

SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, European Union CLP EC 1272/2008 and the Global Harmonization Standard

PART I What is the material and what do I need to know in an emergency?

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE

IDENTIFICATION of the SUBSTANCE or PREPARATION:

TRADE NAME (AS LABELED):

PROGESTERONE CAPSULE

CHEMICAL NAME:

For Active Ingredient: Pregn-4-ene-3, 20-dione

CHEMICAL CLASS:

For Active Ingredient: Progestational Steroid

THERAPEUTIC CLASS:

Progesterin Hormone Replacement

RELEVANT USE of the SUBSTANCE:

Human Pharmaceutical

USES ADVISED AGAINST:

Other than Relevant Use

HOW SUPPLIED:

100 mg: Peach Capsule: NDC:0093-5353-01: 100 in 1 bottle;

200 mg Pale Yellow Capsule: NDC:0093-5354-01: 100 in 1 bottle

COMPANY/UNDERTAKING IDENTIFICATION:

U.S. SUPPLIER/MANUFACTURER'S NAME:

TEVA

ADDRESS:

1090 Horsham Road

North Wales, PA 19454

215-591-3000 [08:00 AM --> 05:00 PM]

TEVA/TAPI

Sicor srl-Via Terrazzano

77-20017 Cho (MI), Italy

+39 02 93197 306 [08:00 AM --> 05:00 PM]

BUSINESS PHONE:

EMERGENCY PHONE:

United States/Canada/Puerto Rico: 1-800/424-9300 (Chemtrec) [24-hrs]

International: 01-703-527-3887 (Chemtrec) [24-hours]

EMAIL:

TevaSDSRequest@tevapharm.com

DATE OF PREPARATION: March 17, 2014

DATE OF REVISION: New

ALL WHMIS required information is included in appropriate sections based on the ANSI Z400.1-2010 format. This material has been classified in accordance with the hazard criteria of the CPR and the SDS contains all the information required by the CPR. The material is also classified per all applicable EU Directives through EC 1907: 2006, the European Union CLP EC 1272/2008 and the Global Harmonization Standard.

2. HAZARD IDENTIFICATION

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

EMERGENCY OVERVIEW: Product Description: This product is supplied as odorless capsules which are peach (100 mg) and pale yellow (200 mg). **Health Hazards:** In the workplace, exposure via inhalation and skin contact may cause irritation. Eye contact with drug product can cause mechanical irritation. In men, exposure to female hormones has been associated with testicular atrophy, increased risk of prostate cancer, gynecomastia, loss of libido and potency. As a progesterone-only hormone, this material is possibly carcinogenic in humans. In therapeutic, the most common adverse effects reported include, headaches, breast pain, irregular vaginal bleeding or spotting, stomach or abdominal cramps, nausea, vomiting, hair loss, fluid retention, vaginal yeast infections. Due to the Peanut Oil component, ingestion of this product by persons with peanut allergies may cause sensitization and allergic reactions; reactions have the potential to be severe. These effects may be possible as a result of workplace exposure. Refer to Section 11 (Toxicological Information) for additional information on adverse effects. **Flammability Hazards:** This product requires substantial pre-heating before ignition occurs. When involved in a fire, this product may decompose and produce irritating vapors and toxic compounds (including acrolein, carbon, iron, titanium and nitrogen oxides). **Reactivity Hazards:** This product is not reactive. **Environmental Hazards:** Release of this product to the environment may cause harm to aquatic or terrestrial organisms. **Emergency Recommendations:** Emergency responders must wear personal protective equipment suitable for the situation to which they are responding.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	LABEL ELEMENTS EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements
ACTIVE INGREDIENT				
Progesterone Pregn-4-ene-3, 20-dione	57-83-0	200-350-6	Proprietary	SELF CLASSIFICATION <u>EU 67/548</u> Classification: Reproductive Toxicity Cat. 3, Carcinogenic Cat. 3 Risk Phrase Codes: R62, R64, R40 Hazard Symbols: Xn <u>GHS and EU 1272/2008</u> Classification: Reproductive Toxicity Cat. 2, Carcinogenic Cat. 2 Adverse Effects on or Via Lactation Hazard Codes: H361f, H351, H362 Hazard Symbol/Pictogram: GHS08
EXCIPIENTS				
Black Iron Oxide	1309-33-7	215-166-1	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Gelatin	9000-70-8	232-554-6	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Glycerin	56-81-5	200-289-5	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Lecithin	8002-43-5	232-307-2	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Peanut Oil	8002-03-7	232-296-4	Proprietary	SELF CLASSIFICATION <u>EU 67/548</u> Classification: Irritant Risk Phrase Codes: R43 Hazard Symbols: Xn <u>GHS and EU 1272/2008</u> Classification: Skin Sensitization Cat. 1B Hazard Codes: H317 Hazard Symbol/Pictogram: GHS08
Polyethylene Glycol	25322-68-3	NLP # 500-038-2	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Polyvinyl Acetate Phthalate	34481-48-6	Not Listed	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Propylene Glycol	57-55-6	200-338-0	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Red Iron Oxide (100 mg only)	1309-37-1	215-168-2	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Titanium Dioxide	13463-67-7	236-675-7	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.
Yellow Iron Oxide (200 mg only)	20344-49-4	Not Listed	Proprietary	EU 67/548: Classification: Not applicable. GHS & EU 1272/2008: Classification: Not applicable.

See Section 16 for full classification information of this product.

PART II What should I do if a hazardous situation occurs?

4. FIRST-AID MEASURES

DESCRIPTION OF FIRST AID MEASURES: Contaminated individuals must be taken for medical attention if any adverse effects occur. Remove contaminated clothing and shoes. Take a copy of this SDS to health professional with victim. Wash clothing and thoroughly clean shoes before reuse.

Skin Exposure: If skin contact with this product occurs, flush affected area with water. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effects occur after flushing.

Inhalation: If dusts are inhaled, remove victim to fresh air. The contaminated individual must seek medical attention if any adverse effects occur.

Eye Exposure: If dusts from product enter the eyes, open contaminated individual's eyes while under gently running water. Use sufficient force to open eyelids. Have contaminated individual "roll" eyes. Minimum flushing is for 20 minutes. Contaminated individual must seek medical attention if adverse effect occurs or continues after flushing.

Ingestion: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, seek immediate medical attention. If alert, victim should drink up to three glasses of water. Do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain emergency medical attention.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: In therapeutic use, pre-existing skin conditions, abnormal genital bleeding, breast cancer, severe benign or malignant liver tumors, acute liver or cardiovascular disease (with a greater risk for smokers and diabetics) may be aggravated. Workplace exposure may also aggravate these conditions. Persons who may have hypersensitivity reactions to this product and its components or other disorders described in Section 11 (Toxicological Information) may experience aggravation upon exposure.

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive medical attention. There is no antidote for this material. Treatment should be symptomatic and supportive.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not available.

AUTOIGNITION TEMPERATURE: Not available.

FLAMMABLE LIMITS (in air by volume, %): Not applicable.

FIRE EXTINGUISHING MEDIA: Unless incompatibilities exist for surrounding materials, carbon dioxide, water spray, 'ABC' type chemical extinguishers, foam, dry chemical and halon extinguishers can be used to fight fires involving this product.

UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

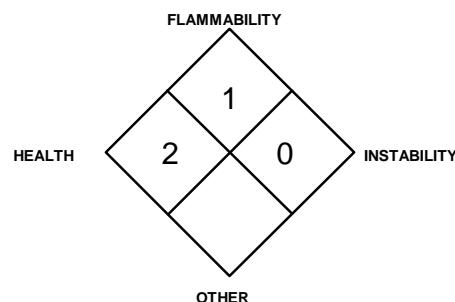
SPECIAL HAZARDS ARISING FROM THE SUBSTANCE: This product must be substantially pre-heated before ignition can occur. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including acrolein, carbon, iron, titanium and nitrogen oxides).

Explosion Sensitivity to Mechanical Impact: Not applicable.

Explosion Sensitivity to Static Discharge: Not sensitive.

SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. All personal protective gear and contaminated fire-response equipment should be decontaminated with soapy water and thoroughly rinsed before being returned to service. Move fire-exposed containers if it can be done without risk to firefighters. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

NFPA RATING



Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate
3 = Serious 4 = Severe

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES: Spill kits, clearly labeled, should be kept in or near preparation and administrative areas. It is suggested that kits include a respirator, chemical splash goggles, two pairs of gloves, two sheets (12" x 12") of absorbent material, 250-mL and 1-liter spill control pillows, a small scoop to collect glass fragments (if applicable) and two large waste disposal bags. Absorbents should be able to be incinerated. Avoid generating airborne dusts of this material during spill response procedures as described below.

PROTECTIVE EQUIPMENT:

Small Spills/Spills in Hoods: Personnel wearing nitrile or other appropriate gloves, labcoat or other protective clothing and eye protection should immediately clean incidental spills (e.g. a single container).

Large Spills: For large spills (e.g., a pallet of containers), proper protective equipment, including double nitrile or appropriate gloves, and protective clothing (i.e., disposable Tyvek coveralls). When there is any danger of airborne dusts being generated, use a full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator.

METHODS FOR CLEAN-UP AND CONTAINMENT:

Cleanup of Small Spills: Pick-up or wipe-up spilled capsules with damp absorbent sheets to prevent generation of dusts. Decontaminate the spill area (three times) using a bleach and detergent solution and then rinse with clean water.

Large Spills: Restrict access to the spill areas. Gently wet down area and carefully sweep up spilled product, avoiding the generation of airborne dusts. The dispersion of particles into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Do not apply chemical in-activators as they may produce hazardous by-products. Thoroughly clean all contaminated surfaces three times using a bleach and detergent solution and then rinse with clean water.

All Spills: Use procedures described above and then place all spill residues in an appropriate, labeled container and seal. Move to a secure area. Dispose of in accordance with Federal, State, and local hazardous waste disposal regulations (see Section 13, Disposal Considerations). For spills on water, contain, minimize dispersion and collect. Dispose of recovered material and report spill per regulatory requirements.

ENVIRONMENTAL PRECAUTIONS: Prevent product from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

REFERENCE TO OTHER SECTIONS: Review Sections 2, 8, 11 and 12 before proceeding with cleanup. See Section 13, Disposal Considerations for more information.

PART III How can I prevent hazardous situations from occurring?

7. HANDLING and STORAGE

PRECAUTIONS FOR SAFE HANDLING: All employees who handle this product should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat or drink while handling this product. After handling this product, wash face and hands thoroughly prior to eating, drinking, smoking or applying cosmetics. Ensure this material is used with adequate ventilation. Appropriate personal protective equipment must be worn (see Section 8, Exposure Controls - Personal Protection). Open containers slowly on a stable surface in areas that have been designated for use of this material. Minimize all exposures to this product. Avoid generation of dusts. Areas in which this product is used should be wiped down, so that particulates do not accumulate.

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight and sources of intense heat. Recommended Storage Temperature: 20-25°C (68-77°F). Store away from incompatible materials (see Section 10, Stability and Reactivity). Product should be stored in secondary containers. Keep containers tightly closed when not in use.

7. HANDLING and STORAGE (Continued)

CONDITIONS FOR SAFE STORAGE (continued): Inspect all incoming containers before storage, to ensure containers are properly labeled and not damaged. Have appropriate extinguishing equipment in the storage area (e.g., sprinkler system, portable fire extinguishers). Empty containers may contain residual material; therefore, empty containers should be handled with care and disposed of properly.

SPECIFIC END USE(S): This product is a human pharmaceutical.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear nitrile or other appropriate gloves (double gloving is recommended), goggles, and lab coat. Prevent dispersion of particulates by wetting or dampening surfaces prior to clean up of equipment. If applicable, wash equipment using a bleach and detergent solution and then rinse with clean water

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

Ventilation and Engineering Controls: General: Use with adequate ventilation. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations and deluge showers are available and accessible in areas where this product is used. Wear appropriate personal protect equipment consistent with the recommendations of this SDS. Prevent accumulation of product on work surfaces by routinely cleaning areas appropriately.

Workplace Exposure Limits/Control Parameters:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER mg/m ³
		TWA mg/m ³	STEL mg/m ³	TWA mg/m ³	STEL mg/m ³	TWA mg/m ³	STEL mg/m ³	IDLH mg/m ³	
Progesterone	57-83-0	NE	NE	NE	NE	NE	NE	NE	Teva OEL TWA = 1.25 µg/m ³ (established 20Sept2012) Carcinogen: IARC-2B
Black Iron Oxide Red Iron Oxide Yellow Iron Oxide Exposure limits given are for CAS# 1309-37-1 (Fe ₂ O ₃)	1309-33-7 1309-37-1 20344-49-4	5 (resp. fract.)	NE	10 (fume)	NE	5 (dusts & fume, as Fe)	NE	2500 (dust & fume, as Fe)	Carcinogen: IARC-3, MAK-3B, TLV-A4
Gelatin	9000-70-8	NE	NE	NE	NE	NE	NE	NE	NE
Glycerin	56-81-5	10 mg/m ³ (mist); NIC: Withdraw TLV due to insufficient data	NE	15 (total dust), 5 (resp. fraction)	NE	NE	NE	NE	DFG MAK: TWA = 50 (inhalable fraction) PEAK = 2•MAK 15 min. average value, 1-hr interval, 4 per shift DFG MAK Pregnancy Risk Classification: C
Lecithin	8002-43-5	NE	NE	NE	NE	NE	NE	NE	NE
Peanut Oil	8002-03-7	NE	NE	NE	NE	NE	NE	NE	NE
Polyethylene Glycol	25322-68-3	NE	NE	NE	NE	NE	NE	NE	DFG MAKs: TWA = 1000 (inhalable fraction) PEAK = 8•MAK 15 min. average value, 1-hr interval, 4 per shift DFG MAK Pregnancy Risk Classification: C AIHA WEEL: TWA = 10 (aerosol only)
Polyvinyl Acetate Phthalate	34481-48-6	NE	NE	NE	NE	NE	NE	NE	NE
Propylene Glycol	57-55-6	NE	NE	NE	NE	NE	NE	NE	AIHA WEEL: TWA = 10
Titanium Dioxide	13463-67-7	10	NE	15 (total dust) 10 (vacated 1989 PEL)	NE	See NIOSH Pocket Guide Appendix A	5000 (Ca)	NE	Carcinogen: IARC-2B, MAK-3A, NIOSH-Ca, TLV-A4; NIC: TLV-A3

NE = Not Established

NIC = Notice of Intended Change

See Section 16 for Definitions of Other Terms Used

International Occupational Exposure Limits: Exposure limits available for some excipient components are given below.

GELATINS:

Russia: STEL = 10 mg/m³, JUN 2003

GLYCERIN:

Belgium: TWA = 10 mg/m³, MAR 2002

Finland: TWA = 20 mg/m³, SEP 2009

France: VME = 10 mg/m³, FEB 2006

Korea: TWA = 10 mg/m³ (mist), 2006

Mexico: TWA = 10 mg/m³ (inhalable), 2004

The Netherlands: MAC-TGG = 10 mg/m³, 2003

New Zealand: TWA = 10 mg/m³ (mist), JAN 2002

Switzerland: MAK-W = 50 mg/m³, KZG-W = 100 mg/m³, DEC 2006

United Kingdom: TWA = 10 mg/m³, 2007

In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

IRON OXIDES:

ARAB Republic of Egypt: TWA = 3 ppm (5 mg/m³) (fume), JAN 1993

Australia: TWA = 0.1 mg(Fe)/m³, JUL 2008

Australia: TWA = 5 mg(Fe)/m³ (fume), JUL 2008

Belgium: TWA = 2 ppm (5 mg(Fe)/m³) (fume), MAR 2002

Denmark: TWA = 3.5 mg(Fe)/m³, OCT 2002

Finland: TWA = 5 mg(Fe)/m³, fume, SEP 2009

IRON OXIDES (continued):

