



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 2.1

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
Pfizer Pharmaceuticals Group
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1-212-573-2222

Pfizer Ltd
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Sandwich, Kent
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Ethynodiol Diacetate and Ethinyl Estradiol Tablets

Trade Name: Demulen(R)
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as oral contraceptive.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Corn Starch	9005-25-8	232-679-6	*
Microcrystalline cellulose	9004-34-6	232-674-9	*
Magnesium stearate	557-04-0	209-150-3	*
Ethinyl Estradiol	57-63-6	200-342-2	35 / 50 mcg ***
Ethynodiol Diacetate	297-76-7	206-044-9	1 mg ***

Ingredient	CAS Number	EU EINECS List	%
Calcium Acetate	62-54-4	200-540-9	*
Lactose Monohydrate	64044-51-5	Not listed	*
Povidone	9003-39-8	Not listed	*
Hydrogenated castor oil	8001-78-3	232-292-2	*
FD&C Yellow No. 6; (Sunset yellow)	2783-94-0	220-491-7	*
Dicalcium phosphate	10103-46-5	233-283-6	*
Lactose NF, anhydrous	63-42-3	200-559-2	*
FD & C Blue No. 1	3844-45-9	223-339-8	*

Additional Information: * Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White, Blue and Pink Tablets
Signal Word: DANGER

Statement of Hazard: May be harmful if swallowed.
May cause cancer.
May damage fertility or the unborn child.

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Additional Hazard Information:

Short Term:

Active ingredient may be harmful if swallowed.

Long Term:

Occupational studies have shown that males working with estrogen-like compounds have shown clinical signs of hyperestrogenism including enlarged breasts and milk secretion. Loss of libido, breast tenderness, and changes in sex hormone levels have also occurred. Occupational exposure in females has resulted in menstrual irregularities (breakthrough bleeding, menstrual flow changes, spotting and amenorrhea).

Known Clinical Effects:

Clinical use of estrogens has resulted in breast changes (enlargement, tenderness, and secretion), along with effects on the genitourinary (changes in vaginal bleeding), and GI systems. Effects on the skin, eyes, and CNS have also been reported. The use of oral contraceptives is associated with increased risks of myocardial infarction, thromboembolism, stroke, hepatic neoplasia, and gallbladder disease.

EU Indication of danger:

Carcinogenic: Category 1
Toxic to reproduction: Category 1
Harmful

EU Hazard Symbols:



EU Risk Phrases:

R22 - Harmful if swallowed.
R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Eye Contact:

Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact:

Wash skin with soap and water. If irritation occurs or persists, get medical attention.

Ingestion:

Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation:

Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing Media:

Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products:

May include oxides of carbon.

Fire Fighting Procedures:

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

Fire / Explosion Hazards:

Not applicable

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6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills:	Contain the source of the spill or leak if it is safe to do so. Spills should be handled by vacuuming or wet mopping. Avoid brush sweeping and generation of airborne dust.

7. HANDLING AND STORAGE

General Handling:	If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.
Storage Conditions:	Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Corn Starch

OSHA - Final PELS - TWAs:	= 15 mg/m ³ TWA	total
	= 5 mg/m ³ TWA	
ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA	
Australia TWA	= 10 mg/m ³ TWA	

Microcrystalline cellulose

OSHA - Final PELS - TWAs:	= 15 mg/m ³ TWA	total
	= 5 mg/m ³ TWA	
ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA	
Australia TWA	= 10 mg/m ³ TWA	

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m ³ TWA	except stearates of toxic metals
Australia TWA	= 10 mg/m ³ TWA	

Ethinyl Estradiol

Pfizer OEL TWA-8 Hr:	40 ng/m ³ , Skin
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Ethynodiol Diacetate

Pfizer OEL TWA-8 Hr:	0.25ug/m ³
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The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Analytical Method: Analytical method available for ethinyl estradiol; ethynodiol. Contact Pfizer Inc for further information.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.

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Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Tablets	Color:	White, Blue, Pink
Odor:	Odorless	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

Conditions to Avoid: None known

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Ethinyl Estradiol

Mouse Oral LD50 1737 mg/kg
Rat Oral LD50 1200 mg/kg

Ethynodiol Diacetate

Rat Oral LD 50 > 5000 mg/kg

Povidone

Rat Oral LD50 100 g/kg

Lactose Monohydrate

Rat Oral LD 50 29700 mg/kg

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

FD&C Yellow No. 6; (Sunset yellow)

Rat Oral LD50 > 10,000 mg/kg

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Mouse Oral LD50 > 6,000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Non-irritating

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Ethynodiol Diacetate

7 Year(s) Dog Oral 0.125 mg/kg/day LOEL Reproductive system

10 Year(s) Non-human Primate Oral 5 ug/kg/day LOEL Mammary gland, Endocrine system

10 Year(s) Non-human Primate Oral 5 µg/kg/day NOEL Female reproductive system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Ethinyl Estradiol

Embryo / Fetal Development Mouse No route specified 0.02 mg/kg/day LOEL Embryotoxicity, Not teratogenic

Ethynodiol Diacetate

Embryo / Fetal Development Mouse No route specified 1.0 mg/kg LOEL Teratogenic

Embryo / Fetal Development Rat Subcutaneous 2.0 mg/kg/day NOEL Not Teratogenic

Embryo / Fetal Development Rabbit Subcutaneous 0.05 mg/kg/day NOEL Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Ethinyl Estradiol

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Chromosome Aberration Human Lymphocytes Positive

Sister Chromatid Exchange Human Lymphocytes Positive

Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive

In Vivo Micronucleus Mouse Bone Marrow Positive

Ethynodiol Diacetate

In Vitro Mammalian Cell Mutagenicity Positive

Sex-Linked Recessive Lethal Test *Drosophila* Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Ethinyl Estradiol

80 Week(s) Mouse Oral, in feed 0.07 mg/kg/day LOEL Tumors, Pituitary gland

104 Week(s) Rat No route specified 0.07 mg/kg/day LOEL Malignant tumors, Liver

105 Week(s) Rat Oral, in feed 0.053 mg/kg/day NOEL Not carcinogenic

Ethynodiol Diacetate

Not specified Male Mouse Oral Benign tumors, Liver

Not specified Male Rat Oral Benign tumors, Mammary gland

Carcinogen Status: See below

Ethinyl Estradiol

IARC: Group 1

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NTP: Listed
OSHA: Present

Ethynodiol Diacetate

IARC: Group 2B
OSHA: Present

Povidone

IARC: Group 3

FD & C Blue No. 1

IARC: Group 3

FD&C Yellow No. 6; (Sunset yellow)

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Carcinogenic: Category 1
Toxic to reproduction: Category 1
Harmful

EU Risk Phrases:
R22 - Harmful if swallowed.
R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

EU Safety Phrases:

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S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:

DANGER

May be harmful if swallowed.

May cause cancer.

May damage fertility or the unborn child.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Calcium Acetate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-540-9

Lactose Monohydrate

Australia (AICS):	Present
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Corn Starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6

Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-674-9

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3

Povidone

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Hydrogenated castor oil

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	232-292-2

Ethinyl Estradiol

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California Proposition 65	carcinogen, initial date 1/1/88 developmental toxicity, initial date 4/1/90 (when mixed with Norethisterone)
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	200-342-2
FD&C Yellow No. 6; (Sunset yellow)	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	220-491-7
Dicalcium phosphate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	233-283-6
Lactose NF, anhydrous	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-559-2
FD & C Blue No. 1	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	223-339-8
Ethynodiol Diacetate	
Australia (AICS):	Present
EU EINECS List	206-044-9

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet