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

Material Name: Ethynodiol Diacetate and Ethinyl Estradiol Tablets

Trade Name: Demulen(R)
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as oral contraceptive.

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corn Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>*</td>
</tr>
<tr>
<td>Ethinyl Estradiol</td>
<td>57-63-6</td>
<td>200-342-2</td>
<td>35 / 50 mcg ***</td>
</tr>
<tr>
<td>Ethynodiol Diacetate</td>
<td>297-76-7</td>
<td>206-044-9</td>
<td>1 mg ***</td>
</tr>
<tr>
<td>Calcium Acetate</td>
<td>62-54-4</td>
<td>200-540-9</td>
<td>*</td>
</tr>
<tr>
<td>Lactose Monohydrate</td>
<td>64044-51-5</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Povidone</td>
<td>9003-39-8</td>
<td>Not listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydrogenated castor oil</td>
<td>8001-78-3</td>
<td>232-292-2</td>
<td>*</td>
</tr>
<tr>
<td>FD&amp;C Yellow No. 6; (Sunset yellow)</td>
<td>2783-94-0</td>
<td>220-491-7</td>
<td>*</td>
</tr>
<tr>
<td>Dicalcium phosphate</td>
<td>10103-46-5</td>
<td>233-283-6</td>
<td>*</td>
</tr>
<tr>
<td>Lactose NF, anhydrous</td>
<td>63-42-3</td>
<td>200-559-2</td>
<td>*</td>
</tr>
<tr>
<td>FD &amp; C Blue No. 1</td>
<td>3844-45-9</td>
<td>223-339-8</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White, Blue and Pink Tablets
Signal Word: DANGER

Statement of Hazard:
May be harmful if swallowed.
May cause cancer.
May damage fertility or the unborn child.
MATERIAL SAFETY DATA SHEET

Material Name: Ethynodiol Diacetate and Ethinyl Estradiol Tablets
Revision date: 15-Dec-2006
Page 2 of 8
Version: 2.1

Additional Hazard Information:
Short Term: Active ingredient may be harmful if swallowed.
Long Term: Occupational studies have shown that males working with estrogen-like compounds have shown clinical signs of hyperestrogenism including enlarged breasts and milk secretion. Loss of libido, breast tenderness, and changes in sex hormone levels have also occurred. Occupational exposure in females has resulted in menstrual irregularities (breakthrough bleeding, menstrual flow changes, spotting and amenorrhea).

Known Clinical Effects:
Clinical use of estrogens has resulted in breast changes (enlargement, tenderness, and secretion), along with effects on the genitourinary (changes in vaginal bleeding), and GI systems. Effects on the skin, eyes, and CNS have also been reported. The use of oral contraceptives is associated with increased risks of myocardial infarction, thromboembolism, stroke, hepatic neoplasia, and gallbladder disease.

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

EU Hazard Symbols:

EU Risk Phrases:
R22 - Harmful if swallowed.
R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: May include oxides of carbon.

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

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: Contain the source of the spill or leak if it is safe to do so. Spills should be handled by vacuuming or wet mopping. Avoid brush sweeping and generation of airborne dust.

7. HANDLING AND STORAGE

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Corn Starch
- OSHA - Final PELS - TWAs: 
  - Total = 15 mg/m³ TWA
  - Skin = 5 mg/m³ TWA
- ACGIH Threshold Limit Value (TWA)
  - Total = 10 mg/m³ TWA
  - Skin = 10 mg/m³ TWA

Microcrystalline cellulose
- OSHA - Final PELS - TWAs: 
  - Total = 15 mg/m³ TWA
  - Skin = 5 mg/m³ TWA
- ACGIH Threshold Limit Value (TWA)
  - Total = 10 mg/m³ TWA
  - Skin = 10 mg/m³ TWA

Magnesium stearate
- ACGIH Threshold Limit Value (TWA)
  - Total = 10 mg/m³ TWA except stearates of toxic metals
  - Skin = 10 mg/m³ TWA

Ethynyl Estradiol
- Pfizer OEL TWA-8 Hr: 40 ng/m³, Skin

Ethynodiol Diacetate
- Pfizer OEL TWA-8 Hr: 0.25ug/m³
  - The exposure limit(s) listed for solid components are only relevant if dust may be generated.


Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:
- Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection: Not required for the normal use of this product. 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:

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>Odorless</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

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)

**Ethynodiol Diacetate**
- Rat Oral LD50 1200 mg/kg
- Rabbit Dermal LD50 > 2000 mg/kg

**Ethinyl Estradiol**
- Mouse Oral LD50 1737 mg/kg
- Rat Oral LD50 > 5000 mg/kg
- Rabbit Dermal LD50 > 2000 mg/kg
- Rat Inhalation LC50 > 2000 mg/m³

**Povidone**
- Rat Oral LD50 100 g/kg

**Lactose Monohydrate**
- Rat Oral LD50 29700 mg/kg

**Microcrystalline cellulose**
- Rat Oral LD50 > 5000 mg/kg

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

**FD&C Yellow No. 6; (Sunset yellow)**
- Rat Oral LD50 > 10,000 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

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)
- Ethynodiol Diacetate
  - 7 Year(s) Dog, Oral, 0.125 mg/kg/day LOAEL Reproductive system
  - 10 Year(s) Non-human Primate, Oral, 5 µg/kg/day LOAEL Mammary gland, Endocrine system
  - 10 Year(s) Non-human Primate, Oral, 5 µg/kg/day NOAEL Female reproductive system

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

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

Ethynodiol Diacetate
- Embryo / Fetal Development Mouse, No route specified, 1.0 mg/kg LOEL Teratogenic
- Embryo / Fetal Development Rat, Subcutaneous, 2.0 mg/kg/day NOEL Not Teratogenic
- Embryo / Fetal Development Rabbit, Subcutaneous, 0.05 mg/kg/day NOEL Not Teratogenic

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

Ethynodiol Diacetate
- Not specified Male Mouse Oral, Benign tumors, Liver
- Not specified Male Rat Oral, Benign tumors, Mammary gland

Carcinogen Status: See below

Ethinyl Estradiol
- IARC: Group 1
12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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
Harmful

EU Risk Phrases: R22 - Harmful if swallowed.
R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
DANGER
May be harmful if swallowed.
May cause cancer.
May damage fertility or the unborn child.

Canada - WHMIS: Classifications

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

Calcium Acetate
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 200-540-9

Lactose Monohydrate
Australia (AICS): Present

Corn Starch
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present
EU EINECS List 232-679-6

Microcrystalline cellulose
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present
EU EINECS List 232-674-9

Magnesium stearate
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 209-150-3

Povidone
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present

Hydrogenated castor oil
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 232-292-2

Ethynil 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)  
Present

Australia (AICS):  
Present

Standard for the Uniform Scheduling for Drugs and Poisons:  
Schedule 4

EU EINECS List  
200-342-2

FD&C Yellow No. 6; (Sunset yellow)  
Inventory - United States TSCA - Sect. 8(b)  
Present

Australia (AICS):  
Present

EU EINECS List  
220-491-7

Dicalcium phosphate  
Inventory - United States TSCA - Sect. 8(b)  
Present

Australia (AICS):  
Present

EU EINECS List  
233-283-6

Lactose NF, anhydrous  
Inventory - United States TSCA - Sect. 8(b)  
Present

Australia (AICS):  
Present

EU EINECS List  
200-559-2

FD & C Blue No. 1  
Inventory - United States TSCA - Sect. 8(b)  
Present

Australia (AICS):  
Present

EU EINECS List  
223-339-8

Ethynodiol Diacetate  
Australia (AICS):  
Present

EU EINECS List  
206-044-9

## 16. OTHER INFORMATION

### Reasons for Revision:

Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

### Prepared by:

Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet