1. Identification

Product identifier: Ethinyl Estradiol Related Compound B

Other means of identification:
- Catalog number: 1260023
- Chemical name: 19-Nor-17alpha-pregna-1,3,5(10),9(11)-tetraen-20-yne-3,17-diol monohydrate

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
- Telephone: RS Technical Services 301-816-8129
- Website: www.usp.org
- 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:
- Carcinogenicity: Category 1
- Reproductive toxicity: Category 1

Environmental hazards: Not classified.

OSHA defined hazards: Not classified.

Label elements

- Signal word: Danger
- Hazard statement: 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.
  - Response: 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.

3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Chemical name: Ethinyl Estradiol Related Compound B</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
</table>

Material name: Ethinyl Estradiol Related Compound B

1260023  Version #: 04  Revision date: 11-09-2017  Issue date: 06-28-2010
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 ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed: Pharmaceutical related compound of unknown potency. It is not known if occupational exposure 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: Dry chemical or CO2. Foam. 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: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use water spray to cool unopened containers.

Specific methods:

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. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment. For personal protection, see section 8 of the SDS.

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

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

7. Handling and storage

Precautions for safe handling: 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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential. Cover all containers for solutions and slurries while being transferred. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). No open handling.

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: No exposure limits noted for ingredient(s).

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

Appropriate engineering controls: 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. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). No open handling.

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 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. Consider double gloves.

Other
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 out-of-doors. Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task.

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

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. Pharmacological effects may be seen with occupational exposure.

9. Physical and chemical properties

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

Physical state
Solid.

Form
Powder.

Color
White. Yellow.

Odor
Not available.

Odor threshold
Not available.

pH
Not available.

Melting point/freezing point
357.98 - 359.42 °F (181.1 - 181.9 °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
Not available.

Vapor density
Not available.

Relative density
Not available.

Solubility(ies)

Solubility (water)
Not available.

Auto-ignition temperature
Not available.

Decomposition temperature
Not available.

Viscosity
Not available.

Other information

Chemical family
Steroid.

Molecular formula
C20H22O2 . H20

Molecular weight
312.39

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
None known.

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**
  Knowledge about health hazard is incomplete.

- **Eye contact**
  Knowledge about health hazard is incomplete.

- **Ingestion**
  Knowledge about health hazard is incomplete.

**Symptoms related to the physical, chemical, and toxicological characteristics**


Information on toxicological effects

- **Acute toxicity**
  Not known.

- **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.

- **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**
    Not listed.

    Not regulated.

  - **US. National Toxicology Program (NTP) Report on Carcinogens**
    Not listed.

- **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**
    Pharmaceutical related compound of unknown potency. It is not known if occupational exposure may cause physiological effects.

12. Ecological information

- **Ecotoxicity**
  The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

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

- **Bioaccumulative potential**
  No data available.

- **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
Not regulated as dangerous goods.

IATA
Not regulated as dangerous goods.

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 1910.1001-1050)
Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - No
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical
Yes

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)
Not regulated.

US state regulations
This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

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>No</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 (NDLS)</td>
<td>No</td>
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<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
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<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
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<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
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<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
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<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
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<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
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<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
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<tr>
<td>Country(s) or region</td>
<td>Inventory name</td>
<td>On inventory (yes/no)*</td>
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<tr>
<td>---------------------------</td>
<td>----------------------------------------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</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**: 11-09-2017  
**Version #**: 04  
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