SAFETY DATA SHEET

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

Product identifier
Product Name Taytulla

Other means of identification
Product Code FG00079
Synonyms norethindrone acetate and ethinyl estradiol capsules and ferrous fumarate capsules), for oral use.

Recommended use of the chemical and restrictions on use
Recommended Use Contraceptive Agent

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet
Manufacturer Allergan plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525
E-mail address SDS@Allergan.com

Emergency telephone number
Emergency Telephone Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification
OSHA Regulatory Status
This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

<table>
<thead>
<tr>
<th>Classification</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germ cell mutagenicity</td>
<td>Category 2</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Category 1A</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Category 1B</td>
</tr>
<tr>
<td>Effects on or via lactation</td>
<td>Yes</td>
</tr>
<tr>
<td>Specific target organ toxicity (repeated exposure)</td>
<td>Category 2</td>
</tr>
</tbody>
</table>

Label elements

Emergency Overview

Danger

Hazard statements
H341 - Suspected of causing genetic defects
H350 - May cause cancer
H360 - May damage fertility or the unborn child
H362 - May cause harm to breast-fed children
H373 - May cause damage to organs through prolonged or repeated exposure
<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Symptoms</th>
<th>Medical Conditions Aggravated by Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ferrous Fumarate</td>
<td>Adverse reactions include vascular events, liver disease, serious cardiovascular events and stroke, irregular uterine bleeding, nausea, breast tenderness, headache.</td>
<td>This product should be avoided during pregnancy. During therapeutic use, pre-existing skin conditions, abnormal genital bleeding, venous disorders, including past history of deep vein thrombophlebitis or thromboembolic disorders, cerebral vascular or coronary artery disease, known or suspected carcinoma of the breast, carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia, undiagnosed abnormal genital bleeding, kidney/eye/nerve/blood vessel disease, severe headaches/migraines, diabetes, adrenal gland problems, cholestatic jaundice of pregnancy or jaundice with prior pill use or other liver conditions, hepatic adenomas or carcinomas, gallbladder or cardiovascular disease (with a greater risk for smokers) may be aggravated. Workplace exposure may also aggravate these conditions. Persons who may have hypersensitivity reactions to estrogens and/or progesterones may experience aggravation upon exposure.</td>
</tr>
<tr>
<td>Norethindrone Acetate</td>
<td>Common adverse effects from the therapeutic use of this product are weight gain, nausea, edema, and acne. These effects may also be experienced from occupational exposure. Additional effects include blood coagulation, swelling, changes in weight, jaundice, headache, migraine, mood swings, depression, insomnia, and optic nerve inflammation (which can lead to partial or complete vision loss). The most common effects from therapeutic use of products containing Ethinyl Estradiol are headache, menstrual disorder, breast pain, abdominal pain, nausea, flu syndrome, acne, vaginal moniliasis, depression, diarrhea, asthenia, dysmenorrhea, back pain, infection, pharyngitis, inter-menstrual bleeding, migraine, vomiting, dizziness, nervousness, vaginitis, sinusitis, cystitis, bronchitis, gastroenteritis, allergic reaction, urinary tract infection, pruritus, emotional lability, rash, upperrespiratory infection. Chronic toxicity increases the risk of cardiovascular disease, including myocardial infarction, cerebrovascular disease, thromboembolic disease, gallbladder disease, and certain cancers in some people. Chronic toxicity from Ethinyl Estradiol, like other estrogens, increases the risk for stroke, myocardial infarction and thromboembolic disease in certain populations. Jaundice, hypertension, nasal congestion, headache, dizziness and fluid retention may occur. Endometrial, breast, and certain liver cancers may occur at a higher incidence than the general population.</td>
<td>In therapeutic use, dermatitis and other skin disorders as well as menstrual disorders, pre-diabetic and diabetic conditions, heart disease, liver disorders, and benign or malignant liver tumors may be aggracket by exposure to this product. Persons handling the product in the workplace may experience adverse reaction under the same conditions.</td>
</tr>
<tr>
<td>Ethinyl Estradiol</td>
<td>The most common effects from therapeutic use of products containing Ethinyl Estradiol are headache, menstrual disorder, breast pain, abdominal pain, nausea, flu syndrome, acne, vaginal moniliasis, depression, diarrhea, asthenia, dysmenorrhea, back pain, infection, pharyngitis, inter-menstrual bleeding, migraine, vomiting, dizziness, nervousness, vaginitis, sinusitis, cystitis, bronchitis, gastroenteritis, allergic reaction, urinary tract infection, pruritus, emotional lability, rash, upperrespiratory infection. Chronic toxicity increases the risk of cardiovascular disease, including myocardial infarction, cerebrovascular disease, thromboembolic disease, gallbladder disease, and certain cancers in some people. Chronic toxicity from Ethinyl Estradiol, like other estrogens, increases the risk for stroke, myocardial infarction and thromboembolic disease in certain populations. Jaundice, hypertension, nasal congestion, headache, dizziness and fluid retention may occur. Endometrial, breast, and certain liver cancers may occur at a higher incidence than the general population.</td>
<td>This product should be avoided during pregnancy. During therapeutic use, pre-existing skin conditions, abnormal genital bleeding, venous disorders, including past history of deep vein thrombophlebitis or thromboembolic disorders, cerebral vascular or coronary artery disease, known or suspected carcinoma of the breast, carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia, undiagnosed abnormal genital bleeding, kidney/eye/nerve/blood vessel disease, severe headaches/migraines, diabetes, adrenal gland problems, cholestatic jaundice of pregnancy or jaundice with prior pill use or other liver conditions, hepatic adenomas or carcinomas, gallbladder or cardiovascular disease (with a greater risk for smokers) may be aggravated. Workplace exposure may also aggravate these conditions. Persons who may have hypersensitivity reactions to estrogens and/or progesterones may experience aggravation upon exposure.</td>
</tr>
</tbody>
</table>