France: VME = 5 mg(Fe)/m³ (fume), FEB 2006

Germany: MAK = 1.5 mg(Fe)/m³ (respirable), 2005

Hungary: TWA = 6 mg/m³ (resp), SEP 2000

Japan: OEL = 1 mg/m³ (respirable), 4 mg/m³ (total), APR 2007

Korea: TWA = 10 mg/m³, 2006

Korea: TWA = 5 mg/m³, 2006

Mexico: TWA = 10 mg/m³; STEL = 20 mg/m³, 2004

The Netherlands: MAC-TGG = 5 mg(Fe)/m³, 2003

The Netherlands: MAC-TGG = 10 mg/m³, 2003

New Zealand: TWA = 5 mg(Fe)/m³ (dust and fume), JAN 2002

New Zealand: TWA = 10 mg/m³ (inspirable dust), JAN 2002

Norway: TWA = 3 mg/m³, JAN 1999

The Philippines: TWA = 10 mg/m³ (fume), JAN 1993

Poland: MAC(TWA) fume = 5 mg/m³, MAC(STEL) = 10 mg/m³, JAN 1999

Russia: TWA = 6 mg/m³, JUN 2003

Sweden: TWA = 3.5 mg(Fe)/m³ (resp. dust), JUN 2005

Switzerland: MAK-W = 3 mg/m³, DEC 2006

Thailand: TWA = 10 mg/m³ (fume), JAN 1993

Turkey: TWA = 10 mg/m³ (fume), JAN 1993

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/CONTROL PARAMETERS (continued):

International Occupational Exposure Limits (continued):

IRON OXIDES (continued):

United Kingdom: TWA = 4 mg/m³ (respirable), 2005
United Kingdom: TWA = 10 mg/m³ (inhalable), 2005

United Kingdom: TWA = 5 mg(Fe)/m³; STEL = 10 mg(Fe)/m³, 2005

In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

POLYETHYLENE GLYCOL

Germany: MAK = 1000 mg/m³ (inhalable), 2005

The Netherlands: MAC-TGG = 1000 mg/m³, 2003

PROPYLENE GLYCOL:

Australia: TWA = 10 mg/m³ (particulates), JUL 2008

Australia: TWA = 150 ppm (474 mg/m³) (total), JUL 2008

New Zealand: TWA = 10 mg/m³ (particulates only), JAN 2002

New Zealand: TWA = 150 ppm (474 mg/m³) (vapor and particulates), JAN 2002

Russia: STEL = 7 mg/m³, JUN 2003

United Kingdom: TWA = 10 mg/m³ (particulate), 2005

United Kingdom: TWA = 150 ppm (474 mg/m³) (total vapor), 2005

TITANIUM DIOXIDE:

ARAB Republic of Egypt: TWA = 15 mg/m³, JAN 1993

Belgium: TWA = 10 mg/m³, MAR 2002

TITANIUM DIOXIDE (continued):

Denmark: TWA = 6 mg(Ti)/m³, OCT 2002

France: VME = 10 mg/m³, FEB 2006

Germany: MAK = 1.5 mg/m³ (respirable), 2005

Japan: OEL = 1 mg/m³ (respirable), 4 mg/m³ (total), APR 2007

Korea: TWA = 10 mg/m³, 2006

Mexico: TWA = 10 mg(Ti)/m³; STEL = 20 mg(Ti)/m³, 2004

The Netherlands: MAC-TGG = 10 mg/m³, 2003

New Zealand: TWA = 10 mg/m³ (inspirable dust), JAN 2002

Norway: TWA = 5 mg/m³, JAN 1999

Poland: MAC(TWA) = 10 mg(Ti)/m³, MAC(STEL) = 30 mg(Ti)/m³, JAN 1999

Russia: TWA = 10 mg/m³, JUN 2003

Sweden: TWA = 5 mg/m³ (total dust), JUN 2005

Switzerland: MAK-W = 3 mg/m³, DEC 2006

Turkey: TWA = 15 mg/m³, JAN 1993

United Kingdom: TWA = 10 mg/m³ (inhalable), 2005

United Kingdom: TWA = TWA 4 mg/m³ (respirable), 2005

In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

PROTECTIVE EQUIPMENT: The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132, including U.S. Federal OSHA Respiratory Protection (29 CFR 1910.134), OSHA Eye Protection 29 CFR 1910.133, OSHA Hand Protection 29 CFR 1910.138, OSHA Foot Protection 29 CFR 1910.136 and OSHA Body Protection 29 CFR 1910.132), equivalent standards of Canada (including CSA Respiratory Standard Z94.4-02, Z94.3-M1982, Industrial Eye and Face Protectors and CSA Standard Z195-02, Protective Footwear), or standards of EU member states (including EN 529:2005 for respiratory PPE, CEN/TR 15419:2006 for hand protection, and CR 13464:1999 for face/eye protection). Please reference applicable regulations and standards for relevant details.

Respiratory Protection: Maintain airborne contaminant concentrations below exposure limits listed above, if applicable. For materials without listed exposure limits, minimize respiratory exposure. If necessary, use only respiratory protection authorized under appropriate regulations. Oxygen levels below 19.5% are considered IDLH by U.S. OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under U.S. OSHA's Respiratory Protection Standard (1910.134-1998).

Eye Protection: Wear splash goggles or safety glasses as appropriate for the task. If necessary, refer to appropriate regulations.

Hand Protection: Wash hands and wrists before putting on and after removing gloves. During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. When used in medical administration of the product, double glove with nitrile or other appropriate gloves to avoid contact and/or absorption of the product. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS. Because all gloves are to some extent permeable and their permeability increases with time, they should be changed regularly (hourly is preferable) or immediately if torn or punctured. If necessary refer to appropriate regulations.

Skin Protection: Use appropriate protective clothing for the task (e.g., lab coat, etc.). If necessary, refer to the U.S. OSHA Technical Manual (Section VII: Personal Protective Equipment) or other appropriate regulations.

9. PHYSICAL and CHEMICAL PROPERTIES

The following information is for the product as a whole.

PHYSICAL FORM: Capsules.

ODOR: Practically odorless.

MOLECULAR WEIGHT: Mixture.

HOW TO DETECT THIS SUBSTANCE (identification/warning properties): The appearance may be a distinguishing characteristic of this product in event of accidental release.

The following information is for the Progesterone ingredient.

FORM: Crystalline solid.

MOLECULAR WEIGHT: 314.47

ODOR: Odorless.

BOILING POINT @ 760 mmHg: 459.14°C (858.5°F) [predict.]

VAPOR PRESSURE (air = 1) @ 25°C: 0.0±1.1 mmHg [predict.]

EVAPORATION RATE (nBuAc = 1): Not applicable.

SOLUBILITY IN WATER: Insoluble

OTHER SOLUBILITIES: Soluble in alcohol, acetone, dioxane, concentrated sulfuric acid; sparingly soluble in vegetable oils.

COEFFICIENT WATER/OIL DISTRIBUTION: Log Kow: 3.87; Log P: 3.87

COLOR: As described in Section 2.

ODOR THRESHOLD: Not applicable.

MOLECULAR FORMULA: Mixture.

HOW TO DETECT THIS SUBSTANCE (identification/warning properties): The appearance may be a distinguishing characteristic of this product in event of accidental release.

COLOR: White to creamy white.

MOLECULAR FORMULA: C₂₁H₃₀O₂

ODOR THRESHOLD: Not applicable.

MELTING POINT: 236-240°C (456.8-464°F)

SPECIFIC GRAVITY (water = 1): 1.17 g/cm³

FLASH POINT: 166.7±25.7°C (332.1±78.3°F) [predict.]

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: Stable under normal conditions.

DECOMPOSITION PRODUCTS: **Combustion:** Products of thermal decomposition may include carbon, iron, acrolein, titanium and nitrogen oxides. **Hydrolysis:** None known.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: Incompatible with strong oxidizing agents, and strong acids.

POSSIBILITY OF HAZARDOUS REACTION/POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Exposure to or contact with extreme temperatures, incompatible chemicals.

PART IV Is there any other useful information about this material?

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: The main route of occupational exposure to this product is via inhalation of dusts and skin contact. The anticipated symptoms of exposure, by route of exposure are described further in this section.

