



SAFETY DATA SHEET

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

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

PRODUCT IDENTIFIER/TRADE/MATERIAL NAME: MINASTRIN 24 FE™ (Norethindrone Acetate/Ethinyl Estradiol, and Ferrous Fumarate) TABLET KIT

DESCRIPTION: Kit with Norethindrone Acetate/Ethinyl Estradiol and Ferrous Fumarate Tablets

PRODUCT USE: Human Pharmaceutical

USES ADVISED AGAINST: Non-Pharmaceutical Use

CHEMICAL NAME: For Active Ingredients: Norethindrone Acetate: [(17 α)-17-(acetyloxy)-19-norpregna-4-en-20-yn-3-one]

Ethinyl Estradiol: 19-Nor-17 α -pregna-1,3,5 (10)-trien-20-yne-3,17-diol,

Ferrous Fumarate: (Z)-but-2-enedioate;iron(2+)

CHEMICAL FAMILY: For Active Ingredients: Norethindrone Acetate: Synthetic Progestin Hormone

Ethinyl Estradiol: Synthetic Estrogen Hormone

Ferrous Fumarate: Organic Iron Salt

HOW SUPPLIED: Kit with 24 white, round chewable tablets with 1 mg Norethindrone Acetate and 20 mcg Ethinyl Estradiol and 4 brown, round tablets with 75 mg Ferrous Fumarate

OTHER DESIGNATIONS: NDC#: 0430053550, 0430054050

FORMULA: For Active Ingredients: Norethindrone Acetate: C₂₂H₂₈O₃

Ethinyl Estradiol: C₂₀H₂₄O₂

Ferrous Fumarate: C₄H₂FeO₄

SUPPLIER OF THE SAFETY DATA SHEET

RESPONSIBLE PARTY U.S.:

ALLERGAN

U.S. ADDRESS:

5 Giralda Farms

Madison, NJ 07940

U.S. BUSINESS PHONE/GENERAL SDS INFORMATION

+1-800-272-5525

RESPONSIBLE PARTY EUROPE:

EUROPEAN ADDRESS:

EUROPEAN BUSINESS PHONE:

EMERGENCY PHONE (U.S./NORTH AMERICA): CHEMTREC: 1-800-424-9300 (24 hours) U.S., Canada, Puerto Rico

EMERGENCY PHONE (OUTSIDE U.S.): CHEMTREC: +1-703-527-3887 (24 hours) Outside North America

Email: SDS@Allergan.com

NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, Canadian WHMIS [Controlled Products Regulations], EU Directives through EC 1907: 2006, and European Union CLP EC 1272/2008, required information is included in appropriate sections based on the U.S. ANSI Z400.1-2010 format. This product has been classified in accordance with the hazard criteria of the countries listed above.

DATE OF PREPARATION: May 28, 2019

DATE OF REVISION:

2. HAZARDS IDENTIFICATION

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 exempted from classification and other criteria of 1272/2008.

EU 67/548/EEC LABELING AND 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 a kit with twenty-eight (28) tablets; 24 white, round chewable tablets with 1 mg Norethindrone Acetate and 20 mcg Ethinyl Estradiol and 4 brown, round tablets with 75 mg Ferrous Fumarate. Also, some are in mint flavor.

Health Hazards: In the workplace, exposure to dusts from product via inhalation or skin and eye contact may cause irritation. Non-therapeutic ingestion may be harmful. Hormones can be absorbed via skin contact and may cause adverse effect by this route of exposure if contact is chronic and prolonged. In therapeutic use, the most common adverse effects can include nausea, vomiting, bleeding between menstrual periods, weight gain, breast tenderness, headache, and difficulty wearing contact lenses. When formulated in therapeutic use, estrogen-progestogen mixtures are known human carcinogens. Individuals who have had allergic reactions to products containing estrogens and/or progestins may experience allergic reactions to this material. Chronic exposure may cause temporary impairment of fertility in both genders; interference with egg and sperm production. In men, exposure to female hormones has been associated with testicular atrophy, increased risk of prostate cancer, gynecomastia, loss of libido and potency. Individuals who have had allergic reactions to products containing progestogens may experience allergic reactions to this material.

2. HAZARDS IDENTIFICATION (Continued)

EMERGENCY OVERVIEW (continued):

Health Hazards (continued): May cause harm to the fetus during pregnancy. Other adverse effects seen from therapeutic use are described in Section 11 (Toxicological information).

Flammability Hazards: If heated to high temperatures for a prolonged period, the product may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including iron, carbon, sodium, magnesium and nitrogen oxides).

Reactivity Hazards: This product is not reactive.

Environmental Hazards: Studies indicate Ethinyl Estradiol can cause feminization in males and disturbances in fecundity. Progesterone hormones can cause harm to aquatic organisms. Large quantities of this product released to the aquatic and terrestrial environment may have an adverse effect.

Emergency Considerations: Emergency responders should wear appropriate protection for the situation to which they respond.

