1. Identification

Product identifier Ethinyl Estradiol

Other means of identification
- Catalog number: 1260001
- Chemical name: 19-Norpregna-1,3,5(10)-triene-20-yn-3,17-diol, (17alpha)-

Recommended use: Specified quality tests and assay use only.

Recommended restrictions: Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

- Manufacturer: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway, Rockville, MD 20852-1790
- Website: www.usp.org
- E-mail: RSTECH@usp.org
- Telephone: RS Technical Services 301-816-8129
- Emergency phone number: CHEMTREC within US & Canada 1-800-424-9300, CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards:
- Acute toxicity, oral: Category 4
- Carcinogenicity: Category 1
- Reproductive toxicity: Category 1

Environmental hazards: Not classified.

OSHA defined hazards: Not classified.

Label elements

- Signal word: Danger
- Hazard statement: Harmful if swallowed. May cause cancer. May damage fertility or the unborn child.
- Precautionary statement:
  - Prevention: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection. Wash thoroughly after handling.
  - Response: If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If exposed or concerned: Get medical advice/attention.
  - Storage: Store locked up.
  - Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC): None known.

Supplemental information: None.

3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethinyl Estradiol</td>
<td></td>
<td>57-63-6</td>
<td>100</td>
</tr>
</tbody>
</table>
4. First-aid measures

Inhalation
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Skin contact
Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact
Rinse with water. Get medical attention if irritation develops and persists.

Ingestion
Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Get medical advice/attention if you feel unwell.

Most important symptoms/effects, acute and delayed
Prolonged exposure may cause chronic effects.

Indication of immediate medical attention and special treatment needed
Provide general supportive measures and treat symptomatically. Administer charcoal as a slurry. Acute poisoning should be managed with anti-emetic medication and/or intravenous fluids for rehydration if vomiting is excessive. Support respiratory and cardiovascular function.

[IPCS-InChem 2010; Meditext 2010]

5. Fire-fighting measures

Suitable extinguishing media
Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters
Wear suitable protective equipment.

Fire fighting equipment/instructions
Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards
No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up
For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. Wash spill site.

Environmental precautions
Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling
Use of a designated area is recommended for handling of potent materials. As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.

Conditions for safe storage, including any incompatibilities
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethinyl Estradiol (CAS 57-63-6)</td>
<td>TWA</td>
<td>0.02 micrograms/m3</td>
</tr>
</tbody>
</table>

Biological limit values
No biological exposure limits noted for the ingredient(s).
Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Individual protection measures, such as personal protective equipment

**Eye/face protection**
Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

**Skin protection**
Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

**Hand protection**

**Other**
For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.

**Respiratory protection**
Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

**Thermal hazards**
Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations**
Handle in accordance with good industrial hygiene and safety practice.

### 9. Physical and chemical properties

**Appearance**

- **Physical state**: Solid.
- **Form**: Crystalline powder.
- **Color**: White. Off-white.
- **Odor**: Odorless.
- **Odor threshold**: Not available.
- **pH**: Not available.
- **Melting point/freezing point**: 356 - 366.8 °F (180 - 186 °C)
- **Initial boiling point and boiling range**: Not available.
- **Flash point**: Not available.
- **Evaporation rate**: Not available.
- **Flammability (solid, gas)**: Not available.

**Upper/lower flammability or explosive limits**

- **Flammability limit - lower (%)**: Not available.
- **Flammability limit - upper (%)**: Not available.
- **Explosive limit - lower (%)**: Not available.
- **Explosive limit - upper (%)**: Not available.

**Vapor pressure**: < 0.0000001 kPa at 25 °C

**Vapor density**: Not available.

**Relative density**: Not available.

**Solubility(ies)**

- **Solubility (water)**: Insoluble.
- **Solubility (other)**: Soluble in ethanol, in chloroform, in acetone, in dioxane, in diethyl ether, and in solutions of fixed alkali hydroxides.

**Partition coefficient (n-octanol/water)**

- **3.67**

**Auto-ignition temperature**: 914 °F (490 °C)

**Decomposition temperature**: Not available.
Viscosity
Not available.

Other information
Chemical family
Steroid.
Molecular formula
C20H24O2
Molecular weight
296.4

10. Stability and reactivity
Reactivity
The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability
Material is stable under normal conditions.
Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.
Conditions to avoid
Contact with incompatible materials.
Incompatible materials
Oxidizing agents. Metals.
Hazardous decomposition products
Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information
Information on likely routes of exposure
Inhalation
Knowledge about health hazard is incomplete.
Skin contact
Based on information from therapeutic use, this material may cause: Endocrine effects.
Eye contact
Knowledge about health hazard is incomplete.
Ingestion
Harmful if swallowed. Based on information from therapeutic use, this material may cause: Endocrine effects.

Symptoms related to the physical, chemical, and toxicological characteristics

Information on toxicological effects
Acute toxicity
Harmful if swallowed.

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethinyl Estradiol (CAS 57-63-6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral LD50</td>
<td>Mouse</td>
<td>2500 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>950 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1200 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>960 mg/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation
Knowledge about health hazard is incomplete.
Serious eye damage/eye irritation
Knowledge about health hazard is incomplete.

