SAFETY DATA SHEET

1. Identification

Product identifier  Ethinyl Estradiol

Other means of identification

- Catalog number: 1260001
- CAS number: 57-63-6
- Chemical name: 19-Norpregna-1,3,5(10)-trien-20-yne-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, United States
- Website: www.usp.org
- Telephone: RS Technical Services 301-816-8129
- E-mail: RSTECH@usp.org
- 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: 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.
  - Prevention: If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If exposed or concerned: Get medical advice/attention.
  - Response: Store locked up.
  - Storage: Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC)  This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.

Supplemental information  Highly potent pharmacologically active material.
3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethinyl Estradiol</td>
<td>57-63-6</td>
<td></td>
<td></td>
<td></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. Remove contaminated clothing. Get medical attention if irritation develops and persists.

**Eye contact**
Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

**Ingestion**
If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. 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**
Endocrine system effects. Highly potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

**Indication of immediate medical attention and special treatment needed**
Provide general supportive measures and treat symptomatically.

**General information**
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

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

**Unsuitable extinguishing media**
None known.

**Specific hazards arising from the chemical**
Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

**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. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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.

**Methods and materials for containment and cleaning up**
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. For waste disposal, see section 13 of the SDS.

**Environmental precautions**
Avoid discharge into drains, water courses or onto the ground.
7. Handling and storage

Precautions for safe handling
Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. 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. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

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
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

<table>
<thead>
<tr>
<th>Material Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TWA 0.01 micrograms/m3</td>
<td></td>
</tr>
</tbody>
</table>

Biological limit values
No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls
No open handling. For laboratory operations, conduct powder handling operations in an isolator or equivalent. Put powder into solution or a tightly capped container prior to removal from containment. Isolator should be equipped with bag out ports or transfer chamber. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection
Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection
Hand protection
Wear double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other
Train employees in proper gowning and degowning practices. Wear disposable laboratory coat and disposable sleeve covers appropriate to the task, two pairs of gloves, and safety glasses with side shields. An anteroom or transition area is recommended for gowning and degowning. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or outdoors.

Respiratory protection
Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards
Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations
Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance descriptions are general information and not specific to any USP lot.

Physical state
Solid.

Form
Crystalline powder.

Color
White. Light yellow.

Odor
Odorless.

Odor threshold
Not available.

pH
Not available.
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting point/freezing point</td>
<td>357.8 - 365 °F (181 - 185 °C)</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits</td>
<td></td>
</tr>
<tr>
<td>Flammability limit - lower</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flammability limit - upper</td>
<td>Not available.</td>
</tr>
<tr>
<td>Explosive limit - lower (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Explosive limit - upper (%)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>&lt; 0.0000001 kPa at 25 °C</td>
</tr>
<tr>
<td>Vapor density</td>
<td>Not available.</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not available.</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Solubility (water)</td>
<td>Insoluble.</td>
</tr>
<tr>
<td>Solubility (other)</td>
<td>Chloroform: Soluble.</td>
</tr>
<tr>
<td></td>
<td>Acetone: Soluble.</td>
</tr>
<tr>
<td></td>
<td>Dioxane: Soluble.</td>
</tr>
<tr>
<td></td>
<td>Diethyl ether: Soluble.</td>
</tr>
<tr>
<td></td>
<td>Ethanol: Soluble.</td>
</tr>
<tr>
<td>Partition coefficient (n-octanol/water)</td>
<td>3.67</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>914 °F (490 °C)</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>Not available.</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not available.</td>
</tr>
<tr>
<td>Other information</td>
<td></td>
</tr>
<tr>
<td>Chemical family</td>
<td>Steroid.</td>
</tr>
<tr>
<td>Dust explosion properties</td>
<td></td>
</tr>
<tr>
<td>St class</td>
<td>2</td>
</tr>
<tr>
<td>Minimum ignition energy (MIE) - dust cloud</td>
<td>&lt; 3 mJ</td>
</tr>
<tr>
<td>Molecular formula</td>
<td>C20H24O2</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>296.4</td>
</tr>
</tbody>
</table>

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.
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: 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</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Mouse</td>
<td>1737 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>1200 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>950 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
Knowledge about health hazard is incomplete.

Respiratory sensitization
Knowledge about health hazard is incomplete.

Skin sensitization
Knowledge about health hazard is incomplete.

Germ cell mutagenicity
Knowledge about mutagenicity is incomplete.

Mutagenicity

Ames test
Result: Negative.

Chromosome aberration
Result: Positive.

Micronucleus test
Result: Positive.

Sister chromatid exchange
Result: Positive.

Carcinogenicity
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 1910.1001-1052)
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.

Further information
Highly potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
12. Ecological information

<table>
<thead>
<tr>
<th>Ecotoxicity</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic</td>
<td>Daphnia magna</td>
<td>EC50</td>
</tr>
<tr>
<td>Crustacea</td>
<td>Oncorhynchus mykiss (reported as Salmo gairdneri)</td>
<td>LC50</td>
</tr>
</tbody>
</table>

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

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.

14. Transport information

DOT
UN number UN3077
UN proper shipping name Environmentally hazardous substances, solid, n.o.s. (Ethinyl Estradiol)
Transport hazard class(es)
Class 9
Subsidiary risk -
Packing group III
Packaging exceptions E1
Packaging non bulk 213
Packaging bulk 240

IATA
UN number UN3077
UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (Ethinyl Estradiol)
Transport hazard class(es)
Class 9
Subsidiary risk -
Packing group III
Other information
Passenger and cargo aircraft Allowed with restrictions.
Cargo aircraft only Allowed with restrictions.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.
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.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)
Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical

Yes

Classified hazard categories
Combustible dust
Acute toxicity (any route of exposure)
Carcinogenicity
Reproductive toxicity

SARA 313 (TRI reporting)
Not regulated.

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

California Proposition 65
WARNING: This product can expose you to Ethinyl Estradiol, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California Proposition 65 - CRT: Listed date/Carcinogenic substance
Ethinyl Estradiol (CAS 57-63-6) Listed: January 1, 1988

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 (NDSL)</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Material name: Ethinyl Estradiol
<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<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>Taiwan</td>
<td>Taiwan Chemical Substance Inventory (TCSI)</td>
<td>Yes</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 | 10-02-2019 |
| Version # | 04 |

Further information

Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

Disclaimer

USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.