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

Product Name: Contraceptive Products

Common Name: Not available

Chemical Name: Not applicable

Synonyms: Alesse, LoOvral, Lo-Ovral 28 and Ferrous Fumarate (Iron), Lybrel, Ovral, Ethinyl Estradiol, Levonorgestrel, Norgestrel, Minesse, Alesse/Loette, Harmonet, Harmonet-28, Trinulet, Trinordiol 28, Minulet 21, Minulet 28, Microval, Minules, Norditil 28, Nordiil, Biphasil 28, Biphasil, Biphasic, Estrogen-Progestin Combination Contraceptive (COC), Progestin Only Concentrate, Ange, Gestodone, Min-Ovral, Overette, Nordette, Triphasil

Product Use: Pharmaceutical product

Classification: Hormones and Synthetic Substitutes

Supplier: Wyeth

P.O. Box 8299
Philadelphia, PA 19101 USA.
Telephone: 1-610-688-4400

Emergency Telephone Number: Chemtrec USA, Puerto Rico, Canada 1-800-424-9300
Chemtrec International 1-703-527-3887

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Common Name</th>
<th>CAS-No</th>
<th>EC No.</th>
<th>Composition</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norgestrel</td>
<td>6533-00-2</td>
<td>229-433-5</td>
<td>0.5 mg/tablet</td>
<td>T; N; R40, 60, 61, 64, 50/33; S45, 53, 60, 61</td>
</tr>
<tr>
<td>Ethinyl Estradiol</td>
<td>57-63-6</td>
<td>200-342-2</td>
<td>0 - 0.05 mg/tablet</td>
<td>T, N; R40, 50/53, 60, 63; S45, 53, 60</td>
</tr>
<tr>
<td>Levonorgestrel</td>
<td>797-63-7</td>
<td>212-349-8</td>
<td>0 - 0.25 mg/tablet</td>
<td>T; R40, 60, 61, 64; S45, 53</td>
</tr>
<tr>
<td>Gestodene</td>
<td>60282-87-3</td>
<td>262-145-8</td>
<td>0 - 0.1 mg/tablet</td>
<td>T, N; R40, 50/53, 60, 61, 64; S45, 53, 60, 61</td>
</tr>
<tr>
<td>Ferrous Fumarate</td>
<td>141-01-5</td>
<td>205-477-7</td>
<td>0 - 75 mg/tablet</td>
<td>None assigned</td>
</tr>
<tr>
<td>Inactive Ingredients</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Remainder</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

3. HAZARDS IDENTIFICATION

Emergency Overview
This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance: Pharmaceutical tablet
Physical State: Solid
Odor: Not available

Potential Physical Hazards: Powders and solids are presumed to be combustible.

Potential Health Effects:

- Eyes: Not available
- Skin: Not available
- Inhalation: Not available
Ingestion

The most common effects may include uterine bleeding irregularities, change in menstrual flow, breast changes (tenderness, pain, enlargement, secretion, lumps), hirsutism, changes in libido, loss of scalp hair, melasma/chloasma, mood changes, depression, vaginitis, candidiasis, cardiovascular disease, cerebrovascular disease, vascular disease, venous and arterial thrombotic and thromboembolic events, other vascular problems (myocardial infarction, thromboembolism, stroke, hypertension, thromboembolic disorders), hepatic neoplasia, and gallbladder disease.

May impair fertility. May cause harm to the unborn child. May cause cancer. Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use.

Please see Patient Package Insert for further information.

Therapeutic Target Organ(s)

Reproductive System.

Potential Environmental Effects

Listed by NTP and IARC. Not listed by OSHA.

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### 4. FIRST AID MEASURES

**Eye Contact**

In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.

**Skin Contact**

Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

**Inhalation**

Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.

**Ingestion**

If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

---

### 5. FIRE-FIGHTING MEASURES

**Flammable Properties**

Not flammable

**Extinguishing Media**

**Suitable Extinguishing Media**

Use water spray, foam, dry chemical or carbon dioxide.

**Unsuitable Extinguishing Media**

Do NOT use water jet.

**Fire Fighting**

Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.

**Hazardous Combustion Products**

Carbon oxides, nitrogen oxides.

**Protective Equipment and Precautions for Firefighters**

In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

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### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions**

Refer to protective measures listed in Sections 7 and 8.

**Environmental Precautions**

Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.
7. HANDLING AND STORAGE

Handling
For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.

Storage
No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Common Name</th>
<th>Exposure Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestodene</td>
<td>0.02 mcg/m³</td>
</tr>
<tr>
<td>Levonorgestrel</td>
<td>0.05 mcg/m³</td>
</tr>
<tr>
<td>Norgestrel</td>
<td>0.08 mcg/m³</td>
</tr>
<tr>
<td>Ethinyl Estradiol</td>
<td>0.01 mcg/m³</td>
</tr>
</tbody>
</table>

Engineering Controls
Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated. General ventilation shall not be used as the primary control system. Isolators, fume hoods, or biological safety cabinets may be used based on a risk assessment.

Personal Protective Equipment

- **Eye/face Protection**: Provide eye protection based on risk assessment.
- **Skin Protection**: Wear nitrile or latex gloves. Wear protective garment.
- **Respiratory Protection**: Base respirator selection on a risk assessment.
- **General Hygiene Considerations**: When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.
- **Other**: Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>Pharmaceutical tablet</td>
</tr>
<tr>
<td><strong>Color</strong></td>
<td>Various</td>
</tr>
<tr>
<td><strong>Odor Threshold</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Specific Gravity</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Solubility</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Partition Coefficient</strong> (n-octanol/water)</td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Boiling Point</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Flash Point</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Flammability Limits in Air</strong></td>
<td>Upper Not applicable</td>
</tr>
<tr>
<td><strong>Explosion Limits</strong></td>
<td>Upper Not applicable</td>
</tr>
<tr>
<td><strong>Autoignition Temperature</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Melting Point</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Water Solubility</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Evaporation Rate</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Vapor Pressure</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Flash Point</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Autoignition Temperature</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Melting Point</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Lower</strong></td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Chemical Stability
Stable at room temperature.

Conditions to Avoid
No data available

Materials to Avoid
No materials to be especially mentioned.

Hazardous Decomposition Products
None under normal use.

Possibility of Hazardous Reactions
None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Ferrous Fumarate
- LD50 Oral: 3850 mg/kg rats, 1570 mg/kg mice
- Acute Dermal Irritation: Not applicable
- Primary Eye Irritation: Not applicable
- Sensitization: Not applicable

Gestodene
- LD50 Oral: 600 mg/kg rats, 400 mg/kg mice
- Acute Dermal Irritation: Not irritating to rabbit skin.
- Primary Eye Irritation: Not applicable
- Sensitization: Not a dermal sensitizer in guinea pigs.

Levonorgestrel
- LD50 Oral: > 4000 mg/kg rats
- Acute Dermal Irritation: Not applicable
- Primary Eye Irritation: Not applicable
- Sensitization: Not applicable

Norgestrel
- LD50 Oral: 5010 mg/kg rats
- Acute Dermal Irritation: Not applicable
- Primary Eye Irritation: Not applicable
- Sensitization: Not applicable

Ethynyl Estradiol
- LD50 Oral: 960 mg/kg rats
- Acute Dermal Irritation: Not applicable
- Primary Eye Irritation: Not applicable
- Sensitization: Not applicable

Multiple Dose Toxicity

Ferrous Fumarate
- No Toxicologic Effect: Not applicable
- Dose/Species/Study Length:
**Gestodene**
- **Carcinogenicity**: Not applicable
- **Genetic Toxicity**: Not applicable
- **Reproductive Toxicity**: Not applicable
- **Developmental Toxicity**: Not applicable

**Levonorgestrel**
- **Carcinogenicity**: Not applicable
- **Genetic Toxicity**: Not applicable
- **Reproductive Toxicity**: Not applicable
- **Developmental Toxicity**: Not applicable

**Norgestrel**
- **Carcinogenicity**: Not applicable
- **Genetic Toxicity**: Not applicable
- **Reproductive Toxicity**: Not applicable
- **Developmental Toxicity**: Not applicable