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/Symbol
ACTIVE INGREDIENTS:				
Norethindrone Acetate [(17 α)-17-(acetyloxy)-19-norpregna-4-en-20-yn-3-one]	51-98-9	200-132-0	Proprietary	SELF-CLASSIFICATION <u>EU 67/548</u> Classification: Reproductive Toxicity Cat. 2, Reproductive Toxicity Cat. 3, Carcinogenic Cat. 3 Risk Phrase Codes: R61, R62, R40 Hazard Symbols: T, Xn <u>GHS and EU 1272/2008</u> Classification: Reproductive Toxicity Cat. 1B, Carcinogenic Cat. 2 Hazard Codes: H360Df, H351 Hazard Symbol/Pictogram: GHS08
Ethinyl Estradiol (19-nor-17 α -pregna-1,3,5(10)-trien-20-yne-3,17-diol)	57-63-6	200-342-2	Proprietary	SELF CLASSIFICATION <u>EU 67/548</u> Classification: Reproductive Toxicity Cat. 2, Reproductive Toxicity Cat. 2, Germ Cell Mutagen Cat. 3, Carcinogenic Cat. 2, Harmful, Dangerous for the Environment Risk Phrases: R61, R62, R45, R68, R22, R53 Hazard Symbol: T, Xn <u>EU/GHS 1272/2008</u> Classification: Reproductive Toxicity Cat. 1A, Carcinogenic Cat. 1B, Germ Cell Mutagen Cat. 2, Acute Oral Toxicity Cat. 4, Aquatic Toxicity Cat. 4 Hazard Statement Codes: H302, H360Df, H350, H341, H413 Hazard Symbol/Pictogram: GHS07, GHS08
Ferrous Fumarate (Z)-but-2-enedioate;iron(2+)	141-01-5	205-447-7	Proprietary	SELF CLASSIFICATION <u>EU 67/548</u> Classification: Harmful Risk Phrase Codes: R22 Hazard Symbols: Xn <u>GHS & EU 1272/2008</u> Classification: Acute Oral Toxicity Cat. 4 Hazard Codes: H302 Hazard Symbol/Pictogram: GHS07
EXCIPIENTS:				
Acacia (active tablets only)	9000-01-5	232-519-5	Proprietary	<u>EU (67/548/EEC):</u> No Classification Applicable <u>EU/GHS 1272/2008:</u> No Classification Applicable
Corn Starch (active tablets only)	9005-25-8	232-679-6	Proprietary	<u>EU (67/548/EEC):</u> No Classification Applicable <u>EU/GHS 1272/2008:</u> No Classification Applicable
Lactose Monohydrate (active tablets only)	64044-51-1	200-559-2	Proprietary	<u>EU (67/548/EEC):</u> No Classification Applicable <u>EU/GHS 1272/2008:</u> No Classification Applicable
Mannitol (inert tablets only)	87-78-5	201-770-2	Proprietary	<u>EU (67/548/EEC):</u> No Classification Applicable <u>EU/GHS 1272/2008:</u> No Classification Applicable
Magnesium Stearate	557-04-0	209-150-3	Proprietary	<u>EU (67/548/EEC):</u> No Classification Applicable <u>EU/GHS 1272/2008:</u> No Classification Applicable
Microcrystalline Cellulose (inert tablets only)	9004-34-6	232-674-9	Proprietary	<u>EU (67/548/EEC):</u> No Classification Applicable <u>EU/GHS 1272/2008:</u> No Classification Applicable
Povidone (inert tablets only)	9003-39-8	Not Listed	Proprietary	<u>EU (67/548/EEC):</u> No Classification Applicable <u>EU/GHS 1272/2008:</u> No Classification Applicable
Sodium Starch Glycolate (inert tablets only)	9063-38-1	Not Listed	Proprietary	<u>EU (67/548/EEC):</u> No Classification Applicable <u>EU/GHS 1272/2008:</u> No Classification Applicable
Spearmint Flavoring (active tablets only)	No Information	No Information	Proprietary	<u>EU (67/548/EEC):</u> No Classification Applicable <u>EU/GHS 1272/2008:</u> No Classification Applicable
Sucralose (active tablets only)	56038-13-2	259-952-2	Proprietary	<u>EU (67/548/EEC):</u> No Classification Applicable <u>EU/GHS 1272/2008:</u> No Classification Applicable

See Section 16 for full classification information.

3. COMPOSITION and INFORMATION ON INGREDIENTS (Continued)

CHEMICAL NAME	CAS #	EINECS #	% w/w	LABEL ELEMENTS
EXCIPIENTS (continued):				
Sucrose (inert tablets only)	57-50-1	200-334-9	Proprietary	EU (67/548/EEC): No Classification Applicable EU/GHS 1272/2008: No Classification Applicable
Talc (active tablets only)	14807-96-6	238-877-9	Proprietary	EU (67/548/EEC): No Classification Applicable EU/GHS 1272/2008: No Classification Applicable

See Section 16 for full classification information.

4 FIRST-AID MEASURES

PROTECTION OF FIRST AID RESPONDERS: First-aid responders should not attempt to treat victims of exposure to this material without adequate personal protective equipment. Rescuers should be taken for medical attention, if necessary.

DESCRIPTION OF FIRST AID MEASURES: Victim(s) must be taken for medical attention. Remove victim(s) to fresh air, as quickly as possible. Only trained personnel should administer supplemental oxygen and/or cardio-pulmonary resuscitation, when necessary. Take copy of label and SDS to physician or other health professional with victim(s).

Inhalation: If dusts or particulates from this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect occurs after removal to fresh air.

Skin Exposure: If the product contaminates the skin and adverse effect occurs, begin decontamination with running water. Minimum flushing is for 20 minutes. Do not interrupt flushing. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Seek medical attention if adverse effect occurs after flushing.

Eye Exposure: If particulates from this product enter the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 20 minutes. Do not interrupt flushing. Seek immediate medical attention after flushing if adverse effect occurs.

Ingestion Exposure: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Rinse mouth with water immediately. Victim should drink large quantities of water. If milk is available, victim should drink it after drinking water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

IMPORTANT SYMPTOMS AND EFFECTS: See Sections 2 (Hazard Identification) and 11 (Toxicological Information).

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: This product should be avoided during pregnancy. During therapeutic use, pre-existing skin conditions, abnormal genital bleeding, venous disorders, including past history of deep vein thrombophlebitis or thromboembolic disorders, cerebral vascular or coronary artery disease, known or suspected carcinoma of the breast, carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia, undiagnosed abnormal genital bleeding, kidney/eye/nerve/blood vessel disease, severe headaches/migraines, diabetes, adrenal gland problems, cholestatic jaundice of pregnancy or jaundice with prior pill use or other liver conditions, hepatic adenomas or carcinomas, gallbladder or cardiovascular disease (with a greater risk for smokers) may be aggravated. Workplace exposure may also aggravate these conditions. Persons who may have hypersensitivity reactions to estrogens and/or progesterones 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 immediate medical attention. No specific antidote is known. Treatment should be supportive for symptoms.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not established.

AUTOIGNITION TEMPERATURE: Not established.

FLAMMABLE LIMITS & METHOD OF DETERMINATION (in air by volume, %): Not determined.

FIRE EXTINGUISHING MEDIA: Use extinguishing media appropriate for surrounding fire.

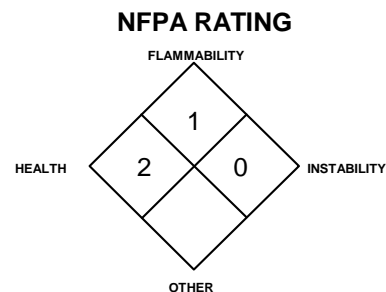
UNSUITABLE EXTINGUISHING MEDIA: None known.

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL: This product may ignite if highly heated for a prolonged period of time. When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., iron, carbon, sodium, magnesium and nitrogen oxides).

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. Contaminated protective equipment should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.



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

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: In the event of a spill, clear the area and protect people.

PROTECTIVE EQUIPMENT:

Small Spills: For incidental spills (e.g., 1 vial of tablets), wear double latex or nitrile disposable gloves and eye protection.

Large Spills: For large spills (e.g., a pallet of vials), protective apparel should be used with a respirator when there is any danger of airborne dusts being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit.

METHODS FOR CLEANUP AND CONTAINMENT:

Small Spills: Pick-up or sweep-up spilled tablets.

Large Spills: Trained personnel following pre-planned procedures should handle non-incident releases. Access to the spill areas should be restricted. Sweep up spilled product carefully, avoiding the generation of airborne dusts.

All Spills: Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Move to a secure area. Do not mix with wastes from other materials. If necessary, discard contaminated response equipment or rinse with soapy water before returning such equipment to service. Dispose of in accordance with applicable international, national, state, and local procedures (see Section 13, Disposal Considerations).

ENVIRONMENTAL PRECAUTIONS: Prevent material 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.

7. HANDLING and USE

PRECAUTIONS FOR SAFE HANDLING: Employees must be trained to properly handle this product. Particular care in working with this material must be practiced in pharmacies and other preparation areas, during manufacture of pharmaceutical preparations, and during patient administration. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics in work areas where this product is handled or stored. Wash thoroughly after handling this product or equipment and containers of this product. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Use of this product should be performed in a designated area for working with drugs. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. If necessary, work areas must be regularly cleaned and decontaminated.

PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store this product in original container. Store at 20°C to 25°C (68°F to 77°F). (See USP Controlled Room Temperature.) Inspect bottles containing this product for leaks or damage. Store away from incompatible materials (see Section 10, Stability and Reactivity).

SPECIFIC END USE(S): This product human pharmaceutical. Follow all industry standards for use of this product.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

Ventilation and Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS.

Occupational/Workplace Exposure Limits/Guidelines:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		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	mg/m ³
Norethindrone Acetate	51-98-9	NE	NE	NE	NE	NE	NE	NE	Watson STEL: 0.03 µg/m ³
Ethinyl Estradiol	57-63-6	NE	NE	NE	NE	NE	NE	NE	Watson WEL: 0.5 µg/m ³
Ferrous Fumarate	141-01-5	NE	NE	NE	NE	NE	NE	NE	Watson WEL: 1000 µg/m ³
Acacia	9000-01-5	NE	NE	NE	NE	NE	NE	NE	NE
Corn Starch	9005-25-8	10	NE	15 (total dust), 5 (resp. fract.)	NE	10 (total dust), 5 (resp. fract.)	NE	NE	Carcinogen: TLV-A4
Lactose Monohydrate	64044-51-5	NE	NE	NE	NE	NE	NE	NE	NE
Magnesium Stearate	557-04-0	10	NE	NE	NE	NE	NE	NE	Carcinogen: TLV-A4
Mannitol	87-78-5	NE	NE	NE	NE	NE	NE	NE	NE
Microcrystalline Cellulose Exposure limits are for celluloses	9004-34-6	10	NE	15 (total dust), 5 (resp. fraction)	NE	10 (total dust), 5 (resp. fraction)	NE	NE	NE
Povidone	9003-39-8	NE	NE	NE	NE	NE	NE	NE	Carcinogen: IARC-3
Sodium Starch Glycolate	9063-38-1	NE	NE	NE	NE	NE	NE	NE	NE
Spearmint Flavoring	Mixture	NE	NE	NE	NE	NE	NE	NE	NE
Sucralose	56038-13-2	NE	NE	NE	NE	NE	NE	NE	NE
Sucrose	57-50-1	10	NE	15 (total dust), 5 (resp. fract.)	NE	10 (total dust), 5 (resp. fraction)	NE	NE	Carcinogen: TLV-A4

NE = Not Established.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/CONTROL PARAMETERS (continued):

Occupational/Workplace Exposure Limits/Guidelines:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m ³	STEL mg/m ³	TWA mg/m ³	STEL mg/m ³	TWA mg/m ³	STEL mg/m ³		
Talc	14807-96-6	2 (respirable fraction)	NE	20 mppcf (containing < 1% quartz)		2 (respirable dust) and containing < 1% quartz	NE	Carcinogen: IARC-3, MAK-3b (respirable fraction), TLV-A4	

NE = Not Established. mppcf = Millions of Particle per Cubic Foot

International Occupational Exposure Limits: In addition to the exposure limit values cited in this section, other exposure limits have been established by various countries for the components of this product. The exposure limits given may not be the most current; individual country authorities should be contacted to check on more current limits.

CORN STARCH:

Belgium: TWA = 10 mg/m³, MAR 2002
 Korea: TWA = 10 mg/m³, 2006
 New Zealand: TWA = 10 mg/m³ (inspirable dust), JAN 2002
 Russia: STEL = 10 mg/m³, JUN 2003
 Switzerland: MAK-W = 3 mg/m³, DEC 2006
 United Kingdom: TWA = 10 mg/m³ (inhalable dust), OCT 2007
 United Kingdom: TWA = 4 mg/m³ (respirable dust), OCT 2007
 In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

FERROUS FUMARATE:

Australia: TWA = 0.1 mg(Fe)/m³, JUL 2008
 Belgium: TWA = 1 mg(Fe)/m³, MAR 2002
 Finland: TWA = 1 mg(Fe)/m³, SEP 2009
 Norway: TWA = 1 mg(Fe)/m³, JAN 1999

MAGNESIUM STEARATE:

New Zealand: TWA = 10 mg/m³ (inspirable dust), JAN 2002
 Sweden: TWA = 5 mg/m³, JUN 2005

MICROCRYSTALLINE CELLULOSE:

Belgium: TWA = 10 mg/m³, MAR 2002
 France: VME = 10 mg/m³, FEB 2006

MICROCRYSTALLINE CELLULOSE (continued):