Inhalation: Inhalation of dusts generated by damaged capsules of this product may irritate the nose, throat, and lungs. In addition, inhalation may result in adverse effects as described under 'Other Potential Health Effects'.

Contact with Skin or Eyes: It is anticipated that this product may irritate contaminated skin or eyes. Symptoms of skin contact may include itching and redness. Symptoms of eye contact can include redness, pain, and watering (mechanical irritation).

Skin Absorption: Absorption of hormones through the skin may contribute to the effects of exposure as described in "Other Potential Health Effects".

Ingestion: Ingestion of this product (i.e., through poor hygiene practices) may irritate the mouth, throat, and other tissues of the gastrointestinal system. Repeated ingestion may cause damage to organs and other effects described under 'Other Potential Health Effects'.

Injection: Not a potential route of exposure for capsules.

OTHER POTENTIAL HEALTH EFFECTS: In therapeutic use, the most common adverse effects reported include, headaches, breast pain, irregular vaginal bleeding or spotting, stomach or abdominal cramps, nausea, vomiting, hair loss, fluid retention, vaginal yeast infections. Androgenic side effects such as acne, hirsutism (increased body hair growth) and weight gain occur rarely. Increased concentrations of progestins increase the normal oral flora growth rate, leading to an increase in inflammation of the gingival tissues and increased bleeding. Fluid retention may be caused by some progestins, especially high doses, and may aggravate these conditions of asthma, significant cardiac insufficiency, epilepsy, hypertension, migraine headaches or significant renal dysfunction. Individuals who have had allergic reactions to products containing progestogens may experience allergic reactions to this material. Transient drowsiness or dizziness may occur. Exposure to female hormones in men can also include testicular atrophy, increased risk of prostate cancer, loss of libido and potency, gynecomastia (the abnormal growth of breast tissue), increased risk of prostate cancer and infertility from decrease in FSH and subsequent effects on sperm maturation. Changes in FSH levels affect the ovulatory cycle in women which may lead to decreased fertility. Chronic therapeutic use may present an increased risk of ovarian, breast endometrial cancers. These effects may be possible as a result of workplace exposure. The actual risk in the workplace is not known. Body systems adversely affected during therapeutic use are provided below. More details are also given in the Teva Active Ingredient SDS for this product.

- Body as a Whole
- Cardiovascular System
- Central Nervous System
- Eyes
- Gastrointestinal System
- Hypersensitivity Reactions
- Liver

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2*
----------------------	--------	----

FLAMMABILITY HAZARD	(RED)	1
----------------------------	-------	---

PHYSICAL HAZARD	(YELLOW)	0
------------------------	----------	---

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate
3 = Serious 4 = Severe * = Chronic hazard

HEALTH EFFECTS OR RISKS FROM EXPOSURE:

Acute: Dusts from product may cause irritation if inhaled and in contact with skin or eyes. Accidental ingestion may be harmful.

Chronic: Dermatitis (inflammation and redness of the skin) may occur after chronic, low-level skin contact. May cause harm to fetus, as retinoid. Potential fetal harm and adverse effects on fertility. Contains suspect human carcinogen. May cause adverse effects on fertility. Chronic exposure to this material may cause adverse effects as described under 'Other Potential Health Effects'. No other chronic effects have been reported from workplace exposure.

TARGET ORGANS: It is anticipated that for Occupational Exposure the target organs are: **Acute:** Skin, eyes, respiratory system. **Chronic:** Possible fetal harm. In therapeutic use this product may have an impact on the body systems listed under 'Other Potential Health Effects'.

TOXICITY DATA: The following toxicity data are currently available for the active ingredient. Only human data, LD50 Oral-Rat, LD50 Oral-Mouse, LD50 Skin-Rabbit, LD50 Skin-Rat, LC50 Inhalation-Rat, LC50 Inhalation-Mouse, and mutagenic data are presented due to the large amount of data available. Additional data are available for excipients, but are not provided in this SDS. Contact Teva for information.

PROGESTERONE:

TDLo (Oral-Woman) 200 mg/kg: female 20 day(s) pre-mating: Reproductive: Maternal Effects: uterus, cervix, vagina
TDLo (Oral-Woman) 113 mg/kg: female 6-32 week(s) after conception: Reproductive: Specific Developmental Abnormalities: urogenital system
TDLo (Oral-Woman) 120 mg/kg: female 20 day(s) pre-mating: Reproductive: Fertility: other measures of fertility
TDLo (Oral-Woman) 120 mg/kg: female 20 day(s) pre-mating: Reproductive: Maternal Effects: menstrual cycle changes or disorders, Fertility: female fertility index (e.g. # females pregnant per # sperm positive females; # females pregnant per # females mated), other measures of fertility

PROGESTERONE (continued):

TDLo (Oral-Woman) 100 mg/kg: female 20 day(s) pre-mating: Reproductive: Maternal Effects: uterus, cervix, vagina
TDLo (Intramuscular-Man) 50 mg/kg: male 70 day(s) pre-mating: Reproductive: Paternal Effects: spermatogenesis (incl. genetic material, sperm morphology, motility, and count), breast development
TDLo (Intramuscular-Man) 15 mg/kg: male 21 day(s) pre-mating: Reproductive: Paternal Effects: impotence
TDLo (Intramuscular-Man) 2.8 mg/kg: Behavioral: somnolence (general depressed activity), changes in psychophysiological tests; Nutritional and Gross Metabolic: body temperature increase

11. TOXICOLOGICAL INFORMATION (Continued)

TOXICITY DATA:

PROGESTERONE (continued):

TDLo (Intramuscular-Woman) 4 mg/kg: Behavioral: changes in psychophysiological tests; Cardiac: pulse rate increase, without fall in BP; Nutritional and Gross Metabolic: body temperature increase
TDLo (Parenteral-Woman) 600 µg/kg: female 67-71 day(s) after conception: Reproductive: Specific Developmental Abnormalities: urogenital system
TDLo (Parenteral-Woman) 32 mg/kg: female 3 week(s) pre-mating: Reproductive: Maternal Effects: menstrual cycle changes or disorders
TDLo (Intravaginal-Woman) 210 mg/kg: female 3 week(s) pre-mating: Reproductive: Maternal Effects: menstrual cycle changes or disorders
TDLo (Intravaginal-Woman) 475 µg/kg: female 1 year(s) pre-mating: Reproductive: Maternal Effects: menstrual cycle changes or disorders

PROGESTERONE (continued):

TDLo (Intravaginal-Woman) 280 mg/kg/5 weeks-intermittent: Endocrine: other changes; Blood: changes in serum composition (e.g. TP, bilirubin, cholesterol)
TDLo (Unreported-Woman) 386 mg/kg: female 18-34 week(s) after conception: Reproductive: Specific Developmental Abnormalities: urogenital system
DNA Inhibition (Human Lymphocyte) 5 µmol/L
DNA Inhibition (Human Kidney) 100 µg/L
Cytogenetic Analysis (Human Kidney) 100 µg/L
Sister Chromatid Exchange (Human Lymphocyte) 12 mg/L/22 hours
Micronucleus Test (Human Lymphocyte) 20 mg/L
Micronucleus Test (Human Fibroblast) 8 mg/L/22 hours
Micronucleus Test (Human Fibroblast) 12 mg/L

CARCINOGENIC POTENTIAL OF COMPONENTS:

The following information is for the active ingredient.
Progesterone has not been tested for carcinogenicity in animals by the oral route of administration. When implanted into female mice, progesterone produced mammary carcinomas, ovarian granulosa cell tumors and endometrial stromal sarcomas. In dogs, long-term intramuscular injections produced nodular hyperplasia and benign and malignant mammary tumors. Subcutaneous or intramuscular injections of progesterone decreased the latency period and increased the incidence of mammary tumors in rats previously treated with a chemical carcinogen.

Some studies suggest that oral contraceptive use has been associated with an increase in the risk of cervical intraepithelial neoplasia in some populations of women. However, there continues to be controversy about the extent to which such findings may be due to differences in sexual behavior and other factors. There is insufficient data to determine whether the use of Progestin-only oral contraceptives increases the risk of developing cervical intraepithelial neoplasia.

The active ingredient is listed by agencies tracking the carcinogenic potential as follows.

Progesterone: IARC-2B (Possibly Carcinogenic to Humans) as Progestogen-only contraceptives

The excipient components are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

IRON OXIDES (based on CAS# 1309-37-1): ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); IARC-3 (Unclassifiable as to Carcinogenicity in Humans); MAK-3B [respirable fraction] (Substances For Which in vitro tests or animal studies have yielded evidence of carcinogenic effects that is not sufficient for classification of the substance in one of the other categories.)

TITANIUM DIOXIDE: ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); IARC-2B (Possibly Carcinogenic to Humans); MAK-3A (Substances Which Cause Concern that They Could Be Carcinogenic for Man But Cannot Be Assessed Conclusively Because of Lack of Data. Substances for which the criteria for classification in Category 4 or 5 are fulfilled, but for which the database is insufficient for the establishment of a MAK value.); NIOSH-Ca (Potential Occupational Carcinogen with No Further Categorization); Notice of Intended Change: ACGIH TLV-A3 (Confirmed Animal Carcinogen with Unknown Relevance to Humans)

No other component of this product is found on the following lists: U.S. EPA, U.S. NTP, U.S. OSHA, U.S. NIOSH, GERMAN MAK, IARC, or ACGIH and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

IRRITANCY OF PRODUCT: Inhalation of dusts from this product may be irritating to the respiratory system. Dusts will also be irritating to the eyes.

SENSITIZATION TO THE MATERIAL: In therapeutic use, allergic reactions rash, itching, swelling, severe dizziness, anaphylaxis, and trouble breathing have been reported.

REPRODUCTIVE TOXICITY INFORMATION: There are no adequate and well-controlled studies of Progesterone in pregnant women; however, when administered therapeutically, Progesterone is not expected to cause fetal harm when administered to a pregnant woman. This product is rated by the FDA for therapeutic risk as Pregnancy Risk Category B. Refer to Definition of Terms for full Pregnancy Risk category definitions.

Mutagenicity: Progesterone did not show evidence of genotoxicity in *in vitro* studies for point mutations or for chromosomal damage.

In vivo studies for chromosome damage have yielded positive results in mice at oral doses of 1000 mg/kg and 2000 mg/kg.

Embryotoxicity/Teratogenicity: Reproductive studies have been performed in mice at doses up to 9 times the human oral dose, in rats at doses up to 44 times the human oral dose, in rabbits at a dose of 10 mcg/day delivered locally within the uterus by an implanted device, in guinea pigs at doses of approximately one-half the human oral dose and in rhesus monkeys at doses approximately the human dose, all based on body surface area, and have revealed little or no evidence of harm to the fetus due to Progesterone.

Reproductive Toxicity: Reproductive studies detailed above also revealed little or no evidence of impaired fertility. Exogenously administered Progesterone has been shown to inhibit ovulation in a number of species and it is expected that high doses given for an extended duration would impair fertility until the cessation of treatment in females. However, exposure to female hormones in men can result in infertility due to disruption of FSH levels and maturation of sperm. Irregular menstrual patterns are common among women using progestin-only oral contraceptives. If follicular development occurs, atresia of the follicle is sometimes delayed and the follicle may continue to grow beyond the size it would attain in a normal cycle. Generally these enlarged follicles disappear spontaneously. Often they are asymptomatic; in some cases they are associated with mild abdominal pain. In general, no adverse effects have been found on breastfeeding performance or on the health, growth, or development of the infant. May cause suppression of lactation. Small amounts of progestins pass into the breast milk of nursing mothers, resulting in detectable steroid levels in infant plasma. Very rarely, adverse effects in the infant/child have been reported, including jaundice. Because of the potential for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

BIOLOGICAL EXPOSURE INDICES: Currently, there are no Biological Exposure Indices (BEIs) determined for the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

Values for the active ingredient are available for the active ingredient, however, this information is not provided in this SDS. Contact Teva for more information.

MOBILITY: Currently, there is no specific information available on the potential mobility of this product.

PERSISTENCE AND BIODEGRADABILITY: Currently, there is no specific information on persistence and biodegradability of this product. Some biodegradation is expected.

12. ECOLOGICAL INFORMATION (Continued)

BIO-ACCUMULATION POTENTIAL: Currently, no specific information is available on the bioconcentration potential of this product.

ECOTOXICITY: This product may be harmful to contaminated plant and animal life, especially in large quantities. All releases to terrestrial, atmospheric and aquatic environments should be avoided. No aquatic toxicity data are available for the active ingredient.

RESULTS OF PBT AND vPvB ASSESSMENT: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

OTHER ADVERSE EFFECTS: The components of this product are not listed as having ozone depletion potential.

ENVIRONMENTAL EXPOSURE CONTROLS: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT/DISPOSAL METHODS: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All protective clothing, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed. Incineration is recommended for the product and disposable equipment. Shipment of wastes must be done with appropriately permitted and registered transporters. Reusable equipment should be cleaned with soap and water and thoroughly rinsed.

DISPOSAL CONTAINERS: Waste materials must be placed in and shipped in appropriate 5-gallon or 55-gallon poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers be done to all applicable regulations.

PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING: Wear proper protective equipment when handling waste materials.

U.S. EPA WASTE NUMBER: Not applicable.

EWC WASTE CODE: Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION: This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product does not meet the criteria of classification of Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product does not meet the criteria as Dangerous Goods, per rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is NOT classified as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product does not meet the criteria as Dangerous Goods of the United Nations Economic Commission for Europe.

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: Not applicable.

ENVIRONMENTAL HAZARDS: This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and is not specifically listed in Annex III under MARPOL 73/78.

15. REGULATORY INFORMATION

ADDITIONAL U.S. REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity (TPQ): There are no specific Threshold Planning Quantities for the components of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) may apply, per 40 CFR 370.20.

U.S. SARA Hazard Categories (Section 311/312, 40 CFR 370-21): ACUTE: Yes; CHRONIC: Yes; FIRE: No; REACTIVE: No; SUDDEN RELEASE: No

U.S. CERCLA Reportable Quantity (RQ): Not applicable.

U.S. TSCA Inventory Status: This product is regulated under Food and Drug Administration (FDA) standards; this product is not subject to requirements under TSCA.

Other U.S. Federal Regulations: Under the Hazard Communication Standard (HCS), Section (b)(5)(ii) drugs are subject to labeling requirements by the FDA under the Federal Food, Drug and Cosmetic Act and are exempt from labeling provisions of the HCS; this section of the HCS exempts only labeling requirements and not requirements for a Safety Data Sheet for drugs.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): The Progesterone component is on the California Proposition 65 lists. WARNING! This product contains a compound known to the State of California to cause cancer.

State Regulations: Regulated Medical Waste.

15. REGULATORY INFORMATION (Continued)

ADDITIONAL CANADIAN REGULATIONS:

Canadian DSL/NDSL Status: This product is regulated by the Therapeutic Products Programme (TPP) of Health Canada; it is exempt from the requirements of CEPA.

Canadian Environmental Protection Act (CEPA) Priority Substances Lists: Components are not on the CEPA substances lists.

Other Canadian Regulations: Requirements under the Canadian Heath Canada, Laboratory Biosafety Guidelines may be applicable.

Canadian WHMIS Classification and Symbols: The WHMIS Requirements of the Hazardous Products Act does not apply in respect of the advertising, sale or importation of any cosmetic, device, drug or food within the meaning of the Food and Drugs Act.

ADDITIONAL EUROPEAN REGULATIONS:

Safety, Health, and Environmental Regulations/Legislation Specific for the Product: Formulated, finished medicinal products for human use are subject to Directive 2001/83/EC and subsequent amendments to the directive.

Chemical Safety Assessment: No Data Available. The chemical safety assessment is required for some substances according to European Union Regulation (EC) 1907/2006, Article 14.

