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

Product Identifier

Material Name: Levonorgestrel Tablets

Trade Name: MICROVAL

Chemical Family: 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

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

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

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

EU Classification:

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

EU Risk Phrases:

R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R64 - May cause harm to breastfed babies.
R40 - Limited evidence of a carcinogenic effect

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
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

### Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
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<tr>
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<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
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</thead>
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<tr>
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<td>Povidone</td>
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</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.
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.
SAFETY DATA SHEET

Material Name: Levonorgestrel Tablets
Revision date: 03-Nov-2014

7. HANDLING AND STORAGE

Precautions for Safe Handling
Restrict access to work area. 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. 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.

Calcium carbonate
- Australia TWA: 10 mg/m³
- Bulgaria OEL - TWA: 10.0 mg/m³
- France OEL - TWA: 10 mg/m³
- Latvia OEL - TWA: 6 mg/m³
- Poland OEL - TWA: 10 mg/m³
- Portugal OEL - TWA: 10 mg/m³
- Vietnam OEL - TWAs: 10 mg/m³

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

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

Maize starch
- ACGIH Threshold Limit Value (TWA): 10 mg/m³
- Australia TWA: 10 mg/m³
- Belgium OEL - TWA: 10 mg/m³
- Bulgaria OEL - TWA: 10.0 mg/m³
- Czech Republic OEL - TWA: 4.0 mg/m³
- Greece OEL - TWA: 10 mg/m³
- Ireland OEL - TWAs: 10 mg/m³
- OSHA - Final PELS - TWAs: 4 mg/m³
- Portugal OEL - TWA: 10 mg/m³
- Slovakia OEL - TWA: 4 mg/m³
- Spain OEL - TWA: 10 mg/m³
- Switzerland OEL -TWAs: 3 mg/m³

Polyethylene glycol
- Austria OEL - MAKs: 1000 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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<td>Portugal OEL - TWA</td>
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<tr>
<td>2 mg/m³</td>
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<td>Slovakia OEL - TWA</td>
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<tr>
<td>1000 mg/m³</td>
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<tr>
<td>Slovenia OEL - TWA</td>
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<tr>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
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<tr>
<td>1000 ppm</td>
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</table>

**Sucrose**

- ACGIH Threshold Limit Value (TWA) 10 mg/m³
- Australia TWA 10 mg/m³
- Belgium OEL - TWA 10 mg/m³
- Bulgaria OEL - TWA 10 mg/m³
- Estonia OEL - TWA 10 mg/m³
- France OEL - TWA 10 mg/m³
- Ireland OEL - TWAs 10 mg/m³
- Latvia OEL - TWA 5 mg/m³
- Lithuania OEL - TWA 10 mg/m³
- OSHA - Final PELs - TWAs: 15 mg/m³
- Portugal OEL - TWA 10 mg/m³
- Slovakia OEL - TWA 6 mg/m³
- Spain OEL - TWA 10 mg/m³

**Talc (non-asbestiform)**

- ACGIH Threshold Limit Value (TWA) 2 mg/m³
- Australia TWA 2.5 mg/m³
- Austria OEL - MAKs 2 mg/m³
- Belgium OEL - TWA 2 mg/m³
- Bulgaria OEL - TWA 1.0 fiber/cm³
- Estonia OEL - TWA 6.0 mg/m³
- Finland OEL - TWA 3.0 mg/m³
- France OEL - TWA 10 mg/m³
- Greece OEL - TWA 2 mg/m³
- Hungary OEL - TWA 10 mg/m³
- Ireland OEL - TWAs 0.8 mg/m³
- Lithuania OEL - TWA 2 mg/m³
- Netherlands OEL - TWA 0.25 mg/m³
- OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
- Poland OEL - TWA 4.0 mg/m³
- Portugal OEL - TWA 2 mg/m³
- Romania OEL - TWA 2 mg/m³
- Slovakia OEL - TWA 2 mg/m³
- Slovenia OEL - TWA 10 mg/m³
- Spain OEL - TWA 2 mg/m³
- Sweden OEL - TWAs 2 mg/m³
- Switzerland OEL -TWAs 2 mg/m³

**Revision date:** 03-Nov-2014

**Version:** 1.0
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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).

**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

**Odor:** No data available.

**Molecular Formula:** 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)

Levonorgestrel
No data available

Lactose NF, monohydrate
No data available

Polyethylene glycol
No data available

Magnesium stearate
No data available

Povidone
No data available

Talc (non-asbestiform)
No data available

Beeswax
No data available

Carnauba wax
No data available

Calcium carbonate
No data available

Maize starch
No data available

Sucrose
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: 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)

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

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

Talc (non-asbestiform)  
Rat Oral LD50 > 1600 mg/kg

Calcium carbonate  
Rat Oral LD50 6450 mg/kg

Sucrose  
Rat Oral LD50 29.7 g/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.
11. TOXICOLOGICAL INFORMATION

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
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

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

Levonorgestrel
Bacterial Mutagenicity (Ames)  Salmonella  Negative
Sucrose
Bacterial Mutagenicity (Ames)  Salmonella  Negative

Carcinogen Status:  See below

Levonorgestrel
IARC:  Group 2B (Possibly Carcinogenic to Humans)
Povidone
IARC:  Group 3 (Not Classifiable)
Talc (non-asbestiform)
IARC:  Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview:  The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

Toxicity:

Persistence and Degradability:  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

Beeswax
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 232-383-7

Calcium carbonate
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
15. REGULATORY INFORMATION

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<td>Carnauba wax</td>
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Material Name: Levonorgestrel Tablets

Revision date: 03-Nov-2014

Version: 1.0
15. REGULATORY INFORMATION

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Sucrose

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Talc (non-asbestiform)

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16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

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

Carcinogenic: Category 3
Toxic to reproduction: Category 1
Toxic to Reproduction: Category 2

R40 - Limited evidence of a carcinogenic effect
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R64 - May cause harm to breastfed babies.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.
Revision date: 03-Nov-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