



# MATERIAL SAFETY DATA SHEET

Revision date: 05-Dec-2011

Version: 1.2

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

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-212-573-2222

Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300  
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161  
Emergency telephone number:  
International CHEMTREC (24 hours): +1-703-527-3887

**Material Name: Estradiol / Trimegestone Sugar Coated Tablets**

Trade Name:	TOTELLE
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as oral contraceptive

## 2. HAZARDS IDENTIFICATION

Appearance: Tablets  
Signal Word: DANGER

Statement of Hazard: May cause cancer.  
May damage fertility or the unborn child.

### Additional Hazard Information:

**Short Term:** Dust may be absorbed through the skin and cause systemic effects. May be harmful if swallowed. (based on components) Accidental ingestion may cause effects similar to those seen in clinical use.

**Long Term:** Occupational exposure to components of this mixture has resulted in menstrual irregularities in women and breast changes (enlargement, mammary secretions), loss of libido, and changes in sex hormone levels in men.

**Known Clinical Effects:** The use of oral contraceptives is associated with increased risks of myocardial infarction, thromboembolism, stroke, hepatic neoplasia, and gallbladder disease. The most common adverse effects seen during clinical use of oral contraceptives are menstrual irregularities.

**EU Indication of danger:** Carcinogenic: Category 1  
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.  
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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### 2. HAZARDS IDENTIFICATION

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

**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.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Calcium sulfate	7778-18-9	231-900-3	Not Listed	*
Estradiol	50-28-2	200-023-8	Carc. Cat.1; R45 Repr. Cat.1; R60 Repr. Cat.1; R61 N; R50/53	0.3
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Propylene glycol	57-55-6	200-338-0	Not Listed	*
Starch	9005-25-8	232-679-6	Not Listed	*
Sucrose	57-50-1	200-334-9	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	*
Trimegestone	74513-62-5	Not Listed	Repr. Cat.1; R60/61 Carc. Cat.2; R45 Mut. Cat.3; R68 N, R51/53	0.04-0.08
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Carnauba wax	8015-86-9	232-399-4	Not Listed	*
FD & C Blue No. 2, Aluminum lake	16521-38-3	240-589-3	Not Listed	*
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	*
Pharmaceutical glaze	Not assigned	Not Listed	Not Listed	*
Povidone	9003-39-8	Not Listed	Not Listed	*
Glyceryl oleate	25496-72-4	247-038-6	Not Listed	*

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

For the full text of the R phrases mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

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**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** Not applicable

### 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:** Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, Restrict access to work area. avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**Storage Conditions:** Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Calcium sulfate

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Austria OEL - MAKs	5 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	6 mg/m <sup>3</sup>
Germany (DFG) - MAK	1.5 mg/m <sup>3</sup> respirable fraction 4 mg/m <sup>3</sup> inhalable fraction
Hungary OEL - TWA	6 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Poland OEL - TWA	10.0 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	6 mg/m <sup>3</sup>
Slovenia OEL - TWA	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

#### Estradiol

Pfizer OEL TWA-8 Hr:	0.2 µg/m <sup>3</sup> , Skin
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#### Magnesium stearate

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>

#### Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	2 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Romania OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

#### Propylene glycol

Australia TWA	150 ppm 474 mg/m <sup>3</sup> 10 mg/m <sup>3</sup>
Ireland OEL - TWAs	150 ppm 470 mg/m <sup>3</sup> 10 mg/m <sup>3</sup>
Latvia OEL - TWA	7 mg/m <sup>3</sup>
Lithuania OEL - TWA	7 mg/m <sup>3</sup>

#### Starch

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>

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## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	4.0 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	4 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

### Sucrose

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	10 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

### Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA)	2 mg/m <sup>3</sup>
Australia TWA	2.5 mg/m <sup>3</sup>
Austria OEL - MAKs	2 mg/m <sup>3</sup>
Belgium OEL - TWA	2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	1.0 fiber/cm <sup>3</sup>
	6.0 mg/m <sup>3</sup>
	3.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	2.0 mg/m <sup>3</sup>
	10 mg/m <sup>3</sup>
Denmark OEL - TWA	0.3 fiber/cm <sup>3</sup>
Finland OEL - TWA	0.5 fiber/cm <sup>3</sup>
	5 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	2 mg/m <sup>3</sup>
Hungary OEL - TWA	2 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	0.8 mg/m <sup>3</sup>
Lithuania OEL - TWA	2 mg/m <sup>3</sup>
	1 mg/m <sup>3</sup>
Netherlands OEL - TWA	0.25 mg/m <sup>3</sup>
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
Poland OEL - TWA	4.0 mg/m <sup>3</sup>
	1.0 mg/m <sup>3</sup>
Portugal OEL - TWA	2 mg/m <sup>3</sup>
Romania OEL - TWA	2 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Slovakia OEL - TWA	2 mg/m <sup>3</sup>
	10 mg/m <sup>3</sup>
Slovenia OEL - TWA	2 mg/m <sup>3</sup>
Spain OEL - TWA	2 mg/m <sup>3</sup>
Sweden OEL - TWAs	2 mg/m <sup>3</sup>
	1 mg/m <sup>3</sup>

#### Trimegestone

Pfizer OEL TWA-8 Hr:	0.06µg/m <sup>3</sup>
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#### Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Austria OEL - MAKs	5 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Denmark OEL - TWA	6 mg/m <sup>3</sup>
Estonia OEL - TWA	5 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
	5 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
Latvia OEL - TWA	10 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Poland OEL - TWA	10.0 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Romania OEL - TWA	10 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 mg/m <sup>3</sup>

#### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

#### Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

#### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

#### Hands:

Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.

#### Eyes:

Wear safety glasses or goggles if eye contact is possible.

#### Skin:

Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

#### Respiratory protection:

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.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablet	Color:	Various
Molecular Formula:	Mixture	Molecular Weight:	Mixture

### 10. STABILITY AND REACTIVITY

Chemical Stability:	Stable under normal conditions of use.
Conditions to Avoid:	Fine particles (such as dust and mists) may fuel fires/explosions.
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, except where noted.
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#### Acute Toxicity: (Species, Route, End Point, Dose)

##### Magnesium stearate

Rat	Oral	LD50	> 2000 mg/kg
Rat	Inhalation	LC50	> 2000 mg/m <sup>3</sup>

##### Microcrystalline cellulose

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

##### Povidone

Rat	Oral	LD50	100 g/kg
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##### Sucrose

Rat	Oral	LD50	29.7 g/kg
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##### Talc (non-asbestiform)

Rat	Oral	LD50	> 1600 mg/kg
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##### Propylene glycol

Mouse	Oral	LD50	22,000 mg/kg
Rat	Oral	LD50	20,000 mg/kg
Rabbit	Dermal	LD50	20,800 mg/kg

##### Titanium dioxide

Rat	Oral	LD50	> 7500 mg/kg
Rat	Subcutaneous	LD 50	50 mg/kg

##### Trimegestone

Rat	Oral	LD50	> 2000 mg/kg
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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.
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### 11. TOXICOLOGICAL INFORMATION

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

##### Microcrystalline cellulose

Skin Irritation	Rabbit	Non-irritating
Eye Irritation	Rabbit	Non-irritating

##### Propylene glycol

Skin Irritation	Rabbit	Mild
Eye Irritation	Rabbit	Mild

##### Trimegestone

Skin Sensitization - M & K	Guinea Pig	Negative
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#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Estradiol

90 Day(s)	Rat	Oral	0.003 mg/kg/day	NOAEL	Blood, Female reproductive system, Male reproductive system, Endocrine system, Liver
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#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### Estradiol

Reproductive & Fertility-Females	Rat	Oral	0.003 mg/kg/day	LOAEL	Reproductive toxicity
Embryo / Fetal Development	Rat	Intramuscular	30 mg/kg/day	LOAEL	Fetotoxicity