Respiratory or skin sensitization
Respiratory sensitization
Knowledge about health hazard is incomplete.
Skin sensitization
Knowledge about health hazard is incomplete.
Germs cell mutagenicity
Knowledge about mutagenicity is incomplete.
Results for genotoxicity and mutagenicity studies were mixed.
Carcinogenicity
May cause cancer. May cause cancer.
Long term use of estrogens in humans has shown an increased risk of endometrial, breast and ovarian cancer. In certain animal specials, long term continuous administration of estrogens increased the frequency of cancer of the breast, cervix, vagina, pancreas, testis, uterus and liver.

IARC Monographs. Overall Evaluation of Carcinogenicity
Ethinyl Estradiol (CAS 57-63-6) 1 Carcinogenic to humans.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not regulated.
US. National Toxicology Program (NTP) Report on Carcinogens
Ethinyl Estradiol (CAS 57-63-6) Known To Be Human Carcinogen.

Reproductive toxicity
May damage fertility or the unborn child.
Studies suggest an association between congenital malformations in the fetus and maternal use of some estrogens during pregnancy.

Specific target organ toxicity - single exposure
Knowledge about health hazard is incomplete.
Specific target organ toxicity - repeated exposure
Knowledge about health hazard is incomplete.

Aspiration hazard
Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity

<table>
<thead>
<tr>
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<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethinyl Estradiol (CAS 57-63-6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aquatic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crustacea</td>
<td>EC50</td>
<td>Daphnia magna 5.7 mg/l, 48 hours</td>
</tr>
<tr>
<td>Fish</td>
<td>LC50</td>
<td>Oncorhynchus mykiss (reported as Salmo gairdneri) 1.6 mg/l, 96 hours</td>
</tr>
</tbody>
</table>

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulative potential

| Octanol/water partition coefficient log Kow | 3.67 |

Mobility in soil
No data available.

Other adverse effects
No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions
Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations
Dispose in accordance with all applicable regulations.

Hazardous waste code
The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products
Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging
Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

<table>
<thead>
<tr>
<th>UN number</th>
<th>UN3077</th>
</tr>
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<tbody>
<tr>
<td>UN proper shipping name</td>
<td>Environmentally hazardous substances, solid, n.o.s. (Ethinyl Estradiol)</td>
</tr>
<tr>
<td>Transport hazard class(es)</td>
<td>9</td>
</tr>
<tr>
<td>Class</td>
<td>9</td>
</tr>
<tr>
<td>Subsidiary risk</td>
<td>-</td>
</tr>
<tr>
<td>Packing group</td>
<td>III</td>
</tr>
<tr>
<td>Packaging exceptions</td>
<td>E1</td>
</tr>
<tr>
<td>Packaging non bulk</td>
<td>213</td>
</tr>
<tr>
<td>Packaging bulk</td>
<td>240</td>
</tr>
</tbody>
</table>

IATA

<table>
<thead>
<tr>
<th>UN number</th>
<th>UN3077</th>
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<tbody>
<tr>
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</tr>
<tr>
<td>Subsidiary risk</td>
<td>-</td>
</tr>
<tr>
<td>Packing group</td>
<td>III</td>
</tr>
<tr>
<td>Other information</td>
<td>Allowed with restrictions.</td>
</tr>
<tr>
<td>Passenger and cargo aircraft</td>
<td>Allowed with restrictions.</td>
</tr>
<tr>
<td>Cargo aircraft only</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</td>
<td></td>
</tr>
</tbody>
</table>
General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations
This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

- TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) Not regulated.
- CERCLA Hazardous Substance List (40 CFR 302.4) Not listed.
- SARA 304 Emergency release notification Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

<table>
<thead>
<tr>
<th>Hazard categories</th>
<th>Immediate Hazard</th>
<th>Delayed Hazard</th>
<th>Fire Hazard</th>
<th>Pressure Hazard</th>
<th>Reactivity Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARA 302 Extremely hazardous substance</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>SARA 311/312 Hazardous chemical</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SARA 313 (TRI reporting)</td>
<td>Not regulated.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Other federal regulations

- Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List Not regulated.
- Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) Not regulated.
- Safe Drinking Water Act (SDWA) Contaminate candidate list

US state regulations

- US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100) Not listed.
- US. Massachusetts RTK - Substance List Ethinyl Estradiol (CAS 57-63-6)
- US. New Jersey Worker and Community Right-to-Know Act Not listed.
- US. Pennsylvania RTK - Hazardous Substances Ethinyl Estradiol (CAS 57-63-6)
- US. Pennsylvania Worker and Community Right-to-Know Law Ethinyl Estradiol (CAS 57-63-6)
- US. Rhode Island RTK Not regulated.
- US. California Proposition 65 WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

### US - California Proposition 65 - CRT: Listed date/Developmental toxin

Ethinyl Estradiol (CAS 57-63-6) Listed: April 1, 1990

**International Inventories**

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AiCS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSSL)</td>
<td>Yes</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>Yes</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s).

*A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

### 16. Other information, including date of preparation or last revision

- **Issue date**: 06-28-2010
- **Revision date**: 07-29-2016
- **Version #**: 03

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