Precautionary statements
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P405 - Store locked up
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P201 - Obtain special instructions before use
P263 - Avoid contact during pregnancy/while nursing
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P314 - Get medical advice/attention if you feel unwell
P501 - Dispose of contents/container to an approved waste disposal plant

Other Information
Unknown Acute Toxicity
44.8% of the mixture consists of ingredient(s) of unknown toxicity

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>EINECS</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sesame Oil</td>
<td>8008-74-0</td>
<td>232-370-6</td>
<td>10 - 30*</td>
</tr>
<tr>
<td>GELATIN TYPE A NF</td>
<td>9000-70-8</td>
<td>232-554-6</td>
<td>10 - 30*</td>
</tr>
<tr>
<td>Ferrous Fumarate</td>
<td>141-01-5</td>
<td>205-447-7</td>
<td>10 - 30*</td>
</tr>
<tr>
<td>Norethindrone Acetate</td>
<td>51-98-9</td>
<td>200-132-0</td>
<td>1 - 5*</td>
</tr>
<tr>
<td>Ethinyl Estradiol</td>
<td>57-63-6</td>
<td>200-342-2</td>
<td>0.1 - 1*</td>
</tr>
</tbody>
</table>

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

First aid measures
Eye contact
Rinse immediately with plenty of water and seek medical advice.

Skin Contact
Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation
Remove to fresh air.

Ingestion
Consult a physician if necessary.

Chemical Name
Norethindrone Acetate

Note to physicians
Handle this material following standard medical practices and following the recommendations presented on the Package Insert. Naproxen sodium extended-release tablets are contraindicated in patients with known hypersensitivity to naproxen. Naproxen sodium extended-release tablets should not be given to patients who have experienced asthma, urticarial, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients. Naproxen sodium extended-release tablets are contraindicated for the treatment of per-operative pain in the setting of coronary artery bypass graft (CABG) surgery. This material is contraindicated in women who have the following conditions: Thrombophlebitis or thromboembolic disorders, history of deep vein thrombophlebitis or thromboembolic disorders, cerebrovascular or coronary artery disease (current or history), valvular heart disease with thrombogenic complications, uncontrolled hypertension, diabetes with vascular involvement,
headaches with focal neurological symptoms (such as aura),
major surgery with prolonged immobilization, known or suspected
carcinoma of the breast or personal history of breast cancer,
carcinoma of the endometrium or other known or suspected
estrogen-dependent neoplasia, undiagnosed abnormal genital
bleeding, cholestatic jaundice of pregnancy or jaundice with prior
pill use, hepatic adenomas or carcinomas, or active liver disease,
known or suspected pregnancy, hypersensitivity to component of
the product. Cigarette smoking increases the risk of serious
cardiovascular side effects from oral contraceptive use. This risk
increases with age and with the extent of smoking (in
epidemiologic studies, 15 or more cigarettes per day was
associated with a significantly increased risk) and is quite marked
in women over 35 years of age. Women who use oral
contraceptives should be strongly advised not to smoke. The use
of oral contraceptives is associated with increased risk of several
serious conditions including venous and arterial thrombotic and
thromboembolic events (such as myocardial infarction,
thromboembolism, and stroke), hepatic neoplasia, gallbladder
disease, and hypertension, although the risk of serious morbidity
or mortality is very small in healthy women without underlying risk
factors. The risk of morbidity and mortality increases significantly
in the presence of other underlying risk factors such as certain
inherited thrombophilies hypertension, hyperlipidemias, obesity
and diabetes.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
Fire may produce irritating, corrosive and/or toxic gases.

