### 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; MINIDRIL; ADEPAL; TRINORDIOL; NORDETTE; TRIPHASOL; TRIFEME; STEDIRIL; OVRAL; EVANOR; BELESSE; LEIOS; FEMIGOA; TRIGOA; ANGE; OVOPLEX; AMARANCE; MONOFEME; OVRANETTE; BIPAL
- **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

**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 Ltd**
- Ramsgate Road
- Sandwich, Kent
- CT13 9NJ
- United Kingdom
- +00 44 (0)1304 616161

**Emergency telephone number:**
- CHEMTREC (24 hours): 1-800-424-9300
- International CHEMTREC (24 hours): +1-703-527-3887

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

### 2. HAZARDS IDENTIFICATION

**Classification of the Substance or Mixture**
- **GHS - Classification**
  - Reproductive Toxicity: Category 1A
  - Effects on or via lactation
  - Carcinogenicity: Category 2

**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

- **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

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>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
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<tbody>
<tr>
<td>Ethinyl Estradiol</td>
<td>57-63-6</td>
<td>200-342-2</td>
<td>Carc.1A;H350, Repr.1A;H360FD Tox.4, H302 Acute1;H400 Aquatic Chronic1;H410</td>
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<tr>
<td>Iron oxide</td>
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<td>215-168-2</td>
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<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
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<td>212-349-8</td>
<td>Carc.2;H351, Repr.1A;H360FD H362</td>
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<td>Polyethylene glycol</td>
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<td>Magnesium stearate</td>
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<td>209-150-3</td>
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<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
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</thead>
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<td>Fatty acids, montan-wax, ethylene esters</td>
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<td>Polacrilin potassium</td>
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<td>Lactose NF, monohydrate</td>
<td>64044-51-5</td>
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<td>Not Listed</td>
<td>*</td>
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</tbody>
</table>

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: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
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.
SAFETY DATA SHEET

Material Name: Levonorgestrel and Ethinyl Estradiol Tablets
Revision date: 18-May-2016

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.

Ethinyl 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
Switzerland OEL -TWAs 3 mg/m³
Vietnam OEL - TWAs 5 mg/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 - TWAs 10 mg/m³
4 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³

Revision date: 18-May-2016

PZ01190
## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### 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
  - 5 mg/m³
- **Ireland OEL - TWAs**: 10 mg/m³
  - 4 mg/m³
- **Latvia OEL - TWA**: 10 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
- **Russia OEL - TWA**: 10 mg/m³
- **Spain OEL - TWA**: 10 mg/m³
- **Sweden OEL - TWAs**: 5 mg/m³
- **Switzerland OEL - TWAs**: 3 mg/m³
- **Vietnam OEL - TWAs**: 6 mg/m³
  - 5 mg/m³

### Levonorgestrel

- **Pfizer OEL TWA-8 Hr**: 0.05µg/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

### Magnesium stearate

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

### Exposure Controls
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
No data available
Lactose NF, monohydrate
No data available
Microcrystalline cellulose
No data available
Titanium dioxide
No data available
Iron oxide
No data available
Hydroxypropyl methylcellulose
No data available
Polyethylene glycol
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

PZ01190
SAFETY DATA SHEET

Material Name: Levonorgestrel and Ethinyl Estradiol Tablets

Revision date: 18-May-2016

Page 7 of 12

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

Titanium dioxide
  Rat Oral LD50 > 7500 mg/kg
  Rat Subcutaneous LD50 50 mg/kg

Hydroxypropyl methylcellulose
  Rat Oral LD50 > 10,000 mg/kg

Levonorgestrel
  Rat Oral LD50 > 5000 mg/kg
  Mouse Oral LD50 > 4000mg/kg

Ethinyl Estradiol

PZ01190
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)

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
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
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
11. TOXICOLOGICAL INFORMATION

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)

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

Onchorhynchus 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

<table>
<thead>
<tr>
<th>Material Name</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Australia (AICS):</th>
<th>Standard for the Uniform Scheduling for Drugs and Poisons:</th>
<th>EU EINECS/ELINCS List</th>
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</thead>
<tbody>
<tr>
<td>Ethinyl Estradiol</td>
<td>Not Listed</td>
<td>carcinogen initial date 1/1/88</td>
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<td>Schedule 4</td>
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<td>California Proposition 65</td>
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<tr>
<td>Australia (AICS):</td>
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<tr>
<td>Fatty acids, montan-wax, ethylene esters</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
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<td>277-291-8</td>
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<td>California Proposition 65</td>
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<td>Hydroxypropyl methylcellulose</td>
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<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
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<td>EU EINECS/ELINCS List</td>
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<tr>
<td>Iron oxide</td>
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<td>California Proposition 65</td>
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<td>Inventory - United States TSCA - Sect. 8(b)</td>
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<tr>
<td>Microcrystalline cellulose</td>
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# SAFETY DATA SHEET

## 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>CERCLA/SARA 313 Emission reporting</th>
<th>California Proposition 65</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>REACH - Annex XVII - Restrictions on Certain Dangerous Substances:</th>
<th>EU EINECS/ELINCS List</th>
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</thead>
<tbody>
<tr>
<td>Levonorgestrel and Ethinyl Estradiol Tablets</td>
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<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>Use restricted. See item 9[f], powder</td>
<td>232-674-9</td>
</tr>
<tr>
<td>Polacrilon potassium</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
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<td>Not Listed</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Present</td>
<td>Present</td>
<td>236-675-5</td>
<td></td>
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<tr>
<td>Lactose NF, monohydrate</td>
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<td>Not Listed</td>
<td>Present</td>
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<td>Not Listed</td>
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<tr>
<td>Magnesium stearate</td>
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<td>Present</td>
<td>Present</td>
<td>209-150-3</td>
<td></td>
</tr>
</tbody>
</table>
16. OTHER INFORMATION

Text of CLP/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

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

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 16 - Other Information.

Revision date: 18-May-2016
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