16. OTHER INFORMATION

ANSI LABELING (Z129.1, Provided to Summarize Occupational Hazard Information): **WARNING! CANCER HAZARD.** MAY CAUSE CANCER THROUGH THERAPEUTIC USE. DRUG PRODUCT MAY BE ABSORBED THROUGH THE SKIN. CHRONIC EXPOSURE MAY CAUSE TEMPORARY IMPAIRMENT OF FERTILITY IN BOTH GENDERS. MAY CAUSE HARM TO BREAST-FED BABIES. DRUG PRODUCT IN CAPSULE MAY CAUSE RESPIRATORY SYSTEM, EYE, AND SKIN IRRITATION. COMBUSTIBLE IF EXPOSED TO HIGH TEMPERATURES. Do not taste or swallow. Avoid contact with skin, eyes, and clothing. Keep container closed. Use gloves, safety glasses, and appropriate respiratory and body protection.

FIRST-AID: If exposed, seek immediate medical attention. If swallowed, do not induce vomiting. If alert, give victim up to three glasses of water. Never give anything by mouth to an unconscious person. In case of contact, immediately flush skin with copious amounts of warm water for 20 minutes. Remove contaminated clothing and shoes. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. **IN CASE OF FIRE:** Use water fog, dry chemical or CO₂, or alcohol foam. **IN CASE OF SPILL:** Refer to Safety Data Sheet for complete spill response procedures. Spill response should be performed by persons properly trained to do so. Decontaminate area with bleach and detergent solution and triple rinse area. Place spill debris in a suitable container. Refer to SDS for additional information.

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

67/548/EEC EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

CLASSIFICATION FOR COMPONENTS:

Full Text Global Harmonization AND EU CLP Regulation (EC) 1272/2008:

Progesterone: This is a self-classification.

Classification: Reproductive Toxicity Category 2, Carcinogenic Category 2, Adverse Effects on or Via Lactation

Hazard Statement Codes: H361f: Suspected of damaging fertility. H351: Suspected of causing cancer. H362: May cause harm to breast-fed children.

Peanut Oil: This is a self-classification.

Classification: Skin Sensitization Category 1B

Hazard Statements: H317: May cause an allergic skin reaction.

All Other Components: No classification has been published or is applicable.

Full Text EU 67/548/EEC:

Progesterone: This is a self-classification.

Classification: Reproductive Toxicity Category 3, Carcinogenic Category 3

Risk Phrases: R62: Possible risk of impaired fertility. R64: May cause harm to breast-fed babies. R40: Limited evidence of a carcinogenic effect.

Peanut Oil: This is a self-classification.

Classification: Irritant

Risk Phrases: R43: May cause sensitisation by skin contact.

All Other Components: No classification has been published or is applicable.

REVISION DETAILS: New

REFERENCES AND DATA SOURCES: Contact the supplier for information.

METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc. • PO Box 1961, Hilo, HI 96721-1961 • (800) 441-3365

DATE OF PRINTING: March 17, 2014

REVISION HISTORY: New.

The Vendee (or any other third party) assumes full risk and responsibility for any injury or damage that may occur from the manufacture, use or other exposure to the material. No warranty is expressed or implied regarding the accuracy of the data set forth herein or the results that may be obtained from the use or reliance thereof. Teva, Inc. assumes no responsibility for any injury that may arise from the manufacture, use or other exposure to the material if reasonable safety procedures are not adhered to as stipulated in the data sheet attached hereto. Additionally, Teva, Inc. assumes no responsibility for injury to any person proximately caused by the inappropriate or unintended use of the material even if such reasonable safety procedures are followed.

DEFINITIONS OF TERMS

A For information on medical terms used in this SDS consult an on-line database such as Medline Plus: <http://www.nlm.nih.gov/medlineplus/druginformation.html>.

A large number of abbreviations and acronyms appear on a SDS. Some of these, which are commonly used, include the following:

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

FLAMMABILITY HAZARD (continued): 2 (Moderate Hazard-Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not, under normal conditions, form hazardous atmospheres in air, but under high ambient temperatures or moderate heating may release vapor in sufficient quantities to produce hazardous atmospheres in air, Including: Liquids having a flash-point at or above 37.8°C [100°F]; Solid materials in the form of coarse dusts that may burn rapidly but that generally do not form explosive atmospheres; Solid materials in a fibrous or shredded form that may burn rapidly and create flash fire hazards (e.g. cotton, sisal, hemp); Solids and semisolids that readily give off flammable vapors.); 3 (Serious Hazard- Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures, or, unaffected by ambient temperature, are readily ignited under almost all conditions, including: Liquids having a flash point below 22.8°C [73°F] and having a boiling point at or above 38°C [100°F] and below 37.8°C [100°F] (e.g. OSHA Class IB and IC); Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air [e.g., dusts of combustible solids, mists or droplets of flammable liquids]; Materials that burn extremely rapidly, usually by reason of self-contained oxygen (e.g. dry nitrocellulose and many organic peroxides)); 4 (Severe Hazard-Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air, and which will burn readily, including: Flammable gases; Flammable cryogenic materials; Any liquid or gaseous material that is liquid while under pressure and has a flash point below 22.8°C [73°F] and a boiling point below 37.8°C [100°F] (e.g. OSHA Class IA); Material that ignites spontaneously when exposed to air at a temperature of 54.4°C [130°F] or below (e.g. pyrophoric).

PHYSICAL HAZARD: 0 (Water Reactivity: Materials that do not react with water. **Organic Peroxides:** Materials that are normally stable, even under fire conditions and will not react with water. **Explosives:** Substances that are Non-Explosive. **Unstable Compressed Gases:** No Rating. **Pyrophorics:** No Rating. **Oxidizers:** No "0" rating allowed. **Unstable Reactives:** Substances that will not polymerize, decompose, condense or self-react.); 1 (**Water Reactivity:** Materials that change or decompose upon exposure to moisture. **Organic Peroxides:** Materials that are normally stable, but can become unstable at high temperatures and pressures. These materials may react with water, but will not release energy. **Explosives:** Division 1.5 and 1.6 substances that are very insensitive explosives or that do not have a mass explosion hazard. **Compressed Gases:** Pressure below OSHA definition. **Pyrophorics:** No Rating. **Oxidizers:** Packaging Group III; **Solids:** any material that in either concentration tested, exhibits a mean burning time less than or equal to the mean burning time of a 3:7 potassium bromate/cellulose mixture and the criteria for Packing Group I and II are not met. **Liquids:** any material that exhibits a mean pressure rise time less than or equal to the pressure rise time of a 1:1 nitric acid (65%)/cellulose mixture and the criteria for Packing Group I and II are not met. **Unstable Reactives:** Substances that may decompose, condense or self-react, but only under conditions of high temperature and/or pressure and have little or no potential to cause significant heat generation or explosive hazard. Substances that readily undergo hazardous polymerization in the absence of inhibitors.); 2 **Water Reactivity:** Materials that may react violently with water. **Organic Peroxides:** Materials that, in themselves, are normally unstable and will readily undergo violent chemical change, but will not detonate. These materials may also react violently with water. **Explosives:** Division 1.4 – Explosive substances where the explosive effect are largely confined to the package and no projection of fragments of appreciable size or range are expected. An external fire must not cause virtually instantaneous explosion of almost the entire contents of the package. **Compressed Gases:** Pressurized and meet OSHA definition but < 514.7 psi absolute at 21.1°C (70°F) [500 psig]. **Pyrophorics:** No Rating. **Oxidizers:** Packing Group II **Solids:** any material that, either in concentration tested, exhibits a mean burning time of less than or equal to the mean burning time of a 2:3 potassium bromate/cellulose mixture and the criteria for Packing Group I are not met. **Liquids:** any material that exhibits a mean pressure rise time less than or equal to the pressure rise of a 1:1 aqueous sodium chloride solution (40%)/cellulose mixture and the criteria for Packing Group I are not met. **Unstable Reactives:** Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, but have a low potential for significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen at room temperature); 3 (**Water Reactivity:** Materials that may form explosive reactions with water. **Organic Peroxides:** Materials that are capable of detonation or explosive reaction, but require a strong initiating source, or must be heated under confinement before initiation; or materials that react explosively with water. **Explosives:** Division 1.2 – Explosive substances that have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but do not have a mass explosion hazard. **Compressed Gases:** Pressure ≥ 514.7 psi absolute at 21.1°C (70°F) [500 psig]. **Pyrophorics:** No Rating. **Oxidizers:** Packing Group I **Solids:** any material that, in either concentration tested, exhibits a mean burning time less than the mean burning time of a 3:2 potassium bromate/cellulose mixture. **Liquids:** Any material that spontaneously ignites when mixed with cellulose in a 1:1 ratio, or which exhibits a mean pressure rise time less than the pressure rise time of a 1:1 perchloric acid (50%)/cellulose mixture. **Unstable Reactives:** Substances that may polymerize, decompose, condense or self-react at ambient temperature and/or pressure and have a moderate potential to cause significant heat generation or explosion.); 4 (**Water Reactivity:** Materials that react explosively with water without requiring heat or confinement. **Organic Peroxides:** Materials that are readily capable of detonation or explosive decomposition at normal temperature and pressures. **Explosives:** Division 1.1 and 1.2-explosive substances that have a mass explosion hazard or have a projection hazard. A mass explosion is one that affects almost the entire load instantaneously. **Compressed Gases:** No Rating. **Pyrophorics:** Add to the definition of Flammability "4". **Oxidizers:** No "4" rating. **Unstable Reactives:** Substances that may polymerize, decompose, condense or self-react at ambient temperature and/or pressure and have a high potential to cause significant heat generation or explosion.).