Explosion data
Sensitivity to Mechanical Impact
Not impact sensitive.

Sensitivity to Static Discharge
Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition
source is a potential dust explosion hazard.

Protective equipment and precautions for firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full
protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions
Use personal protection recommended in Section 8. Do not touch damaged containers or
spilled material unless wearing appropriate protective clothing.

Environmental precautions
See Section 12 for additional ecological information.

Methods for containment
Prevent further leakage or spillage if safe to do so.

Methods for cleaning up
Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp
to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate
containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Advice on safe handling
Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or
smoke when using this product.

Storage Conditions  
Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

Incompatible materials  
None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
<th>Allergan OEL (µg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ferrous Fumarate 141-01-5</td>
<td>TWA: 1 mg/m³ Fe</td>
<td>(vacated) TWA: 1 mg/m³ Fe</td>
<td>TWA: 1 mg/m³ Fe</td>
<td>1000 µg/m³³</td>
</tr>
<tr>
<td>Norethindrone Acetate 51-98-9</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>0.5 µg/m³³</td>
</tr>
<tr>
<td>Ethinyl Estradiol 57-63-6</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>0.01 µg/m³³</td>
</tr>
</tbody>
</table>

NIOSH IDLH  Immediately Dangerous to Life or Health

Other Information
Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

Appropriate engineering controls

Engineering Controls
The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/face protection  
No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.

Skin and body protection  
During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

Respiratory protection  
Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid</td>
</tr>
<tr>
<td>Color</td>
<td>No information available</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information available</td>
</tr>
<tr>
<td>Odor</td>
<td>No information available</td>
</tr>
<tr>
<td>pH</td>
<td>No information available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No information available</td>
</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>No information available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No information available</td>
</tr>
</tbody>
</table>
Evaporation rate: No information available
Flammability (solid, gas): No information available
Flammability Limit in Air:
- Upper flammability limit: No information available
- Lower flammability limit: No information available
Vapor pressure: No information available
Vapor density: No information available
Specific Gravity: No information available
Water solubility: No information available
Solubility in other solvents: No information available
Partition coefficient: No information available
Autoignition temperature: No information available
Decomposition temperature: No information available
Explosive properties: No information available
Oxidizing properties: No information available

Other Information
Molecular weight: No information available
VOC Content (%): No information available
Density: No information available
Bulk density: No information available

10. STABILITY AND REACTIVITY

Reactivity
Not defined As Reactive substance

Chemical stability
Stable under normal conditions.

Possibility of Hazardous Reactions
None under normal processing.

Conditions to avoid
Aerosol formation.

Incompatible materials
None known based on information supplied.

Hazardous Decomposition Products
None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute toxicity

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Inhalation</th>
<th>Eye contact</th>
<th>Skin Contact</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norethindrone Acetate</td>
<td>Inhalation of airborne dusts generated by this product may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.</td>
<td>Contact of this product with the eyes may cause moderate to severe irritation, redness, and tearing.</td>
<td>Contact with the skin may cause mild irritation, which is alleviated upon rinsing. Prolonged or reaped skin contact may cause dermatitis (dry, red skin).</td>
<td>Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause adverse symptoms. Symptoms of ingestion overexposure may include nausea, vomiting, and diarrhea.</td>
</tr>
</tbody>
</table>

| Ethinyl Estradiol        | Inhalation of airborne dusts generated by this product may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air. | Contact with eyes may cause irritation. | Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. Prolonged contact may cause redness and | If this compound is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT |
breathing fresh air.

irritation. Contact with the skin may cause mild irritation, which is alleviated upon rinsing. Prolonged or reaped skin contact may cause dermatitis (dry, red skin).

INFORMATION. If professional advice is not available, do not induce vomiting. Rinse mouth with water immediately. Victim should drink large quantities of water. If milk is available, victim should drink it after drinking water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