**Ethinyl Estradiol**
- **Carcinogenicity**: Based on tumorigenicity studies in mice, rats, dogs and monkeys, not expected to have any tumorigenic potential relevant to humans in the doses used in oral contraceptive use.
<table>
<thead>
<tr>
<th></th>
<th>Ferrous Fumarate</th>
<th>Gestodene</th>
<th>Levonorgestrel</th>
<th>Norgestrel</th>
<th>Ethinyl Estradiol</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Genetic Toxicity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Reproductive Toxicity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Developmental Toxicity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genetic Toxicity</td>
<td>Regarded as a mutagen and capable of damaging genetic material at low doses.</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td>Reproductive Toxicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Developmental Toxicity</td>
<td>Teratogenic studies indicated developmental effects occurred with altered litter size in female rats exposed in the first 4 days of gestation. In mice, an oral dose given later in gestation caused fetal deaths and musculoskeletal deformities.</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**Bioaccumulation**: Not available

**Target Organ(s) of Toxicity**: No data available

**Mobility**: Not available

**Biodegradability**: Not readily biodegradable.

**Stability in Water**: Not available

**Bioaccumulation**: Not available

**Genetic Toxicity**: Regarded as a mutagen and capable of damaging genetic material at low doses.

**Reproductive Toxicity**: No data available

**Developmental Toxicity**: Teratogenic studies indicated developmental effects occurred with altered litter size in female rats exposed in the first 4 days of gestation. In mice, an oral dose given later in gestation caused fetal deaths and musculoskeletal deformities.

12. ECOLOGICAL INFORMATION

**Chemical Fate Information**

**Ferrous Fumarate**
- **Mobility**: Not available
- **Biodegradability**: Not readily biodegradable.
- **Stability in Water**: Not available
- **Bioaccumulation**: Not available

**Gestodene**
- **Mobility**: Not available
- **Biodegradability**: Not readily biodegradable.
- **Stability in Water**: Not available
- **Bioaccumulation**: Not available

**Levonorgestrel**
- **Mobility**: Not available
- **Biodegradability**: Not readily biodegradable.
- **Stability in Water**: Not available
- **Bioaccumulation**: Not available

**Norgestrel**
- **Mobility**: Not available
- **Biodegradability**: Not readily biodegradable.
- **Stability in Water**: Not available
- **Bioaccumulation**: Not available

**Ethinyl Estradiol**
- **Mobility**: Not available
- **Biodegradability**: Inherently biodegradable.
- **Stability in Water**: Not available
- **Bioaccumulation**: Not available
Ecotoxicity

### Ferrous Fumarate
- **Microorganisms**: Not available
- **Algae**: Not available
- **Daphnia**: Not available
- **Fish**: Not available

### Gestodene
- **Microorganisms**: Not available
- **Algae**: EC50/72h/algae < 1 mg/l
- **Daphnia**: EC50/48h > 7.9 mg/l
- **Fish**: EC50/96h/pimephales promelas < 6.6 mg/l

### Levonorgestrel
- **Microorganisms**: Minimum inhibitory concentration (MIC) > 1000 mg/l for 5 test species.
- **Algae**: Not available
- **Daphnia**: LC50/48h/daphnia > 0.94 mg/l, NOEC = 0.94 mg/l
- **Fish**: Not available

### Norgestrel
- **Microorganisms**: Nostoc sp. MIC = 200 mg/l.
- **Algae**: Not available
- **Daphnia**: Not available
- **Fish**: Not available

### Ethinyl Estradiol
- **Microorganisms**: Minimum inhibitory concentration (MIC) > 1000 mg/l for 3 test species. Clostridium perfringens MIC = 60 mg/l, Nostoc sp. MIC = 40 mg/l.
- **Algae**: Not available
- **Daphnia**: EC50/48h/daphnia = 5.3 mg/l, NOEC = 2.3 mg/l
- **Fish**: Not available

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### 13. DISPOSAL CONSIDERATIONS

**Waste Disposal Method**
Dispose of in accordance with local and national regulations.

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### 14. TRANSPORT INFORMATION

**Transport Information**
This material is not classified as hazardous for transport.

---

### 15. REGULATORY INFORMATION

According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.

---

### 16. OTHER INFORMATION

**Prepared By**
Wyeth Department of Environment, Health & Safety

**Format**
This MSDS was prepared in accordance with Directive 2001/58/EC.

**List of References**
Bayer Schering Pharma MSDS
16. OTHER INFORMATION

Revision Summary  Addition to synonyms

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End of MSDS