SAFETY DATA SHEET

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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:
International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail: pfizer-MSDS@pfizer.com

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

Product Identifier

Material Name: Levonorgestrel and Ethinyl Estradiol Tablets

Trade Name:
LYBREL; ANYA; LOETTE; LOVETTE; MINIIDRIL; ADEPAL; TRINORDIOL; NORDETTE;
TRIPHASOL; TRIFEME; STEDIRIL; OVRAL; EVANOR; BELESSE; LEIOS; FEMIGOA;
TRIGOA; ANGE; OVOPLEX; AMARANCE

Chemical Family:
Synthetic estrogen , Synthetic progestogen

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as oral contraceptive

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1A
Effects on or via lactation
Carcinogenicity: Category 2

EU Classification:
EU Indication of danger: Toxic to reproduction: Category 1
Carcinogenic: Category 3

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.

Label Elements

Signal Word: Danger
Hazard Statements:
H351 - Suspected of causing cancer
H360FD - May damage fertility. May damage the unborn child.
H362 - May cause harm to breast-fed children

Revision date: 09-Oct-2014
Version: 2.0
Page 1 of 13
Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards
Australian Hazard Classification (NOHSC):

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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethinyl Estradiol</td>
<td>57-63-6</td>
<td>200-342-2</td>
<td>Carc. Cat.1;R45 N;R50/53 Cat.1;R60/61;R22</td>
<td>Carc.1A;H350 Repr.1A;H360FD Tox.4, H302 Acute1;H400 Aquatic Chronic1;H410</td>
<td>0.03</td>
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<tr>
<td>Iron oxide</td>
<td>1309-37-1</td>
<td>215-168-2</td>
<td>Not Listed</td>
<td>Not Listed</td>
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<tr>
<td>Levonorgestrel</td>
<td>797-63-7</td>
<td>212-349-8</td>
<td>Repr.Cat.1;R60 Carc.Cat.3;R40 Repr.Cat.2;R61-64</td>
<td>Carc.2;H351 Repr.1A;H360FD H362</td>
<td>0.10-0.15</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Polymethylene glycol</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Fatty acids, montan-wax, ethylene esters</td>
<td>73138-45-1</td>
<td>277-291-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
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<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose NF, monohydrate</td>
<td>64044-51-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polacrilin potassium</td>
<td>39394-76-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
4. FIRST AID MEASURES

**Description of 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.

**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 fire fighting 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**

**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.
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

Precautions for Safe 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.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Ethyl Estradiol
Pfizer OEL TWA-8 Hr: 0.04µg/m³, Skin
Iron oxide
ACGIH Threshold Limit Value (TWA) 5 mg/m³
Australia TWA 5 mg/m³
10 mg/m³
Austria OEL - MAKs 5 mg/m³
10 mg/m³
Belgium OEL - TWA 2 ppm
5 mg/m³
Bulgaria OEL - TWA 5.0 mg/m³
Denmark OEL - TWA 3.5 mg/m³
Estonia OEL - TWA 3.5 mg/m³
Finland OEL - TWA 5 mg/m³
France OEL - TWA 5 mg/m³
Greece OEL - TWA 10 mg/m³
Hungary OEL - TWA 6 mg/m³
Ireland OEL - TWAs 5 mg/m³
10 mg/m³
4 mg/m³
Lithuania OEL - TWA 3.5 mg/m³
OSHA - Final PELS - TWAs: 10 mg/m³
15 mg/m³
Poland OEL - TWA 5 mg/m³
Portugal OEL - TWA 5 mg/m³
Romania OEL - TWA 5 mg/m³
Russia OEL - TWA 6 mg/m³
Slovakia OEL - TWA 1.5 mg/m³
Spain OEL - TWA 5 mg/m³
Sweden OEL - TWAs 3.5 mg/m³
## EXPOSURE CONTROLS / PERSONAL PROTECTION

### Switzerland OEL - TWAs
- 3 mg/m³

### Vietnam OEL - TWAs
- 5 mg/m³

### Levonorgestrel
- Pfizer OEL TWA-8 Hr:
  - 0.05µg/m³

### Microcrystalline cellulose
- **ACGIH Threshold Limit Value (TWA)**: 10 mg/m³
- **Australia TWA**: 10 mg/m³
- **Belgium OEL - TWA**: 10 mg/m³
- **Estonia OEL - TWA**: 10 mg/m³
- **France OEL - TWA**: 10 mg/m³
- **Ireland OEL - TWA**: 10 mg/m³
- **Latvia OEL - TWA**: 2 mg/m³
- **OSHA - Final PELS - TWAs**: 15 mg/m³
- **Portugal OEL - TWA**: 10 mg/m³
- **Russia OEL - TWA**: 6 mg/m³
- **Spain OEL - TWA**: 10 mg/m³
- **Switzerland OEL - TWAs**: 3 mg/m³
- **Vietnam OEL - TWAs**: 10 mg/m³
- **Switzerland OEL - TWAs**: 5 mg/m³

### Polyethylene glycol
- **Austria OEL - MAKs**: 1000 mg/m³
- **Germany - TRGS 900 - TWAs**: 1000 mg/m³
- **Germany (DFG) - MAK**: 1000 mg/m³ average molecular weight 200-600
- **Slovakia OEL - TWA**: 1000 mg/m³
- **Slovenia OEL - TWA**: 1000 mg/m³
- **Switzerland OEL - TWAs**: 1000 ppm

### Titanium dioxide
- **ACGIH Threshold Limit Value (TWA)**: 10 mg/m³
- **ACGIH OELs - Notice of Intended Changes**: Listed
- **Australia TWA**: 10 mg/m³
- **Austria OEL - MAKs**: 5 mg/m³
- **Belgium OEL - TWA**: 10 mg/m³
- **Bulgaria OEL - TWA**: 10.0 mg/m³
- **Denmark OEL - TWA**: 6 mg/m³
- **Estonia OEL - TWA**: 5 mg/m³
- **France OEL - TWA**: 10 mg/m³
- **Greece OEL - TWA**: 10 mg/m³
- **Ireland OEL - TWAs**: 10 mg/m³
- **Latvia OEL - TWA**: 4 mg/m³
- **Lithuania OEL - TWA**: 5 mg/m³
- **OSHA - Final PELS - TWAs**: 15 mg/m³
- **Poland OEL - TWA**: 10.0 mg/m³
- **Portugal OEL - TWA**: 10 mg/m³
- **Romania OEL - TWA**: 10 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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).

- **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:** Various

**Odor:** No data available.

**Odor Threshold:** No data available.

**Molecular Formula:** Mixture

**Molecular Weight:** Mixture

**Solvent Solubility:** No data available

**Water Solubility:** No data available

**pH:** No data available

**Melting/Freezing Point (°C):** No data available

**Boiling Point (°C):** No data available

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

#### Magnesium stearate

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

**Exposure Controls**

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Russia OEL - TWA</th>
<th>Spain OEL - TWA</th>
<th>Sweden OEL - TWAs</th>
<th>Switzerland OEL -TWAs</th>
<th>Vietnam OEL - TWA</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>10 mg/m³</td>
<td>10 mg/m³</td>
<td>5 mg/m³</td>
<td>3 mg/m³</td>
<td>6 mg/m³</td>
</tr>
</tbody>
</table>

**Material Name:** Levonorgestrel and Ethinyl Estradiol Tablets

**Revision date:** 09-Oct-2014
9. PHYSICAL AND CHEMICAL PROPERTIES

No data available
Levonorgestrel
No data available
Ethinyl Estradiol
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

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

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 Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
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.