##### Trimegestone

2 Generation Reproductive Toxicity	Rat	Oral	25 mg/kg/day	NOAEL	Maternal toxicity
2 Generation Reproductive Toxicity	Rabbit	Oral	40 mg/kg/day	LOAEL	Maternal Toxicity, Fetotoxicity

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

##### Estradiol

Sister Chromatid Exchange	Human Lymphocytes	Positive
Micronucleus	Human	Positive
Chromosome Aberration	Human	Negative
In Vivo Direct DNA Damage	Hamster	Positive
In Vivo Micronucleus	Rodent Bone Marrow	Negative

##### Sucrose

Bacterial Mutagenicity (Ames)	Salmonella	Negative
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##### Trimegestone

Bacterial Mutagenicity (Ames)	Salmonella, E. coli	Negative
In Vivo Micronucleus	Mouse	Negative
In Vitro Chromosome Aberration	Human Lymphocytes	Positive
Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Positive at cytotoxic levels

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

##### Estradiol

2 Year(s)	Female Mouse	Oral	0.1 mg/kg	LOEL	Tumors, Mammary gland, Female reproductive system
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### 11. TOXICOLOGICAL INFORMATION

**Carcinogen Status:** See below

#### Estradiol

**IARC:** Group 1 (Carcinogenic to Humans)  
**NTP:** Listed  
**OSHA:** Listed

#### Povidone

**IARC:** Group 3 (Not Classifiable)

#### Talc (non-asbestiform)

**IARC:** Group 3 (Not Classifiable)

#### Titanium dioxide

**IARC:** Group 2B (Possibly Carcinogenic to Humans)  
**OSHA:** Listed

#### Trimegestone

**IARC:** Group 2B (Possibly Carcinogenic to Humans)  
**OSHA:** Present

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided. See Aquatic toxicity data of the active ingredient, below:

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### Estradiol

Fish LC50 96 Hours 2 mg/L

##### Trimegestone

*Daphnia magna* (Water Flea) EC50 48 Hours 17 mg/L

Algae EC50 72 Hours 7.7 mg/L

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

### 13. DISPOSAL CONSIDERATIONS

#### Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

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### 15. REGULATORY INFORMATION

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

**EU Risk Phrases:**  
R45 - May cause cancer.  
R60 - May impair fertility.  
R61 - May cause harm to the unborn child.  
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**EU Safety Phrases:**  
S36/37 - Wear suitable protective clothing and gloves.  
S22 - Do not breathe dust.  
S53 - Avoid exposure - obtain special instructions before use.  
S57 - Use appropriate containment to avoid environmental contamination.

**OSHA Label:**  
DANGER  
May cause cancer.  
May damage fertility or the unborn child.

#### Canada - WHMIS: Classifications

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



#### **Calcium sulfate**

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-900-3

#### **Carnauba wax**

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-399-4

#### **Estradiol**

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### 15. REGULATORY INFORMATION

California Proposition 65	carcinogen initial date 1/1/88
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
	Schedule 5
EU EINECS/ELINCS List	200-023-8
<b>FD &amp; C Blue No. 2, Aluminum lake</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	240-589-3
<b>Lactose NF, monohydrate</b>	
Australia (AICS):	Present
<b>Magnesium stearate</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3
<b>Microcrystalline cellulose</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9
<b>Povidone</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
<b>Propylene glycol</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-338-0
<b>Starch</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6
<b>Sucrose</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9
<b>Talc (non-asbestiform)</b>	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	238-877-9

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### 15. REGULATORY INFORMATION

#### Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5

#### Glyceryl oleate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	247-038-6

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R45 - May cause cancer.  
R60 - May impair fertility.  
R61 - May cause harm to the unborn child.  
R68 - Possible risks of irreversible effects.  
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Reasons for Revision:** Updated Section 3 - Composition / Information on Ingredients. Updated Section 2 - Hazard Identification. Updated Section 15 - Regulatory Information.

**Prepared by:** Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

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**End of Safety Data Sheet**