### Chemical Name

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sesame Oil</td>
<td>N/A</td>
<td>&gt; 2 g/kg (Rabbit)</td>
<td>N/A</td>
</tr>
<tr>
<td>Ferrous Fumarate</td>
<td>= 3850 mg/kg (Rat)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Norethindrone Acetate</td>
<td>6 gm/kg (rat)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Ethinyl Estradiol</td>
<td>= 960 mg/kg (Rat)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Germ cell mutagenicity</th>
<th>Carcinogenicity</th>
<th>Reproductive toxicity</th>
<th>Effects on or via lactation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norethindrone Acetate</td>
<td>Not mutagenic in the standard battery of tests.</td>
<td>Suspected human carcinogen.</td>
<td>May cause irregular vaginal bleeding, decreased libido, and changes in cervical erosion and secretions.</td>
<td>Small amounts of progestin pass into the breast milk, resulting in steroid levels in infant plasma of 1 to 6% of the levels of maternal plasma. Lower infant weight gain, decreased milk production, and decreased composition of nitrogen and protein content of human milk are associated with norethindrone and estrogenic agents.</td>
</tr>
<tr>
<td>Ethinyl Estradiol</td>
<td>Estradiol induced DNA breaks in hamster renal cells, but not in hepatocytes.</td>
<td>There is sufficient evidence in humans for the carcinogenicity of estradiol and estrone.</td>
<td>Studies in mice show prenatal exposure of ethinylestradiol induces reproductive abnormalities, including polyovular follicles, over-independent vaginal epithelial stratification and cornification. Exposure to ethinylestradiol also is linked to suppression of testicular testosterone levels, lower sperm head counts, lower weights of the testis, epididymis and prostate in rats.</td>
<td>Very small amounts are excreted in milk.</td>
</tr>
</tbody>
</table>

### Chronic toxicity

May cause adverse liver effects. Contains a known or suspected reproductive toxin.

### Target Organ Effects

Eyes, Gastrointestinal tract (GI), liver, Reproductive System, Respiratory system, Skin.

### Numerical measures of toxicity - Product Information
Unknown Acute Toxicity

44.8% of the mixture consists of ingredient(s) of unknown toxicity

The following values are calculated based on chapter 3.1 of the GHS document.

- ATEmix (oral) 12053 mg/kg
- ATEmix (dermal) 4420 mg/kg

### 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

99.8% of the mixture consists of components(s) of unknown hazards to the aquatic environment

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Persistence and degradability</th>
<th>Bioaccumulation</th>
<th>Mobility</th>
<th>Partition coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norethindrone Acetate 51-98-9</td>
<td>No information available</td>
<td>No information available</td>
<td>No information available</td>
<td>N/A</td>
</tr>
<tr>
<td>Ethinyl Estradiol 57-63-6</td>
<td>NOT READILY BIODEGRADABLE</td>
<td>No information available</td>
<td>Mobility in soil</td>
<td>3.67</td>
</tr>
</tbody>
</table>

Other adverse effects

No information available

### 13. DISPOSAL CONSIDERATIONS

#### Waste treatment methods

**Disposal of wastes**

Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated packaging**

Do not reuse container. Dispose of contents/containers in accordance with local regulations.

### 14. TRANSPORT INFORMATION

**DOT**

Not regulated

**TDG**

Not regulated

**ICAO (air)**

Not regulated

**IATA**

Not regulated

**IMDG**

Not regulated

**ADR**

Not regulated

**ADN**

Not regulated

### 15. REGULATORY INFORMATION

**International Inventories**

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSCA</td>
<td>Not Listed</td>
</tr>
<tr>
<td>DSL/NDSL</td>
<td>Listed</td>
</tr>
<tr>
<td>EINECS/ELINCS</td>
<td>Listed</td>
</tr>
</tbody>
</table>

**Legend:**

- **TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory
- **DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List
- **EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
US Federal Regulations

Carcinogenicity

The table below indicates whether each agency has listed any ingredient as a carcinogen. This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B).

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norethindrone Acetate</td>
<td>-</td>
<td>Group 2B</td>
<td>-</td>
<td>X</td>
</tr>
<tr>
<td>Ethinyl Estradiol</td>
<td>-</td>
<td>Group 1</td>
<td>-</td>
<td>X</td>
</tr>
</tbody>
</table>

IARC (International Agency for Research on Cancer)
- Group 1 - Carcinogenic to Humans
- Group 2B - Possibly Carcinogenic to Humans

OSHA (Occupational Safety and Health Administration of the US Department of Labor)
- X - Present

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories
- Acute health hazard: Yes
- Chronic Health Hazard: No
- Fire hazard: No
- Sudden release of pressure hazard: No
- Reactive Hazard: No

CWA (Clean Water Act)
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65
This product contains the following Proposition 65 chemicals:

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>California Proposition 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norethindrone Acetate - 51-98-9</td>
<td>Developmental</td>
</tr>
<tr>
<td>Ethinyl Estradiol - 57-63-6</td>
<td>Carcinogen Developmental</td>
</tr>
</tbody>
</table>

U.S. State Right-to-Know Regulations

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ferrous Fumarate</td>
<td>-</td>
<td>-</td>
<td>X</td>
</tr>
<tr>
<td>141-01-5</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Ethinyl Estradiol</td>
<td>-</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>57-63-6</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Revision Date: 02-Oct-2018
Revision Note: No information available

Disclaimer
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End of Safety Data Sheet