



SAFETY DATA SHEET

Revision date: 18-May-2016

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

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

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

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Other Hazards Note:

No data available
 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 | % |
|----------------------------|------------|-----------------------|--|-----------|
| Ethinyl Estradiol | 57-63-6 | 200-342-2 | Carc.1A;H350 Repr.1A;H360FD Tox.4, H302 Acute1;H400 Aquatic Chronic1;H410 | 0.03 |
| Iron oxide | 1309-37-1 | 215-168-2 | Not Listed | * |
| Microcrystalline cellulose | 9004-34-6 | 232-674-9 | Not Listed | * |
| Titanium dioxide | 13463-67-7 | 236-675-5 | Not Listed | * |
| Levonorgestrel | 797-63-7 | 212-349-8 | Carc.2;H351 Repr.1A;H360FD H362 | 0.10-0.15 |
| Polyethylene glycol | 25322-68-3 | Not Listed | Not Listed | * |
| Magnesium stearate | 557-04-0 | 209-150-3 | Not Listed | * |

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

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.

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- 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.

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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/m ³ |
| Australia TWA | 5 mg/m ³ |
| | 10 mg/m ³ |
| Austria OEL - MAKs | 5 mg/m ³ |
| | 10 mg/m ³ |
| Belgium OEL - TWA | 2 ppm |
| | 5 mg/m ³ |
| Bulgaria OEL - TWA | 5.0 mg/m ³ |
| Denmark OEL - TWA | 3.5 mg/m ³ |
| Estonia OEL - TWA | 3.5 mg/m ³ |
| Finland OEL - TWA | 5 mg/m ³ |
| France OEL - TWA | 5 mg/m ³ |
| Greece OEL - TWA | 10 mg/m ³ |
| Hungary OEL - TWA | 6 mg/m ³ |
| Ireland OEL - TWAs | 5 mg/m ³ |
| | 10 mg/m ³ |
| | 4 mg/m ³ |
| Lithuania OEL - TWA | 3.5 mg/m ³ |
| OSHA - Final PELs - TWAs: | 10 mg/m ³ |
| | 15 mg/m ³ |
| Poland OEL - TWA | 5 mg/m ³ |
| Portugal OEL - TWA | 5 mg/m ³ |
| Romania OEL - TWA | 5 mg/m ³ |
| Russia OEL - TWA | 6 mg/m ³ |
| Slovakia OEL - TWA | 1.5 mg/m ³ |
| Spain OEL - TWA | 5 mg/m ³ |
| Sweden OEL - TWAs | 3.5 mg/m ³ |
| Switzerland OEL - TWAs | 3 mg/m ³ |
| Vietnam OEL - TWAs | 5 mg/m ³ |

Microcrystalline cellulose

| | |
|-----------------------------------|----------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| Australia TWA | 10 mg/m ³ |
| Belgium OEL - TWA | 10 mg/m ³ |
| Estonia OEL - TWA | 10 mg/m ³ |
| France OEL - TWA | 10 mg/m ³ |
| Ireland OEL - TWAs | 10 mg/m ³ |
| | 4 mg/m ³ |
| Latvia OEL - TWA | 2 mg/m ³ |
| OSHA - Final PELs - TWAs: | 15 mg/m ³ |

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | |
|-----------------------|---|
| Portugal OEL - TWA | 10 mg/m ³ |
| Romania OEL - TWA | 10 mg/m ³ |
| Russia OEL - TWA | 6 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |
| Switzerland OEL -TWAs | 3 mg/m ³ |
| Vietnam OEL - TWAs | 10 mg/m ³ 5 mg/m ³ |

Titanium dioxide

| | |
|---|---|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| ACGIH OELs - Notice of Intended Changes | Listed |
| Australia TWA | 10 mg/m ³ |
| Austria OEL - MAKs | 5 mg/m ³ |
| Belgium OEL - TWA | 10 mg/m ³ |
| Bulgaria OEL - TWA | 10.0 mg/m ³ |
| Denmark OEL - TWA | 6 mg/m ³ |
| Estonia OEL - TWA | 5 mg/m ³ |
| France OEL - TWA | 10 mg/m ³ |
| Greece OEL - TWA | 10 mg/m ³ 5 mg/m ³ |
| Ireland OEL - TWAs | 10 mg/m ³ 4 mg/m ³ |
| Latvia OEL - TWA | 10 mg/m ³ |
| Lithuania OEL - TWA | 5 mg/m ³ |
| OSHA - Final PELs - TWAs: | 15 mg/m ³ |
| Poland OEL - TWA | 10.0 mg/m ³ |
| Portugal OEL - TWA | 10 mg/m ³ |
| Romania OEL - TWA | 10 mg/m ³ |
| Russia OEL - TWA | 10 mg/m ³ |
| Spain OEL - TWA | 10 mg/m ³ |
| Sweden OEL - TWAs | 5 mg/m ³ |
| Switzerland OEL -TWAs | 3 mg/m ³ |
| Vietnam OEL - TWAs | 6 mg/m ³ 5 mg/m ³ |

Levonorgestrel

| | |
|----------------------|-----------------------|
| Pfizer OEL TWA-8 Hr: | 0.05µg/m ³ |
|----------------------|-----------------------|

Polyethylene glycol

| | |
|---------------------------|---|
| Austria OEL - MAKs | 1000 mg/m ³ |
| Germany - TRGS 900 - TWAs | 1000 mg/m ³ |
| Germany (DFG) - MAK | 1000 mg/m ³ average molecular weight 200-600 |
| Slovakia OEL - TWA | 1000 mg/m ³ |
| Slovenia OEL - TWA | 1000 mg/m ³ |
| Switzerland OEL -TWAs | 1000 ppm |

Magnesium stearate

| | |
|-----------------------------------|----------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m ³ |
| Lithuania OEL - TWA | 5 mg/m ³ |
| Sweden OEL - TWAs | 5 mg/m ³ |

Exposure Controls

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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

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| | |
|--|-------------------|
| 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/m ³ |

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

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11. TOXICOLOGICAL INFORMATION

Mouse Oral LD50 1737 mg/kg

Rat Oral LD50 1200mg/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)

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

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

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| | | | | | |
|-------------|-----|--------------------|-----------------|------|-------------------------|
| 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)

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
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.

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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, or IMDG regulations.

15. REGULATORY INFORMATION

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

Ethinyl Estradiol

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

Fatty acids, montan-wax, ethylene esters

| | |
|---|---------------------------------|
| CERCLA/SARA 313 Emission reporting California Proposition 65 | Not Listed Not Listed |
| Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List | Present Present 277-291-8 |

Hydroxypropyl methylcellulose

| | |
|--|--|
| CERCLA/SARA 313 Emission reporting California Proposition 65 | Not Listed Not Listed |
| Inventory - United States TSCA - Sect. 8(b) Australia (AICS): Standard for the Uniform Scheduling for Drugs and Poisons: EU EINECS/ELINCS List | Present Present Schedule 4 Not Listed |

Iron oxide

| | |
|---|---------------------------------|
| CERCLA/SARA 313 Emission reporting California Proposition 65 | Not Listed Not Listed |
| Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List | Present Present 215-168-2 |

Microcrystalline cellulose

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| | |
|---|---|
| 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 |
| Polacrillin potassium | |
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65 | Not Listed |
| 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 |
| 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 | Schedule 4 |
| EU EINECS/ELINCS List | 212-349-8 |
| 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 |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 3 |
| EU EINECS/ELINCS List | Not Listed |
| 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 |
| 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 |

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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.

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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 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