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

HEALTH HAZARD: 0 (Minimal Hazard: No significant health risk, irritation of skin or eyes not anticipated. **Skin Irritation:** Essentially non-irritating. PII or Draize = "0". **Eye Irritation:** Essentially non-irritating, or minimal effects which clear in < 24 hours [e.g. mechanical irritation]. Draize = "0". **Oral Toxicity LD₅₀ Rat:** < 5000 mg/kg. **Dermal Toxicity LD₅₀ Rat or Rabbit:** < 2000 mg/kg. **Inhalation Toxicity 4-hrs LC₅₀ Rat:** < 20 mg/L.; 1 (Slight Hazard: Minor reversible injury may occur; slightly or mildly irritating. **Skin Irritation:** Slightly or mildly irritating. **Eye Irritation:** Slightly or mildly irritating. **Oral Toxicity LD₅₀ Rat:** > 500-5000 mg/kg. **Dermal Toxicity LD₅₀ Rat or Rabbit:** > 1000-2000 mg/kg. **Inhalation Toxicity LC₅₀ 4-hrs Rat:** > 2-20 mg/L); 2 (Moderate Hazard: Temporary or transitory injury may occur. **Skin Irritation:** Moderately irritating; primary irritant; sensitizer. PII or Draize > 0, < 5. **Eye Irritation:** Moderately to severely irritating and/or corrosive; reversible corneal opacity; corneal involvement or irritation clearing in 8-21 days. Draize > 0, ≤ 25. **Oral Toxicity LD₅₀ Rat:** > 50-500 mg/kg. **Dermal Toxicity LD₅₀ Rat or Rabbit:** > 200-1000 mg/kg. **Inhalation Toxicity LC₅₀ 4-hrs Rat:** > 0.5-2 mg/L); 3 (Serious Hazard: Major injury likely unless prompt action is taken and medical treatment is given; high level of toxicity; corrosive. **Skin Irritation:** Severely irritating and/or corrosive; may destroy dermal tissue, cause skin burns, dermal necrosis. PII or Draize > 5-8 with destruction of tissue. **Eye Irritation:** Corrosive, irreversible destruction of ocular tissue; corneal involvement or irritation persisting for more than 21 days. Draize > 80 with effects irreversible in 21 days. **Oral Toxicity LD₅₀ Rat:** > 1-50 mg/kg. **Dermal Toxicity LD₅₀ Rat or Rabbit:** > 20-200 mg/kg. **Inhalation Toxicity LC₅₀ 4-hrs Rat:** > 0.05-0.5 mg/L); 4 (Severe Hazard: Life-threatening; major or permanent damage may result from single or repeated exposure. **Skin Irritation:** Not appropriate. Do not rate as a "4", based on skin irritation alone. **Eye Irritation:** Not appropriate. Do not rate as a "4", based on eye irritation alone. **Oral Toxicity LD₅₀ Rat:** ≤ 1 mg/kg. **Dermal Toxicity LD₅₀ Rat or Rabbit:** ≤ 20 mg/kg. **Inhalation Toxicity LC₅₀ 4-hrs Rat:** ≤ 0.05 mg/L). **FLAMMABILITY HAZARD: 0 (Minimal Hazard:** Materials that will not burn in air when exposure to a temperature of 815.5°C (1500°F) for a period of 5 minutes.); 1 (Slight Hazard-Materials that must be pre-heated before ignition can occur. Material require considerable pre-heating, under all ambient temperature conditions before ignition and combustion can occur, Including: Materials that will burn in air when exposed to a temperature of 815.5°C (1500°F) for a period of 5 minutes or less; Liquids, solids and semisolids having a flash point at or above 93.3°C [200°F] (e.g. OSHA Class IIIB, or; Most ordinary combustible materials [e.g. wood, paper, etc.];

DEFINITIONS OF TERMS (Continued)

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

HEALTH HAZARD (continued): 2 (continued): Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC₅₀ for acute inhalation toxicity, if its LC₅₀ is less than or equal to 5000 ppm and that does not meet the criteria for either degree of hazard 3 or degree of hazard 4. Dusts and mists with an LC₅₀ for acute inhalation toxicity greater than 2 mg/L but less than or equal to 10 mg/L. Materials with an LD₅₀ for acute dermal toxicity greater than 200 mg/kg but less than or equal to 1000 mg/kg. Compressed liquefied gases with boiling points between -30°C (-22°F) and -55°C (-66.5°F) that cause severe tissue damage, depending on duration of exposure. Materials that are respiratory irritants. Materials that cause severe, but reversible irritation to the eyes or are lacrimators. Materials that are primary skin irritants or sensitizers. Materials whose LD₅₀ for acute oral toxicity is greater than 50 mg/kg but less than or equal to 500 mg/kg. Dusts and mists with an LC₅₀ for acute inhalation toxicity greater than 10 mg/L but less than or equal to 200 mg/L. Materials with an LD₅₀ for acute dermal toxicity greater than 1000 mg/kg but less than or equal to 2000 mg/kg. Materials that slightly to moderately irritate the respiratory tract, eyes and skin. Materials with an LD₅₀ for acute oral toxicity greater than 500 mg/kg but less than or equal to 2000 mg/kg. 3 (materials that, under emergency conditions, can cause serious or permanent injury): Gases and vapors whose LC₅₀ for acute inhalation toxicity is greater than 1,000 ppm but less than or equal to 3,000 ppm. Dusts and mists whose LC₅₀ for acute inhalation toxicity is greater than 0.5 mg/L but less than or equal to 2 mg/L. Materials whose LD₅₀ for acute dermal toxicity is greater than 40 mg/kg but less than or equal to 200 mg/kg. Materials whose LD₅₀ for acute oral toxicity is greater than 5 mg/kg but less than or equal to 50 mg/kg. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC₅₀ for acute inhalation toxicity, if its LC₅₀ is less than or equal to 3000 ppm and that does not meet the criteria for degree of hazard 4. Compressed liquefied gases with boiling points between -30°C (-22°F) and -55°C (-66.5°F) that cause frostbite and irreversible tissue damage. Materials that are respiratory irritants. Cryogenic gases that cause frostbite and irreversible tissue damage. Materials that are corrosive to the respiratory tract. Materials that are corrosive to the eyes or cause irreversible corneal opacity. Materials that are corrosive to the skin. 4 (materials that, under emergency conditions, can be lethal): Gases and vapors whose LC₅₀ for acute inhalation toxicity less than or equal to 1,000 ppm. Dusts and mists whose LC₅₀ for acute inhalation toxicity is less than or equal to 0.5 mg/L. Materials whose LD₅₀ for acute dermal toxicity is less than or equal to 40 mg/kg. Materials whose LD₅₀ for acute oral toxicity is less than or equal to 5 mg/kg. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC₅₀ for acute inhalation toxicity, if its LC₅₀ is less than or equal to 1000 ppm.

