

## 1. Identification

Product identifier	Ethynodiol Diacetate		
<b>Other means of identification</b>			
Catalog number	1268003		
Chemical name	19-Norpregn-4-en-20-yne-3,17-diol, diacetate, (3beta, 17alpha)-		
Synonym(s)	Etynodiol acetate		
Recommended use	Specified quality tests and assay use only.		
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.		
<b>Manufacturer/Importer/Supplier/Distributor information</b>			
Company name	U. S. Pharmacopeia		
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 US		
Telephone	RS Technical Services	301-816-8129	
Website	www.usp.org		
E-mail	RSTECH@usp.org		
Emergency phone number	CHEMTRAC within US & Canada CHEMTRAC outside US & Canada	1-800-424-9300 +1 703-527-3887	

## 2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Carcinogenicity	Category 2
	Reproductive toxicity	Category 1
OSHA hazard(s)	Not classified.	
Label elements		

Signal word	Danger
Hazard statement	Suspected of causing cancer. May damage fertility or the unborn child.
<b>Precautionary statement</b>	
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.
Hazard(s) not otherwise classified (HNOC)	Not classified.

## 3. Composition/information on ingredients

### Substance

### Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Ethynodiol Diacetate	Etnodiol acetate	297-76-7	100

## 4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
------------	---------------------------------------------------------------------

<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Most important symptoms/effects, acute and delayed</b>	Uterine cramps. Gastrointestinal disturbances.
<b>Indication of immediate medical attention and special treatment needed</b>	Progestins: Single acute doses will seldom result in toxicity. Supportive treatment is adequate in most situations. For chronic toxicity, obtain a baseline CBC, hepatic and renal function tests, and treat symptomatically.
<b>General information</b>	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

<b>Suitable extinguishing media</b>	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO <sub>2</sub> .
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire-fighting equipment/instructions</b>	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.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	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.
<b>Methods and materials for containment and cleaning up</b>	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. Clean surface thoroughly to remove residual contamination.

## 7. Handling and storage

<b>Precautions for safe handling</b>	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.
<b>Conditions for safe storage, including any incompatibilities</b>	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

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Exposure guidelines</b>	No exposure standards allocated.
<b>Appropriate engineering controls</b>	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. Avoid any open handling of this material, particularly for grinding, crushing, weighing, or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.

### Individual protection measures, such as personal protective equipment

<b>Eye/face protection</b>	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.
----------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<b>Skin protection</b>	
<b>Hand protection</b>	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.
<b>Other</b>	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.
<b>Respiratory protection</b>	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).
<b>Thermal hazards</b>	Not available.
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

<b>Appearance</b>	White or off-white crystalline powder.
<b>Physical state</b>	Solid.
<b>Form</b>	Powder.
<b>Odor</b>	Odorless.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Approximately 126 - 132 °C
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	< 0.0000001 kPa at 25 °C
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility in water</b>	Insoluble.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Steroid.
<b>Molecular formula</b>	C <sub>24</sub> H <sub>32</sub> O <sub>4</sub>
<b>Molecular weight</b>	384.51
<b>Solubility (other)</b>	Very soluble in chloroform; freely soluble in ether; soluble in alcohol.

## 10. Stability and reactivity

<b>Reactivity</b>	No reactivity hazards known.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	None known.

<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Ingestion</b>	Based on available data, the classification criteria are not met.
<b>Inhalation</b>	Due to lack of data the classification is not possible.
<b>Skin contact</b>	Due to lack of data the classification is not possible.
<b>Eye contact</b>	Due to lack of data the classification is not possible.
<b>Symptoms related to the physical, chemical, and toxicological characteristics</b>	For progestins: Abnormal uterine bleeding. Breast pain or tenderness. Unexpected or increased flow of breast milk. Hot flashes. Loss of sexual desires. Dry mouth. Unusual thirst. Frequent urination. Abdominal pain. Cramping. Nausea. Loss of appetite. Dizziness. Headache. Mood changes. Insomnia. Unusual tiredness or weakness. Swelling in ankles or feet. Unusual or rapid weight gain. Skin rash. Acne. Loss or gain of hair. Brown spots on skin.
<b>Delayed and immediate effects of exposure</b>	For progestins: Hepatitis. Porphyria. Blood clots. Jaundice. Cancer. Menstrual abnormalities.
<b>Medical conditions aggravated by exposure</b>	For progestins: Breast cancer. Uterine cancer. Abnormal vaginal bleeding. Kidney impairment. Liver impairment. Heart disease. Diabetes. Epilepsy. Migraine. Thrombosis. Arterial disease. Depression. Hypertension. Porphyria.

### Acute toxicity

Product	Species	Test Results
Ethynodiol Diacetate (CAS 297-76-7)		
<i>Oral</i>		
LD50	Mouse	3.9 g/kg
	Rat	> 5 g/kg
<b>Skin corrosion/irritation</b>		Due to lack of data the classification is not possible.
<b>Serious eye damage/eye irritation</b>		Due to lack of data the classification is not possible.
<b>Respiratory sensitization</b>		Due to lack of data the classification is not possible.
<b>Skin sensitization</b>		Due to lack of data the classification is not possible.
<b>Germ cell mutagenicity</b>		Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.
<b>Mutagenicity</b>		
Sex-linked recessive lethal mutation assay (Drosophila)		
Result: Negative.		
<b>Carcinogenicity</b>		Suspected of causing cancer. IARC: Group 2B; Possibly carcinogenic to humans.
Tumorigenicity study		
Result: Increased incidence of benign mammary liver tumors and mammary tumors in castrated males.		
Species: Mouse		
Tumorigenicity study		
Result: Increased incidence of benign mammary tumors in males.		
Species: Rat		
<b>Reproductive toxicity</b>		May damage fertility or the unborn child. For progestins: Exposure during early pregnancy may lead to chromosomal abnormalities and congenital malformations, including genital abnormalities.
<b>Specific target organ toxicity - single exposure</b>		Due to lack of data the classification is not possible.
<b>Specific target organ toxicity - repeated exposure</b>		Due to lack of data the classification is not possible.
<b>Aspiration hazard</b>		Based on available data, the classification criteria are not met.

## 12. Ecological information

<b>Ecotoxicity</b>	No ecotoxicity data noted for the ingredient(s).
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulative potential</b>	Not available.
<b>Mobility in soil</b>	Not available.

**Other adverse effects** Not available.

## 13. Disposal considerations

<b>Disposal instructions</b>	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.
<b>Local disposal regulations</b>	Not available.
<b>Hazardous waste code</b>	Not available.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. 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).
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### DOT

Not regulated as a hazardous material by DOT.

### IATA

Not regulated as a dangerous good.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** No information available.

## 15. Regulatory information

**US federal regulations** CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

### 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** No

**SARA 311/312 Hazardous chemical** No

### Other federal regulations

**Safe Drinking Water Act (SDWA)** Not regulated.

**Food and Drug Administration (FDA)** Not regulated.

### US state regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

### International Inventories

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

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

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

<b>Issue date</b>	07-01-2007
<b>Revision date</b>	06-04-2014
<b>Version #</b>	02
<b>Further information</b>	Not available.
<b>Disclaimer</b>	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.
<b>Revision Information</b>	This document has undergone significant changes and should be reviewed in its entirety.