Korea: TWA = 10 mg/m³, 2006
 Mexico: TWA = 10 mg/m³; STEL = 20 mg/m³, 2004
 The Netherlands: MAC-TGG = 2 mg/m³, 2003
 New Zealand: TWA = 10 mg/m³ (inspirable dust), JAN 2002
 Russia: STEL = 10 mg/m³, JUN 2003
 Switzerland: MAK-W = W 6 mg/m³, DEC 2006
 United Kingdom: TWA = 10 mg/m³ (inhalable), 2005
 United Kingdom: TWA = 4 mg/m³; STEL = 20 mg/m³ (respirable), 2005
 In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam, check ACGIH TLV

POVIDONE:

Russia: STEL = 10 mg/m³, JUN 2003

SUCROSE:

Belgium: TWA = 10 mg/m³, MAR 2002
 France: VME = 10 mg/m³, FEB 2006
 Korea: TWA = 10 mg/m³, 2006
 Mexico: TWA = 10 mg/m³; STEL = 20 mg/m³, 2004
 The Netherlands: MAC-TGG = 10 mg/m³, 2003
 New Zealand: TWA = 10 mg/m³ (inspirable dust), JAN 2002
 Peru: TWA = 10 mg/m³, JUL 2005
 United Kingdom: TWA = 10 mg/m³; STEL = 20 mg/m³, OCT 2007

SUCROSE (continued):

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

TALC:

Australia: TWA = 2.5 mg/m³, JUL 2008
 Austria: MAK-TMW = 2 mg/m³, resp, 2007
 Belgium: TWA = 2 mg/m³, MAR 2002
 Denmark: TWA = 0.3 f/cc, carc, MAY 2011
 Finland: TWA = 0.5 mg/m³, NOV 2011
 Finland: TWA = 5 mg/m³, granulated, SEP 2009
 Iceland: TWA = 0.3 f/cc, NOV 2011
 Japan: OEL = 0.5 mg/m³ (resp. dust), 2 mg/m³ (total dust), MAY 2009
 Korea: TWA = 2 mg/m³, 2006
 Mexico: TWA = 2 mg/m³ (respirable), 2004
 The Netherlands: MAC-TGG = 1 mg/m³, 2003
 New Zealand: TWA = 2 mg/m³ (respirable dust), JAN 2002
 Peru: TWA = 2 mg/m³, JUL 2005
 Sweden: TWA = 2 mg/cm³ (total dust); TWA = 1 mg/cm³ (resp. dust), JUN 2005
 Switzerland: MAK-W = 2 mg/m³, DEC 2006
 United Kingdom: TWA = 1 mg/m³ (resp. dust), OCT 2007
 In Argentina, Bulgaria, Colombia, Jordan, Singapore, Vietnam check ACGIH TLV

PERSONAL PROTECTIVE EQUIPMENT: Use of personal protective equipment must be in compliance with U.S. OSHA 29 CFR Subpart I (beginning at 1910.132), Canadian CSA Standards Z94.4-02 and Z94.3-02, EU EN 529:2005, CEN/TR 15419:2006, and CR 13464:1999. Please reference applicable regulations and standards for relevant details.

Respiratory Protection: Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

Eye Protection: No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, splash goggles or safety glasses should be considered.

Hand Protection: During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. During manufacture or other similar industrial operations, wear the appropriate hand protection for the process. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS.

Body Protection: Use appropriate protective clothing for the task (e.g., lab coat, etc.)

9. PHYSICAL and CHEMICAL PROPERTIES

The following information is for the product.

FORM: Round tablets.

ODOR: Odorless.

HOW TO DETECT THIS SUBSTANCE (identification properties): The appearance of this product is a distinguishing characteristic.

The following values are available for the active ingredient, Ferrous Fumarate :

FORM: Powdered solid.

MOLECULAR WEIGHT: 169.91

ODOR: Odorless.

BOILING POINT @ 760 mmHg: 355.5°C (671.9°F) [predict.]

VAPOR PRESSURE (air = 1) @ 25°C: 5.19E-06 mmHg [predict.]

EVAPORATION RATE (nBuAc = 1): Not applicable.

FLASH POINT: 183°C (361.4°F) [predicted]

SOLUBILITY IN WATER @ 25°C: Slightly soluble.

COEFFICIENT WATER/OIL DISTRIBUTION: -0.008 [predict.]

COLOR: As described in Section 2.

ODOR THRESHOLD: Not applicable.

The appearance of this product is a distinguishing characteristic.

COLOR: Reddish brown.

MOLECULAR FORMULA: C₄H₂FeO₄

ODOR THRESHOLD: Odorless.

MELTING POINT: 280°C (536°F)

SPECIFIC GRAVITY (water = 1) @ 20°C: 2.435 g/cm³

pH: Not available.

DECOMPOSITION TEMPERATURE: 220°C (428°F)

OTHER SOLUBILITIES: Not available.

The following values are available for the active ingredient, Ethinyl Estradiol:

FORM: Crystalline solid.

MOLECULAR WEIGHT: 296.41 g/mol

ODOR: Odorless.

BOILING POINT @ 760 mmHg: 457.2°C (854.96°F)

VAPOR PRESSURE (air = 1) @ 25°C: 2.67E-09 mmHg

SOLUBILITY IN WATER @ 27°C: 11.3 mg/L

OTHER SOLUBILITIES: Soluble in ethanol. Soluble in vegetable oils and in solutions of fixed alkali hydroxides.

COEFFICIENT WATER/OIL DISTRIBUTION: Log Kow = 3.67; Log P = 4.52

COLOR: Off-white to white.

MOLECULAR FORMULA: C₂₀H₂₄O₂

ODOR THRESHOLD: Not applicable.

MELTING POINT: 141-146°C (285.8-294.8°F)

SPECIFIC GRAVITY (water = 1): 1.21 g/cm³

FLASH POINT: 211.2°C (412.16°F)

9. PHYSICAL and CHEMICAL PROPERTIES (Continued)

The following values are available for the active ingredient, Norethindrone Acetate:

FORM: Crystalline solid.

MOLECULAR WEIGHT: 340.46

ODOR: Odorless.

BOILING POINT @ 760 mmHg: 454.7°C (850.5°F) [predict.]

VAPOR PRESSURE (air = 1) @ 25°C: 0 mmHg [predict.]

EVAPORATION RATE (nBuAc = 1): Not applicable.

SOLUBILITY IN WATER @ 25°C: 2.745 g/mL

COEFFICIENT WATER/OIL DISTRIBUTION: Log P = 3.796 [predict.]

COLOR: White to off-white.

MOLECULAR FORMULA: C₂₂H₂₈O₃

ODOR THRESHOLD: Not applicable.

MELTING POINT: 162°C (323.6°F)

SPECIFIC GRAVITY (water = 1): 1.15 g/cm³

FLASH POINT: 197.1°C (386.8°F) [predict.]

OTHER SOLUBILITIES: No information available.

10. STABILITY and REACTIVITY

CHEMICAL STABILITY: This product is not reactive.

DECOMPOSITION PRODUCTS: *Combustion:* If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g. iron, carbon, sodium, magnesium and nitrogen oxides).

Hydrolysis: None known.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. Acids and alkalies, and other chemicals that could affect its performance should be avoided.

POSSIBILITY HAZARDOUS REACTION/POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Avoid heat, light, and contact with incompatible chemicals.

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees using this product in an occupational setting. The following paragraphs describe the symptoms of exposure by route of exposure.

Inhalation: Inhalation of airborne dusts generated by this product may slightly irritate the nose, throat, and lungs. No other adverse effects known by inhalation.

Contact with Skin or Eyes: Acute skin contact is not expected to cause adverse effect if product is handled properly. Prolonged or repeated skin contact may cause dermatitis (dry, red skin). Contact with the eyes of airborne dusts generated by damaged tablets of this product may cause mild to moderate irritation, redness, and tearing.

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

Ingestion: Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product caused by poor hygiene practices may be harmful. Acute overdosage of iron may cause nausea and vomiting and, in severe cases, cardiovascular collapse and death. Other symptoms include pallor and cyanosis, melena, shock, drowsiness and coma. The estimated overdose of orally ingested iron is 300 mg/kg body weight. Symptoms of prolonged or repeated ingestion, as may occur when poor industrial hygiene is practiced, may include those described for 'Other Potential Health Effects'.

INJECTION: Injection is not a likely route of exposure for the form of this product.

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: In therapeutic use, the most common adverse effects can include nausea, vomiting, bleeding between menstrual periods, weight gain, breast tenderness, headache, and difficulty wearing contact lenses. When formulated in therapeutic use, estrogen-progestogen mixtures are known human carcinogens. Individuals who have had allergic reactions to products containing estrogens and/or progestins may experience allergic reactions to this material. Chronic exposure may cause temporary impairment of fertility in both genders; interference with egg and sperm production. In men, exposure to female hormones has been associated with testicular atrophy, increased risk of prostate cancer, gynecomastia, loss of libido and potency. Individuals who have had allergic reactions to products containing progestogens may experience allergic reactions to this material. May cause harm to the fetus during pregnancy.

Additional effects related to Ethinyl Estradiol can include headache, menstrual disorder, breast pain, abdominal pain, nausea, flu syndrome, acne, vaginal moniliasis, depression, diarrhea, lack or loss of strength and energy, weakness, dysmenorrhea, back pain, infections including upper respiratory and urinary infections, pharyngitis, inter-menstrual bleeding, migraine, vomiting, dizziness, nervousness, vaginitis, sinusitis, bronchitis, gastroenteritis, allergic reaction, urinary bladder inflammation, itching emotional lability, rash. Chronic toxicity increases the risk of cardiovascular disease, including myocardial infarction, cerebrovascular disease, thromboembolic disease, gallbladder disease, and certain cancers in some people. Chronic toxicity from Ethinyl Estradiol, like other estrogens, increases the risk for stroke, myocardial infarction and thromboembolic disease in certain populations. Jaundice, hypertension, nasal congestion, headache, dizziness and fluid retention may occur.



HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2*
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FLAMMABILITY HAZARD	(RED)	1
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PHYSICAL HAZARD	(YELLOW)	0
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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

11. TOXICOLOGICAL INFORMATION (Continued)

OTHER POTENTIAL HEALTH EFFECTS (continued):

Endometrial, breast, and certain liver cancers may occur at a higher incidence than the general population. Individuals who have had allergic reactions to products containing estrogens and/or progestogens may experience allergic reactions to this material. May cause harm to the fetus during pregnancy. 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. In therapeutic use, Ethinyl Estradiol can be carcinogenic. Additional adverse effects from therapeutic doses of Ethinyl Estradiol have included:

- Thrombophlebitis, arterial thromboembolism, pulmonary embolism, myocardial infarction, cerebral hemorrhage, cerebral thrombosis, high blood pressure, gallbladder disease, and hepatic adenomas or benign liver tumors.
- Mesenteric thrombosis and retinal thrombosis.
- Nausea, vomiting, gastrointestinal symptoms (such as abdominal cramps and bloating), breakthrough bleeding, spotting, change in menstrual flow, cessation of periods, temporary infertility after discontinuation of treatment, swelling, melasma that may persist, breast changes (tenderness, enlargement, secretion), changes in weight, changes in cervical erosion and secretion, diminution in lactation when given immediately postpartum, cholestatic jaundice, migraine, allergic rash, mental depression, reduced tolerance to carbohydrates, vaginal candidiasis, change in corneal curvature, and intolerance to contact lenses.
- Premenstrual syndrome, cataracts, fluid retention, vaginal bleeding, optic neuritis, changes in appetite, cystitis-like syndrome, headache, nervousness, dizziness, hirsutism, loss of scalp hair, erythema multiforme, erythema nodosum, hemorrhagic eruption, vaginitis, porphyria, impaired renal function, hemolytic uremic syndrome, Budd-Chiari syndrome, acne, changes in libido, and colitis.

Additional effects related to therapeutic use of Norethindrone Acetate can include headache, breast pain, irregular vaginal bleeding or spotting, stomach/abdominal cramps/bloating, nausea and vomiting, hair loss. More serious effects can include high blood pressure, liver problems, high blood sugar, fluid retention, enlargements of benign tumors of the uterus ("fibroids"), vaginal yeast infections, mental depression, breast lumps, dizziness and faintness, changes in speech, severe headaches, chest pain, shortness of breath, pains in your legs and changes in vision. 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. In therapeutic use, Norethindrone Acetate has shown carcinogenic effects. May cause harm to the fetus during pregnancy. 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.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Exposure to this product may cause the following health effects:

Acute: Accidental ingestion may be harmful. Eye contact with dusts may cause mechanical irritation.

Chronic: Fetal harm. Repeated skin contact may cause dermatitis (dry, red skin). This material is a known human carcinogen when used in post-menopausal estrogen therapy. Chronic exposure to this material, including absorption through the skin, may cause adverse effects as described under 'Other Potential Health Effects'. No other chronic effects have been reported from workplace exposure.

TARGET ORGANS:

Acute: *Industrial Exposure:* Skin, eyes, respiratory system (dusts from product). *Therapeutic Doses:* Cardiovascular, venous and neurological systems.

Chronic: *Industrial Exposure:* Skin. *Therapeutic Doses:* Fetal harm, and reproductive system and target organs as described under 'Other Potential Health Effects'.

IRRITANCY OF PRODUCT: Dusts from this product may irritate contaminated tissue.

SENSITIZATION TO THE PRODUCT: Individuals who have had allergic reactions to products containing estrogens and/or progestogens may experience allergic reactions to this material.

TOXICITY DATA: Currently the following toxicity data are available for the active components. Due to the large amount of data available, only available human data, skin irritation data, LD50 Oral-Rat, Oral-Mouse, Skin-Rabbit, Skin-Rat, LC50 Inhalation-Rat, Inhalation-Mouse and mutagenic data are provided in this SDS. Additional data for excipients are also available but are not presented in this SDS. Contact Allergen for more information.

FERROUS FUMARATE:

LDLo (Oral-Woman) 400 mg/kg; Behavioral: somnolence (general depressed activity); Lungs, Thorax, or Respiration: dyspnea; Gastrointestinal: nausea or vomiting

LD₅₀ (Oral-Rat) 3850 mg/kg

LD₅₀ (Oral-Mouse) 1570 mg/kg

ETHINYL ESTRADIOL:

TD (Oral-Woman) 102 mg/kg/5 years-intermittent: Tumorigenic: carcinogenic by RTECS criteria; Liver: tumors

ETHINYL ESTRADIOL (continued):

TDLo (Oral-Woman) 160 µg/kg; female 57 week(s) pre-mating: Reproductive: Fertility: other measures of fertility

TDLo (Oral-Woman) 2738 µg/kg/10 years-intermittent: Tumorigenic: carcinogenic by RTECS criteria; Liver: angiosarcoma

TDLo (Oral-Woman) 21 mg/kg/21 days-intermittent: Lungs, Thorax, or Respiration: dyspnea; Gastrointestinal: nausea or vomiting; Nutritional and Gross Metabolic: body temperature increase

TDLo (Oral-Woman) 672 µg/kg/96 weeks-intermittent: Blood: change in clotting factors

11. TOXICOLOGICAL INFORMATION (Continued)

TOXICITY DATA (continued):

ETHINYL ESTRADIOL (continued):

TDLo (Oral-Woman) 500 µg/kg; female 5 day(s) pre-mating; Reproductive: Maternal Effects: uterus, cervix, vagina; Fertility: other measures of fertility
TDLo (Unreported-Woman) 500 µg/kg; female 1-5 day(s) after conception; Reproductive: Fertility: female fertility index (e.g. # females pregnant per # sperm positive females; # females pregnant per # females mated)
TDLo (Oral-Woman) 500 µg/kg; female 5 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)
TDLo (Unreported-Woman) 20 µg/kg; female 4 day(s) after conception; Reproductive: Fertility: female fertility index (e.g. # females pregnant per # sperm positive females; # females pregnant per # females mated)
LD₅₀ (Oral-Rat) 960 mg/kg
LD₅₀ (Oral-Mouse) 950 mg/kg

NORETHINDRONE ACETATE:

TDLo (Oral-Woman) 2190 µg/kg; female 52 week(s) pre-mating; Reproductive: Fertility: female fertility index (e.g. # females pregnant per # sperm positive females; # females pregnant per # females mated)

NORETHINDRONE ACETATE (continued):

TDLo (Oral-Woman) 2 mg/kg; female 20 day(s) pre-mating; Reproductive: Maternal Effects: menstrual cycle changes or disorders
TDLo (Oral-Woman) 1150 µg/kg; female 23 day(s) pre-mating; Reproductive: Fertility: other measures of fertility
TDLo (Implant-Woman) 45 µg/kg; lactating female 15 day(s) post-birth; Reproductive: Maternal Effects: postpartum
TDLo (Implant-Woman) 366 µg/kg; female 21 week(s) pre-mating; Reproductive: Fertility: female fertility index (e.g. # females pregnant per # sperm positive females; # females pregnant per # females mated)
TDLo (Unreported-Woman) 15 mg/kg; female 13-30 week(s) after conception; Reproductive: Specific Developmental Abnormalities: urogenital system
Cytogenetic Analysis (Human Lymphocyte) 1 mg/L
Sister Chromatid Exchange (Human Lymphocyte) 1 mg/L
Micronucleus Test (Intraperitoneal-Mouse) 1 mg/kg
Dominant Lethal Test (Oral-Mouse) 1120 mg/kg/4 weeks
Sister Chromatid Exchange (Parenteral-Mouse) 1 mg/kg
Sex Chromosome Loss and Non-Disjunction (Oral-Mouse) 11200 mg/kg/4 weeks

CARCINOGENIC POTENTIAL OF COMPONENTS: Numerous epidemiological studies have been performed on the incidence of breast, endometrial, ovarian, and cervical cancer in women using oral contraceptives. The risk of having breast cancer diagnosed may be slightly increased among current and recent users of combination oral contraceptives. However, this excess risk appears to decrease over time after discontinuation of combination oral contraceptives and by 10 years after cessation the increased risk disappears. Some studies report an increased risk with duration of use while other studies do not and no consistent relationships have been found with dose or type of steroid. Some studies have found a small increase in risk for women who first use combination oral contraceptives before age 20. Most studies show a similar pattern of risk with combination oral contraceptives regardless of a woman's reproductive history or her family breast cancer history. Breast cancers diagnosed in current or previous oral contraceptive users tend to be less clinically advanced than in nonusers. 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 45-48. However, there continues to be controversy about the extent to which such findings may be due to differences in sexual behavior and other factors. In spite of many studies of the relationship between oral contraceptive use and breast and cervical cancers, a cause-and-effect relationship has not been established.