FLAMMABILITY HAZARD: 0 Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand: Materials that will not burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in accordance with Annex D. 1 Materials that must be preheated before ignition can occur. Materials in this degree require considerable preheating, under all ambient temperature conditions, before ignition and combustion can occur: Materials that will burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in accordance with Annex D. Liquids, solids and semisolids having a flash point at or above 93.4°C (200°F) (i.e. Class IIIB liquids). Liquids with a flash point greater than 35°C (95°F) that do not sustain combustion when tested using the *Method of Testing for Sustained Combustibility*, per 49 CFR 173, Appendix H or the UN *Recommendation on the Transport of Dangerous Goods, Model Regulations* (current edition) and the related *Manual of Tests and Criteria* (current edition). Liquids with a flash point greater than 35°C (95°F) in a water-miscible solution or dispersion with a water non-combustible liquid/solid content of more than 85 percent by weight. Liquids that have no fire point when tested by ASTM D 92 Standard Test Method for Flash and Fire Points by Cleveland Open Cup, up to a boiling point of the liquid or up to a temperature at which the sample being tested shows an obvious physical change. Combustible pellets with a representative diameter of greater than 2 mm (10 mesh). Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. Most ordinary combustible materials. 2 Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not under normal conditions form hazardous atmospheres with air, but under high ambient temperatures or under moderate heating could release vapor in sufficient quantities to produce hazardous atmospheres with air: Liquids having a flash point at or above 37.8°C (100°F) and below 93.4°C (200°F) (i.e. Class II and Class IIIA liquids.) Solid materials in the form of powders or coarse dusts of representative diameter between 420 microns (40 mesh) and 2 mm (10 mesh) that burn rapidly but that generally do not form explosive mixtures in air. Solid materials in fibrous or shredded form that burn rapidly and create flash fire hazards, such as cotton, sisal and hemp. Solids and semisolids that readily give off flammable vapors. Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. 3 Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures or, though unaffected by ambient temperatures, are readily ignited under almost all conditions: Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 37.8°C (100°F) and those liquids having a flash point at or above 22.8°C (73°F) and below 37.8°C (73°F) and below 37.8°C (100°F) (i.e. Class IB and IC liquids). Materials that, on account of their physical form or environmental conditions, can form explosive mixtures with air and are readily dispersed in air. Flammable or combustible dusts with a representative diameter less than 420 microns (40 mesh). Materials that burn with extreme rapidity, usually by reason of self-contained oxygen (e.g. dry nitrocellulose and many organic peroxides). Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent. 4 Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air and will burn readily: Flammable gases. Flammable cryogenic materials. Any liquid or gaseous materials that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 37.8°C (100°F) (i.e. Class IA liquids). Materials that ignite when exposed to air. Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed cup flash point of the solvent.

INSTABILITY HAZARD: 0 Materials that in themselves are normally stable, even under fire conditions: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) below 0.01 W/mL. Materials that do not exhibit an exotherm at temperatures less than or equal to 500°C (932°F) when tested by differential scanning calorimetry. 1 Materials that in themselves are normally stable, but that can become unstable at elevated temperatures and pressures: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 0.01 W/mL and below 10 W/mL. 2 Materials that readily undergo violent chemical change at elevated temperatures and pressures: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 10 W/mL and below 100W/mL.

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

INSTABILITY HAZARD: 3 Materials that in themselves are capable of detonation or explosive decomposition or explosive reaction, but that require a strong initiating source or that must be heated under confinement before initiation: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 100 W/mL and below 1000 W/mL. Materials that are sensitive to thermal or mechanical shock at elevated temperatures and pressures. 4 Materials that in themselves are readily capable of detonation or explosive decomposition or explosive reaction at normal temperatures and pressures: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) of 1000 W/mL or greater. Materials that are sensitive to localized thermal or mechanical shock at normal temperatures and pressures.

FLAMMABILITY LIMITS IN AIR:

Much of the information related to fire and explosion is derived from the National Fire Protection Association (NFPA). **Flash Point** - Minimum temperature at which a liquid gives off sufficient vapors to form an ignitable mixture with air. **Autoignition Temperature**: The minimum temperature required to initiate combustion in air with no other source of ignition. **LEL** - the lowest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source. **UEL** - the highest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source.

TOXICOLOGICAL INFORMATION:

Human and Animal Toxicology: Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. Definitions of some terms used in this section are: **LD₅₀** - Lethal Dose (solids and liquids) which kills 50% of the exposed animals; **LC₅₀** - Lethal Concentration (gases) which kills 50% of the exposed animals; **ppm** concentration expressed in parts of material per million parts of air or water; **mg/m³** concentration expressed in weight of substance per volume of air; **mg/kg** quantity of material, by weight, administered to a test subject, based on their body weight in kg. Other measures of toxicity include **TD₀**, the lowest dose to cause a symptom and **TCL₀** the lowest concentration to cause a symptom; **TD₀, LD₀, and LD₅₀, or TC, TCo, LCL₀, and LCo**, the lowest dose (or concentration) to cause lethal or toxic effects. **Cancer Information:** The sources are: **IARC** - the International Agency for Research on Cancer, **NTP** - the National Toxicology Program, **RTECS** - the Registry of Toxic Effects of Chemical Substances, **OSHA** and **CAL/OSHA**. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Subrankings (2A, 2B, etc.) are also used. **Other Information:** **BEI** - ACGIH Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV.

REPRODUCTIVE TOXICITY INFORMATION:

A **mutagen** is a chemical which causes permanent changes to genetic material (DNA) such that the changes will propagate through generational lines. An **embryotoxin** is a chemical which causes damage to a developing embryo (i.e. within the first eight weeks of pregnancy in humans), but the damage does not propagate across generational lines. A **teratogen** is a chemical which causes damage to a developing fetus, but the damage does not propagate across generational lines. A **reproductive toxin** is any substance which interferes in any way with the reproductive process.

United States FDA Pharmaceutical Pregnancy Categories: **Pregnancy Category A:** Adequate and well-controlled human studies have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of risk in later trimesters). **Pregnancy Category B:** Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women OR Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester. **Pregnancy Category C:** Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. **Pregnancy Category D:** There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks. **Pregnancy Category X:** Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits. **Pregnancy Category N:** FDA has not classified this drug.

ECOLOGICAL INFORMATION:

EC is the effect concentration in water. **BCF** = Bioconcentration Factor, which is used to determine if a substance will concentrate in lifeforms which consume contaminated plant or animal matter. **TL_m** = median threshold limit; Coefficient of Oil/Water Distribution is represented by **log K_{ow}** or **log K_{oc}** and is used to assess a substance's behavior in the environment.

REGULATORY INFORMATION:

U.S. and CANADA:

ACGIH: American Conference of Governmental Industrial Hygienists, a professional association which establishes exposure limits.

This section explains the impact of various laws and regulations on the material. **EPA** is the U.S. Environmental Protection Agency. **NIOSH** is the National Institute of Occupational Safety and Health, which is the research arm of the U.S. Occupational Safety and Health Administration (**OSHA**). **WHMIS** is the Canadian Workplace Hazardous Materials Information System. **DOT** and **TC** are the U.S. Department of Transportation and the Transport Canada, respectively. Superfund Amendments and Reauthorization Act (**SARA**); the Canadian Domestic/Non-Domestic Substances List (**DSL/NDSL**); the U.S. Toxic Substance Control Act (**TSCA**); Marine Pollutant status according to the **DOT**; the Comprehensive Environmental Response, Compensation, and Liability Act (**CERCLA** or **Superfund**); and various state regulations. This section also includes information on the precautionary warnings which appear on the material's package label. **OSHA** - U.S. Occupational Safety and Health Administration.

EUROPEAN and INTERNATIONAL:

The DFG: This is the Federal Republic of Germany's Occupation Health Agency, similar to the U.S. OSHA. **EU** is the European Community (formerly known as the **EEC**, European Economic Community). **EINECS:** This is the European Inventory of Non-Existing Chemical Substances. The **ARD** is the European Agreement Concerning the International Carriage of Dangerous Goods by Road and the **RID** are the International Regulations Concerning the Carriage of Dangerous Goods by Rail. **AICS** is the Australian Inventory of Chemical Substances.