



Conjugated Estrogen Concentrate Solution

Preparation Date 08-Jan-2007

Revision Date 31-Mar-2008

Revision Number 2

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name	Conjugated Estrogen Concentrate Solution
Common Name	Not available
Chemical Name	Not applicable
Synonyms	Premarin, Preserved Condensed Urine Desiccate
Product Use	Pharmaceutical product
Classification	Estrogen Product

Supplier	Wyeth P.O. Box 8299 Philadelphia, PA 19101 USA. Telephone: 1-610-688-4400
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Emergency Telephone Number	Chemtrec USA, Puerto Rico, Canada 1-800-424-9300 Chemtrec International 1-703-527-3887
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2. HAZARDS IDENTIFICATION

Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance Liquid	Physical State Liquid	Odor Distinct odor
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Potential Physical Hazards None known

Potential Health Effects

Eyes	May cause mechanical eye irritation.
Skin	Not available
Inhalation	Not available
Ingestion	The most common effects may include vaginal bleeding irregularities, change in menstrual flow, breast changes (tenderness, pain, enlargement, secretion, lumps), vaginal secretion, vaginal yeast infections, changes in reproductive organs, skin rash, joint pain, diarrhea, dizziness, fatigue and stomach/abdominal cramps/bloating. Increased risks of endometrial cancer, myocardial infarction, pulmonary emboli, deep vein thrombosis, coronary heart disease, stroke, venous thromboembolism, dementia, gallbladder disease, headache and mental depression, colitis, central nervous system effects.

May impair fertility. May cause harm to the unborn child. Excreted in breast milk. May cause cancer.

Therapeutic Target Organ(s) Reproductive organs, Bone

Listed by NTP and IARC Not listed by OSHA

Potential Environmental Effects See Section 12.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Congugated Estrogens	12126-59-9	1.5-2.0%
Water	7732-18-5	>1%
Sodium Acetate Trihydrate	6131-90-4	>1%

4. FIRST AID MEASURES

Eye Contact	In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.
Skin Contact	Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
Inhalation	Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.
Ingestion	If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Flammable Properties	None known.
Extinguishing Media	
Suitable Extinguishing Media	Use water spray, foam, dry chemical or carbon dioxide.
Unsuitable Extinguishing Media	Do NOT use water jet.
Fire Fighting	Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.
Hazardous Combustion Products	Carbon oxides, nitrogen oxides.
Protective Equipment and Precautions for Firefighters	In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Refer to protective measures listed in Sections 7 and 8.
Environmental Precautions	Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.
Methods for Containment	Not available
Methods for Cleaning up	Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

7. HANDLING AND STORAGE

Handling	For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.
Storage	No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name Congugated Estrogens	Exposure Guideline 0.15 mcg/m ³
Engineering Controls	Apply technical measures to comply with the occupational exposure guideline Fully contained systems with no open handling
Personal Protective Equipment	
Eye/face Protection	Provide eye protection based on risk assessment.
Skin Protection	Wear nitrile or latex gloves. Wear protective garment.
Respiratory Protection	Base respirator selection on a risk assessment.
General Hygiene Considerations	When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.
Other	Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Liquid	Physical State	Liquid
Color	Amber	Odor	Distinct odor
Odor Threshold	Not available		
Molecular Formula	Not available	Molecular Weight	Not available
pH	7.4-7.6		
Specific Gravity	1.02	Water Solubility	Not available
Solubility	Not applicable	Evaporation Rate	Not available
Partition Coefficient (n-octanol/water)	Not available	Vapor Density	17.5 mmHg
Vapor Pressure	Not applicable		
Boiling Point	100°C /212°F	Autoignition Temperature	Not applicable
Flash Point	Not available	Method	None
Melting Point	Not applicable		
Flammability Limits in Air	Upper Not applicable	Lower	Not applicable
Explosion Limits	Upper Not applicable	Lower	Not applicable

10. STABILITY AND REACTIVITY

Chemical Stability	Stable at room temperature.
Conditions to Avoid	No data available
Materials to Avoid	May be incompatible with acids, bases and oxidizers.
Hazardous Decomposition Products	None under normal use.
Possibility of Hazardous Reactions	None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Congugated Estrogens	
LD50 Oral	>5000 mg/kg rats IP 325 mg/kg rats IR 1740 mg/kg mice
Acute Dermal Irritation	Not available
Primary Eye Irritation	Severe irritation effects in rabbits.
Sensitization	Not available

Multiple Dose Toxicity

Congugated Estrogens	
No Toxicologic Effect	See Carcinogenicity
Dose/Species/Study Length:	

Maximum Tolerated Dose (MTD), Oral

Congugated Estrogens	
Carcinogenicity	In certain animal species, long-term continuous administration of estrogens increases the frequency of cancers in the breast, cervix, liver, pancreas, testes, uterus, and vagina. Results of animal studies may not apply to humans because of the general hormonal differences of sex steroids among species.
Genetic Toxicity	No specific mutagenic information available.
Reproductive Toxicity	No data available
Developmental Toxicity	No evidence of teratogenic effects.

Congugated Estrogens	
Target Organ(s) of Toxicity	No data available

12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information

Congugated Estrogens

Mobility	Not available
Biodegradability	Considered to be biodegradable under aerobic conditions.
Stability in Water	Not available
Bioaccumulation	Not available

Ecotoxicity

Congugated Estrogens

Microorganisms	Inhibition > 150 mg carbon/liter
Algae	Not available
Daphnia	Not available
Fish	Not available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations.

14. TRANSPORT INFORMATION

Transport Information This material is not classified as hazardous for transport.

U.S. Department of Transport (DOT)	Not regulated
Canadian Transport of Dangerous Goods (TDG)	Not regulated
International Civil Aviation Organization (ICAO)	Not regulated
International Air Transport Association (IATA)	Not regulated
International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO)	Not regulated
Transport of Dangerous Goods by Rail (RID)	Not regulated
Transport of Dangerous Goods by Road (ADR)	Not regulated
Transportation of Dangerous Goods via Inland Waterways (ADN)	Not regulated

15. REGULATORY INFORMATION

USA

Federal Regulations

OSHA Regulatory Status

This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

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 40n of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazardous Categorization

Acute Health Hazard	No
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

This product does not contain any HAPs.

State Regulations**California Proposition 65**

This product contains the following Proposition 65 chemicals:

Common Name	CAS-No	Type
Congugated Estrogens	12126-59-9	Cancer, Developmental Toxicity

Canada

Not classified

WHMIS Hazard Class

Non-controlled

European Union

In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled.

16. OTHER INFORMATION

Prepared By	Wyeth Department of Environment, Health & Safety
Format	This MSDS was prepared in accordance with ANSI Z400.1-2004.
List of References	Product Package Insert
Revision Summary	Changes to Section 2

Disclaimer:

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