Benign hepatic adenomas are associated with oral contraceptive use, although the incidence of benign tumors is rare in the United States. Indirect calculations have estimated the attributable risk to be in the range of 3.3 cases/100,000 for users, a risk that increases after four or more years of use especially with oral contraceptives of higher dose.⁴⁹ Rupture of benign, hepatic adenomas may cause death through intra-abdominal hemorrhage.

Studies from Britain have shown an increased risk of developing hepatocellular carcinoma in long-term (> 8 years) oral contraceptive users. However, these cancers are extremely rare in the U.S. and the attributable risk (the excess incidence) of liver cancers in oral contraceptive users approaches less than one per million users.

The following information is specific to each active ingredient:

Ethinyl Estradiol: When used in estrogen therapy, post-menopausal, Ethinyl Estradiol is rated as an IARC-1 Carcinogenic Compound-Carcinogenic to Humans. There is sufficient evidence in humans for the carcinogenicity of post-menopausal estrogen therapy. Tumors of kidney, bone, testis, uterus and breast, were induced in animals exposed to estrogens. Independent studies have shown an increased risk of endometrial cancer in postmenopausal women placed on unopposed (without a progestin) systemic estrogen replacement therapy for prolonged periods. Since estrogens applied vaginally are extensively absorbed, the risk may apply to them also. The risk of endometrial cancer in systemic estrogen users, which appears to depend on duration of treatment and dose, was 5 to 10 times greater than in nonusers. However, studies have shown that administration of a progestin for 10 to 14 days of an estrogen cycle is associated with a lower incidence of endometrial hyperplasia and endometrial carcinoma than an estrogen-only cycle. There is no risk of endometrial cancer in patients who have undergone hysterectomies and, therefore, no documented need for concurrent progestin therapy.

Norethindrone Acetate: IARC-2A (Probably Carcinogenic to Humans)

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

CORN STARCH, MAGNESIUM STEARATE (as a stearate compound), SUCROSE: ACGIH TLV-A4 (Not Classifiable as Human Carcinogen)

POVIDONE: IARC-3 (Unclassifiable as to Carcinogenicity in Humans)

TALC: ACGIH TLV-A4 (Not Classifiable as a Human Carcinogen); IARC-3 (Unclassifiable as to Carcinogenicity in Humans); MAK-3B [respirable fraction]: (Substances Which Cause Concern that They Could Be Carcinogenic for Man But Cannot Be Assessed Conclusively Because of Lack of Data. 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.)

The remaining components of this product are not 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.

REPRODUCTIVE TOXICITY INFORMATION: This product should not be used in pregnant women. This product may cause fetal harm when administered to a pregnant woman. In the workplace, the risk to the fetus should be communicated and the appropriate action should be taken to prevent exposure in accordance with company policy and regulatory requirements. This product is rated by the FDA for therapeutic risk as Pregnancy Risk 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.)

11. TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION (continued):

Mutagenicity:

Norethindrone Acetate: No information on mutagenicity available.

Ethinyl Estradiol: Estradiol induced DNA breaks in hamster renal cells, but not in hepatocytes. The following additional mutagenic data from testing of Ethinyl Estradiol (only human data are provided).

Unscheduled DNA synthesis (Human Mammary Gland) 5 nmol/L

DNA Inhibition (Human Lymphocyte) 50 µmol/L

Cytogenetic Analysis (Human Lymphocyte) 1 mg/L

Sister Chromatid Exchange (Human Lymphocyte) 1 mg/L

DNA Repair (Human Liver) 5 µmol/L/20 hours

Embryotoxicity/Teratogenicity:

Norethindrone Acetate: Many studies have found no effects on fetal development associated with long-term use of contraceptive doses of oral progestins. The few studies of infant growth and development that have been conducted have not demonstrated significant adverse effects. It is nonetheless prudent to rule out suspected pregnancy before initiating any hormonal contraceptive use. However, several reports suggest an association between intrauterine exposure to progestational drugs in the first trimester of pregnancy and congenital abnormalities in male and female fetuses. Some progestational drugs induce mild virilization of the external genitalia of female fetuses. Use of synthetic progestins during pregnancy has resulted in and increase in the risk of hypospadias in a male fetus.

Ethinyl Estradiol: No specific data available for Ethinyl Estradiol. Reports suggest a link between fetal exposure to female sex hormones and congenital abnormalities, including Down's Syndrome. These include heart defects, and limb defects.

Reproductive Toxicity:

Norethindrone Acetate: 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.

Ethinyl Estradiol: Small amounts of oral contraceptive steroids have been identified in the milk of nursing mothers, and a few adverse effects on the child have been reported, including jaundice and breast enlargement. In addition, oral contraceptives given in the postpartum period may interfere with lactation by decreasing the quantity and quality of breast milk. 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.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, ACGIH Biological Exposure Indices (BEIs) have not been 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, Norethindrone Acetate are available for mobility, persistence and biodegradability and bioaccumulation potential; however, this information is not provided in this SDS. Contact Allergan for more information.

MOBILITY: This product has not been tested for mobility in soil.

PERSISTENCE AND BIODEGRADABILITY: This product has not been tested for persistence or biodegradability. It is expected that the components will slowly degrade in the environment and form a variety of organic and inorganic materials; however, no specific information is known.

BIO-ACCUMULATION POTENTIAL: This product has not been tested for bio-accumulation potential.