Acute Toxicity: (Species, Route, End Point, Dose)

Magnesium stearate
  Rat Oral LD50 > 2000 mg/kg
  Rat Inhalation LC50 > 2000 mg/m³

Microcrystalline cellulose
11. TOXICOLOGICAL INFORMATION

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)

Levonorgestrel
3 Month(s) Monkey Oral 0.025 mg/kg/day NOAEL None identified
6 Month(s) Dog Oral 0.05 mg/kg/day LOAEL Female reproductive system
1 Year(s) Rat Oral 0.5 mg/kg/day NOAEL Female reproductive system, Liver, Pituitary
1 Year(s) Monkey Oral 0.00025 mg/kg/day NOAEL Female reproductive system, Gastrointestinal system

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

Levonorgestrel
Reproductive & Fertility Rat Oral 10 ug/kg/day LOAEL Fertility
Reproductive & Fertility Rabbit Oral 1875 ug/kg/day LOAEL Fertility
Embryo / Fetal Development Rabbit Oral 0.05 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rat Subcutaneous 0.25 mg/kg/day NOAEL Developmental toxicity

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

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

Levonorgestrel
11. TOXICOLOGICAL INFORMATION

Bacterial Mutagenicity (Ames)  Salmonella  Negative

Ethinyl Estradiol
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

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 2B (Possibly Carcinogenic to Humans)

Iron oxide
IARC:  Group 3 (Not Classifiable)

Levonorgestrel
IARC:  Group 2B (Possibly Carcinogenic to Humans)
OSHA:  Listed

Ethinyl Estradiol
IARC:  Group 1 (Carcinogenic to Humans)
NTP:  Listed
OSHA:  Listed

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:

Toxicity:
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

Persistence and Degradability:  No data available
Bio-accumulative Potential:  No data available
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.

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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

Ethinyl Estradiol
CERCLA/SARA 313 Emission reporting Not Listed
carcinogen initial date 1/1/88
developmental toxicity initial date 4/1/90 when mixed with Norethisterone
California Proposition 65 Present
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Schedule 4
Standard for the Uniform Scheduling for Drugs and Poisons:
EU EINECS/ELINCS List 200-342-2

Fatty acids, montan-wax, ethylene esters
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material Name: Levonorgestrel and Ethinyl Estradiol Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Australia (AICS):</strong> Present</td>
</tr>
<tr>
<td><strong>EU EINECS/ELINCS List</strong> 277-291-8</td>
</tr>
</tbody>
</table>

**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

**Iron oxide**
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present

**Lactose NF, monohydrate**
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List: Not Listed

**Levonorgestrel**
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: female reproductive toxicity 5/15/98 implants
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 3
- EU EINECS/ELINCS List: 212-349-8

**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
- REACH - Annex XVII - Restrictions on Certain Dangerous Substances: Use restricted. See item 9[f], powder
- EU EINECS/ELINCS List: 232-674-9

**Polacrilin potassium**
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- 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
15. REGULATORY INFORMATION

Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 3
EU EINECS/ELINCS List: Not Listed

Titanium dioxide
CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: carcinogen initial date 9/2/11 airborne, unbound particles of respirable size
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 236-675-5

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

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Carcinogenicity-Cat.1A; H350 - May cause cancer
Carcinogenicity-Cat.2; H351 - Suspected of causing cancer
Reproductive toxicity-Cat.1A; H360FD - May damage fertility. May damage the unborn child.
Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life
Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects

Carcinogenic: Category 3
Carcinogenic: Category 2
Toxic to reproduction: Category 1
Toxic to Reproduction: Category 2
N - Dangerous for the environment
Xn - Harmful

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.
R64 - May cause harm to breastfed babies.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.
SAFETY DATA SHEET

Material Name: Levonorgestrel and Ethinyl Estradiol Tablets
Revision date: 09-Oct-2014

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 7 - Handling and Storage.

Revision date: 09-Oct-2014
Prepared by: Product Stewardship Hazard Communication

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