



# MATERIAL SAFETY DATA SHEET

Revision date: 09-Mar-2011

Version: 1.0

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

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### Material Name: Levonorgestrel and Ethinyl Estradiol Tablets

Trade Name: LYBREL  
Chemical Family: Synthetic estrogen , Synthetic progestogen  
Intended Use: Pharmaceutical product used as oral contraceptive

## 2. HAZARDS IDENTIFICATION

Appearance: Yellow Tablet  
Signal Word: DANGER

Statement of Hazard: May cause cancer.  
May damage fertility or the unborn child.

### Additional Hazard Information:

Short Term: Dust may be absorbed through the skin and cause systemic effects. May be harmful if swallowed. (based on components) . Accidental ingestion may cause effects similar to those seen in clinical use.

Long Term: Occupational exposure to components of this mixture has resulted in menstrual irregularities in women and breast changes (enlargement, mammary secretions), loss of libido, and changes in sex hormone levels in men.

Known Clinical Effects: The use of oral contraceptives is associated with increased risks of myocardial infarction, thromboembolism, stroke, hepatic neoplasia, and gallbladder disease. The most common adverse effects seen during clinical use of oral contraceptives are menstrual irregularities.

EU Indication of danger: Carcinogenic: Category 1  
Toxic to reproduction: Category 1

### EU Hazard Symbols:



### EU Risk Phrases:

R45 - May cause cancer.  
R60 - May impair fertility.  
R61 - May cause harm to the unborn child.  
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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### 2. HAZARDS IDENTIFICATION

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

**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	EU Classification	%
Ethinyl Estradiol	57-63-6	200-342-2	Carc. Cat.1;R45 N;R50/53 Repr. Cat.1;R60/61 Xn;R22	20 mcg***
Levonorgestrel	797-63-7	212-349-8	Repr.Cat.1;R60 Carc.Cat.3;R40 Repr.Cat.2;R61-64	90 mcg***
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Iron oxide	1309-37-1	215-168-2	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	*
Polacrillin potassium	39394-76-8	Not Listed	Not Listed	*
Fatty acids, montan-wax, ethylene esters	73138-45-1	277-291-8	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*

**Additional Information:** \* Proprietary  
\*\*\* per tablet/capsule/lozenge/suppository  
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:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**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.

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**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.

### 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, Restrict access to work area. 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.

<b>Ethinyl Estradiol</b>	
Pfizer OEL TWA-8 Hr:	0.04µg/m <sup>3</sup> , Skin
<b>Levonorgestrel</b>	
Pfizer OEL TWA-8 Hr:	0.05µg/m <sup>3</sup>
<b>Magnesium stearate</b>	
ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup> TWA
Australia TWA	10 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Belgium OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
Portugal OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

#### Iron oxide

ACGIH Threshold Limit Value (TWA)	1 mg/m <sup>3</sup> TWA 5 mg/m <sup>3</sup> TWA
Australia TWA	1 mg/m <sup>3</sup> 5 mg/m <sup>3</sup>
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany (DFG) - MAK	1.5 mg/m <sup>3</sup> MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELs - TWAs:	10 mg/m <sup>3</sup>
Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

#### Polyethylene glycol

Austria OEL - MAKs	Listed
Germany - TRGS 900 - TWAs	1000 mg/m <sup>3</sup>
Germany (DFG) - MAK	1000 mg/m <sup>3</sup> MAK
Slovenia OEL - TWA	Listed

#### Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup> TWA
Australia TWA	10 mg/m <sup>3</sup>
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Denmark OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Greece OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup> total

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Poland OEL - TWA	Listed
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed
Sweden OEL - TWAs	Listed

#### Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup> TWA
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	Listed
Estonia OEL - TWA	Listed
France OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Latvia OEL - TWA	Listed
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup> total 5 mg/m <sup>3</sup>
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Spain OEL - TWA	Listed

#### 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.

#### Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

#### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

#### Hands:

Impervious, disposable gloves (double suggested) 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 disposable 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:	Tablet	Color:	Yellow
Molecular Formula:	Mixture	Molecular Weight:	Mixture

### 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

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## 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)

#### **Magnesium stearate**

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

#### **Microcrystalline cellulose**

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

#### **Titanium dioxide**

Rat Oral LD50 > 7500 mg/kg  
Rat Subcutaneous LD 50 50 mg/kg

#### **Hydroxypropyl methylcellulose**

Rat Oral LD50 > 10,000 mg/kg

#### **Ethinyl Estradiol**

Mouse Oral LD50 1737 mg/kg  
Rat Oral LD50 1200 mg/kg

#### **Levonorgestrel**

Rat Oral LD50 > 4000 mg/kg  
Mouse Oral LD50 > 4000 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

### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

#### **Ethinyl Estradiol**

Embryo / Fetal Development Mouse No route specified 0.02 mg/kg/day LOEL Embryotoxicity, Not teratogenic

#### **Levonorgestrel**

Reproductive & Fertility Rat Oral 10 ug/kg/day LOAEL Fertility  
Reproductive & Fertility Rabbit Oral 1875 ug/kg/day LOAEL Fertility

### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

#### **Ethinyl Estradiol**

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### 11. TOXICOLOGICAL INFORMATION

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
Chromosome Aberration Human Lymphocytes Positive  
Sister Chromatid Exchange Human Lymphocytes Positive  
Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive  
*In Vivo* Micronucleus Mouse Bone Marrow Positive

#### Levonorgestrel

Bacterial Mutagenicity (Ames) *Salmonella* Negative

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Ethinyl Estradiol

80 Week(s) Mouse Oral, in feed 0.07 mg/kg/day LOEL Tumors, Pituitary gland  
104 Week(s) Rat No route specified 0.07 mg/kg/day LOEL Malignant tumors, Liver  
105 Week(s) Rat Oral, in feed 0.053 mg/kg/day NOEL Not carcinogenic

Carcinogen Status: See below

##### Titanium dioxide

IARC: Group 3 (Not Classifiable)

##### Iron oxide

IARC: Group 3

##### Ethinyl Estradiol

IARC: Group 1  
NTP: Listed  
OSHA: Present

##### Levonorgestrel

IARC: Group 2B  
OSHA: Present

### 12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided. See Aquatic toxicity data of the active ingredient, below:

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

##### Ethinyl Estradiol

*Oncorhynchus mykiss* (Rainbow Trout) LC50 96 Hours 1.6 mg/L  
*Daphnia magna* (Water Flea) EC50 48 Hours 5.7 mg/L  
Algae EC50 0.84 mg/L

#### Aquatic Toxicity Comments:

A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

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### 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:** T  
**EU Indication of danger:** Carcinogenic: Category 1  
Toxic to reproduction: Category 1

**EU Risk Phrases:**  
R45 - May cause cancer.  
R60 - May impair fertility.  
R61 - May cause harm to the unborn child.  
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

**OSHA Label:**  
DANGER  
May cause cancer.  
May damage fertility or the unborn child.

#### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
Class D, Division 2, Subdivision A





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### 15. REGULATORY INFORMATION

#### Ethinyl Estradiol

California Proposition 65	carcinogen, initial date 1/1/88 developmental toxicity, initial date 4/1/90 (when mixed with Norethisterone)
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	200-342-2

#### Levonorgestrel

California Proposition 65	female reproductive toxicity, initial date 5/15/98 (implants)
Australia (AICS):	Listed
EU EINECS/ELINCS List	212-349-8

#### Lactose NF, monohydrate

Australia (AICS):	Listed
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#### Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	209-150-3

#### Fatty acids, montan-wax, ethylene esters

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	277-291-8

#### Hydroxypropyl methylcellulose

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

#### Iron oxide

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 4 Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-168-2

#### Polyethylene glycol

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

#### Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	236-675-5

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### 15. REGULATORY INFORMATION

**Microcrystalline cellulose**

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	232-674-9

### 16. OTHER INFORMATION

**Text of R phrases mentioned in Section 3**

R22 - Harmful if swallowed.

R40 - Limited evidence of a carcinogenic effect

R45 - May cause cancer.

R60 - May impair fertility.

R61 - May cause harm to the unborn child.

R50 - Very toxic to aquatic organisms.

R53 - May cause long-term adverse effects in the aquatic environment.

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Prepared by:** Product Stewardship Hazard Communications  
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**