ECOTOXICITY: This product may be harmful to aquatic and terrestrial organisms; all releases to terrestrial, atmospheric and aquatic environments should be avoided. No aquatic toxicity data are available for the Norethindrone Acetate and Ferrous Fumarate active ingredients. The Ethinyl Estradiol component may cause harm to organisms in the aquatic environment. Studies have been conducted concerning the feminization of marine organisms recently on a large scale. Up to 38% of Chinook Salmon found in the Sacramento and San Joaquin rivers were found to exhibit signs of feminization. Ethinyl Estradiol was found to be one of the many steroid contaminants in this river system. Feminization occurs for the most part during larval development. Impacts reproductive potential of marine organisms by essentially limiting the number of males present in a population. Ethinyl Estradiol is most commonly found in sub-lethal concentrations; however even sub-lethal concentrations when present for multiple generations have negative effects. A study on the development of amphipods showed significant results concerning feminization and adverse effects associated with Ethinyl Estradiol concentrations. Hermaphroditism, disturbed maturation of germ cells, and disturbed spermatogenesis were found in all post F1 generation males exposed to Ethinyl Estradiol. Toxic effects in aquatic organisms have included:

- Feminization of marine organisms
- Disturbed development and lowered fecundity
- Altered courtship behaviors in some fish

OTHER ADVERSE EFFECTS: This product does not contain any component with known ozone depletion potential.

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.

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.

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

13. DISPOSAL CONSIDERATIONS (Continued)

U.S. EPA WASTE NUMBER: Not applicable to wastes consisting only of this product.

EUROPEAN WASTE CODES: 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 REGULATIONS: 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 is NOT classified as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product is NOT classified as Dangerous Goods, by rules of IATA.

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

UNITED NATIONS ECONOMIC COMMISSION FOR EUROPE (UNECE): This product is NOT classified by the United Nations Economic Commission for Europe to be dangerous goods. Refer to current regulations for all additional provisions other information not given here.

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: See the information under the UN ADR and IMO, in this section.

ENVIRONMENTAL HAZARDS: This product is neither environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN). No component meets the criteria of a marine pollutant according to the IMDG Code.

15. REGULATORY INFORMATION

UNITED STATES 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 any component of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

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

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

Other U.S. Federal Regulations: Not applicable.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): Ethinyl Estradiol and Norethindrone Acetate are on the California Proposition 65 lists. WARNING! This product contains compounds known to the state of California to cause cancer and developmental toxicity.

CANADIAN REGULATIONS:

Canadian DSL Inventory Status: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it is exempted from requirements of the DSL/NDL Inventory.

Canadian Environmental Protection Act (CEPA) Priorities Substances Lists: The components of this product are not on the CEPA Priorities Substances Lists.

Other Canadian Regulations: Not 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.

EUROPEAN REGULATIONS:

Safety, Health, and Environmental Regulations/Legislation Specific for the Product: When formulated in a finished medicinal product for human use, this material is 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 (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): **WARNING! CANCER HAZARD. MAY CAUSE CANCER THROUGH THERAPEUTIC USE. MAY BE HARMFUL IF SWALLOWED. MAY BE ABSORBED THROUGH THE SKIN. CHRONIC EXPOSURE MAY CAUSE TEMPORARY IMPAIRMENT OF FERTILITY IN BOTH GENDERS. MAY CAUSE HARM TO THE FETUS DURING PREGNANCY. MAY CAUSE ALLERGIC REACTIONS FROM THERAPEUTIC USE. MAY CAUSE ADVERSE EFFECTS ON AQUATIC ORGANISMS.** Do not take internally without prescription. Avoid unnecessary contact with skin, eyes, and clothing. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. **FIRST-AID:** In case of contact, flush skin or eyes with plenty of water. If adverse respiratory reaction occurs, give oxygen and seek immediate medical attention. If ingested, DO NOT induce vomiting—seek immediate medical attention. **IN CASE OF FIRE:** Use water fog, dry chemical, CO₂, or “alcohol” foam. **IN CASE OF SPILL:** Pick up or sweep up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Safety Data Sheet for additional information.

16. OTHER INFORMATION (Continued)

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 AND CLASSIFICATION 67/548/EEC: 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 OF COMPONENTS:

CLP Regulation (EC) 1272/2008

Ethinyl Estradiol: Published and Self-Classification

Classification: Reproductive Toxicity Category 1A, Carcinogenic Category 1B, Acute Oral Toxicity Category 4, Aquatic Toxicity Category 4

Hazard Statements: H360Df: May damage the unborn child. Suspected of damaging fertility. H350: May cause cancer. H341: Suspected of causing genetic effects. H302: Harmful if swallowed. H413: May cause long-lasting harmful effects to aquatic life.

Ferrous Fumarate: Self-Classification

Classification: Acute Oral Toxicity Category 4

Hazard Statements: H302: Harmful if swallowed.

Norethindrone Acetate: Self-Classification

Classification: Reproductive Toxicity Category 1B, Carcinogenic Category 2

Hazard Statements: H360Df: May damage the unborn child. Suspected of damaging fertility. H351: Suspected of causing cancer.

All Remaining Components: An official classification for these substances has not been published in the CLP 1272: 2008 and a self-classification is not applicable.

67/548/EEC:

Ethinyl Estradiol: Published and Self-Classification

Classification: Reproductive Toxicity Category 2, Reproductive Toxicity Category 3, Carcinogenic Category 2, Germ Cell Mutagen Category 3, Harmful, Dangerous for the Environment

Risk Phrases: R61: May cause harm to the unborn child. R62: Possible risk of impaired fertility. R22: Harmful if swallowed. R45: May cause cancer. R68: Possible risk of irreversible effects. R53: May cause long-term adverse effects in the aquatic environment.

Ferrous Fumarate: Self-Classification

Classification: Harmful

Risk Phrases: R22: Harmful if swallowed.

Norethindrone Acetate: Self-Classification

Classification: Reproductive Toxicity Category 2, Reproductive Toxicity Category 3, Carcinogenic Category 3

Risk Phrases: R61: May cause harm to the unborn child. R62: Possible risk of impaired fertility. R40: Limited evidence of a carcinogenic effect.

All Remaining Components: An official classification for these substances has not been published in Commission Directives and a self-classification is not applicable.

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.

REVISION DETAILS: New.

This Safety Data Sheet is offered pursuant to OSHA's Hazard Communication Standard, 29 CFR, 1910.1200. Other government regulations must be reviewed for applicability to this product. To the best of Allergan, knowledge, the information contained herein is reliable and accurate as of this date; however, accuracy, suitability or completeness are not guaranteed and no warranties of any type, either express or implied, are provided. The information contained herein relates only to this specific product. If this product is combined with other materials, all component properties must be considered. Data may be changed from time to time. Be sure to consult the latest edition.

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc. • PO Box 1961, Hilo, HI 96721 • 800/441-3365 • 808/969-4846

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