# MATERIAL SAFETY DATA SHEET



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

**Pfizer Inc**
**Pfizer Pharmaceuticals Group**
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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: Norethisterone Tablets (5mg)

**Trade Name:** Utovlan
**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 | * |
| Magnesium stearate | 557-04-0 | 209-150-3 | * |
| Norethindrone Acetate | 51-98-9 | 200-132-0 | 3.3 |

| Ingredient | CAS Number | EU EINECS List | % |
|---|---|---|---|
| Lactose Monohydrate | 64044-51-5 | Not listed | * |
| Povidone | 9003-39-8 | Not listed | * |

**Additional Information:** * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** White tablet
**Signal Word:** DANGER

**Statement of Hazard:** Suspected of causing cancer.
May damage fertility or the unborn child.

**Additional Hazard Information:**
**Short Term:** Not acutely toxic (based on components) . May be absorbed through the skin and cause systemic effects.
**Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus. 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:** The most frequently reported adverse effect seen with the use of norethindrone is altered menstruation. Headache, breast tenderness, nausea, and dizziness have also been seen. Androgenic side effects (acne, hirsutism, weight gain) have occurred rarely. Cardiovascular (blood clotting irregularities) and ocular (optic neuritis) effects have also been reported. The use of oral contraceptives is associated with increased risks of myocardial infarction, thromboembolism, stroke, hepatic neoplasia, and gallbladder disease. Clinical use of this drug has caused yellowing of the skin, eyes, and mucous membranes (jaundice) headache depressive mood swelling weight changes

**EU Indication of danger:** Carcinogenic: Category 2
Toxic to reproduction: Category 1

**EU Hazard Symbols:**

**EU Risk Phrases:**

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:** Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder.

**Ingestion:** Get medical attention immediately. 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 determined

## 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:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

**General Handling:** Avoid generating airborne dust. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

**Storage Conditions:** Store away from direct sunlight. Protect from moisture.

**Storage Temperature:** < 25 °C

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Corn Starch**

| | | |
|---|---|---|
| **OSHA - Final PELS - TWAs:** | = 15 mg/m$^3$ TWA<br>= 5 mg/m$^3$ TWA | total |
| **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 | |

**Norethindrone Acetate**

**Pfizer OEL TWA-8 Hr:** 0.8 ug/m$^3$, Skin

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

**Analytical Method:** Analytical method available for Norethindrone Acetate. Contact Pfizer Inc for further information.

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Good general ventilation should be sufficient to control airborne levels.

**Personal Protective Equipment:**

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

**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:** | Tablet | **Color:** | White |
| **Molecular Formula:** | Mixture | **Molecular Weight:** | Mixture |

## 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.
**Conditions to Avoid:** Exposure to sunlight. Exposure to moisture
**Incompatible Materials:** No data available

## 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)**

**Lactose Monohydrate**
Rat Oral LD 50 29700 mg/kg

**Norethindrone Acetate**
Rat Oral LD50 > 5010 mg/kg
Mouse Oral LD50 > 5010 mg/kg

**Magnesium stearate**
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 $mg/m^3$
**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.

**Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))**

**Norethindrone Acetate**
Embryo / Fetal Development Rat No route specified 1 mg/kg/day LOEL Teratogenic
Embryo / Fetal Development Mouse No route specified 0.5 mg/kg/day LOEL Teratogenic
Embryo / Fetal Development Rat No route specified 3.5 mg/kg/day NOAEL Not Teratogenic

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

**Norethindrone Acetate**
Bacterial Mutagenicity (Ames) *Salmonella* Negative
*In Vitro* Chromosome Aberration Human Lymphocytes Positive
*In Vitro* Sister Chromatid Exchange Human Lymphocytes Negative
*In Vivo* Unscheduled DNA Synthesis Rat Hepatocyte Positive
*In Vivo* Direct DNA Damage Mouse Negative

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

**Norethindrone Acetate**
2 Year(s) Male Rat Oral 3-4 mg/kg/day LOEL Malignant tumors, Liver
2 Year(s) Female Rat Oral 3-4 mg/kg/day LOEL Tumors, Female reproductive system
104 Week(s) Male Rat Intramuscular 10 mg/kg/day LOEL Malignant tumors, Mammary gland, Liver, Endocrine system
104 Week(s) Female Rat Intramuscular 10 mg/kg/day LOEL Malignant tumors, Liver, Mammary gland

**Carcinogen Status:** See below

**Povidone**
**IARC:** Group 3

**Norethindrone Acetate**
**IARC:** Group 2B
**NTP:** Listed
**OSHA:** Present

## 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 2
Toxic to reproduction: Category 1

**EU Risk Phrases:**

R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

**EU Safety Phrases:**

S36/37 - Wear suitable protective clothing and gloves.
S45 - In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).
S53 - Avoid exposure - obtain special instructions before use.

**OSHA Label:**
DANGER

Suspected of causing cancer.
May damage fertility or the unborn child.

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**
Class D, Division 2, Subdivision A

**Corn Starch**

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

**Lactose Monohydrate**

| | |
|---|---|
| **Australia (AICS):** | Present |

**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 |

**Norethindrone Acetate**

| | |
|---|---|
| **California Proposition 65** | developmental toxicity, initial date 10/1/91 |
| **Australia (AICS):** | Present |
| **EU EINECS List** | 200-132-0 |

## 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

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

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**End of Safety Data Sheet**