup>3</sup>
Czech Republic OEL - TWA	0.1 mg/m <sup>3</sup>
	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 mg/m <sup>3</sup>
	2.4 mg/m <sup>3</sup>
Latvia OEL - TWA	1 mg/m <sup>3</sup>
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
	Listed
Slovakia OEL - TWA	4.0 mg/m <sup>3</sup>
Slovenia OEL - TWA	0.3 mg/m <sup>3</sup>
Switzerland OEL - TWAs	4 mg/m <sup>3</sup>

#### Starch

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	4.0 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Greece OEL - TWA	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	4 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL -TWAs	3 mg/m <sup>3</sup>
<b>Magnesium Stearate</b>	
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>
<b>Microcrystalline cellulose</b>	
ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	2 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Romania OEL - TWA	10 mg/m <sup>3</sup>
Russia OEL - TWA	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL -TWAs	3 mg/m <sup>3</sup>
Vietnam OEL - TWAs	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
<b>Polyethylene glycol</b>	
Austria OEL - MAKs	1000 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	1000 mg/m <sup>3</sup>
Germany (DFG) - MAK	1000 mg/m <sup>3</sup> average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m <sup>3</sup>
Slovenia OEL - TWA	1000 mg/m <sup>3</sup>
Switzerland OEL -TWAs	1000 mg/m <sup>3</sup>

#### 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.)

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Eyes:</b>	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.)
<b>Skin:</b>	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.)
<b>Respiratory protection:</b>	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

<b>Physical State:</b>	Tablet	<b>Color:</b>	White
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>pH:</b>	No data available.
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Polysorbate 80**

No data available

**Starch**

No data available

**Hydroxypropyl cellulose**

No data available

**Microcrystalline cellulose**

No data available

**Silicon dioxide, colloidal NF**

No data available

**Hydroxypropyl methylcellulose**

No data available

**Methylparaben**

No data available

**Propylparaben**

No data available

**Opadry white**

No data available

**Polyethylene glycol**

No data available

**Gemfibrozil**

Predicted 7.4 Log D 2.7

**Magnesium Stearate**

No data available

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** No data available

**Viscosity:** No data available

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### 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

No data available

#### Products:

## 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 LD 50 6332 mg/kg

Mouse Sub-tenon injection (eye) LD 50 200 mg/kg

#### Gemfibrozil

Mouse Oral LD50 2188 mg/kg

Rat Oral LD50 1831mg/kg

Rat IP LD50 445mg/kg

Mouse IV LD50 > 60mg/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.

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### 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



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**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 (CO<sub>2</sub> Evolution) 38% After 28 Day(s) Not Ready

**Bio-accumulative Potential:**

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**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.

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### 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 female reproductive toxicity 8/20/99
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
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-545-4

#### Hydroxypropyl 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	Not Listed

#### Methylparaben

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	202-785-7

#### Opadry white

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

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**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

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### 15. REGULATORY INFORMATION

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 3
EU EINECS/ELINCS List	Not Listed

### 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.

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Product Stewardship Hazard Communications

**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 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**