

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules (Greenstone LLC)

Product Code(s) PF00039

Trade Name: Not established

Chemical Family: Not determined

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product used as contraceptive agent

1.3. Details of the supplier of the safety data sheet

Greenstone LLC
100 Route 206 North
Peapack, NJ 07977
800-435-7095

1.4. Emergency telephone number

Emergency Telephone CHEMTREC (24 hours): 1-800-424-9300

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Germ cell mutagenicity Category 2 - (H341)
Carcinogenicity Category 1A - (H350)
Reproductive toxicity Category 1A - (H360FD)

2.2. Label elements

Signal word Danger

Hazard statements

H341 - Suspected of causing genetic defects
H350 - May cause cancer
H360FD - May damage fertility. May damage the unborn child

Precautionary Statements

P280 - Wear protective gloves/protective clothing/eye protection/face protection
P201 - Obtain special instructions before use
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P202 - Do not handle until all safety precautions have been read and understood



2.3. Other hazards

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Other hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Hazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Norethindrone Acetate	200-132-0	51-98-9	1 - 5	Carc.1B; H350 Repr. 1A; H360FD	
Ethinyl Estradiol	200-342-2	57-63-6	0.1 - 1	Carc.1A;H350 Repr.1A;H360FD Tox.4, H302 Acute1;H400 Aquatic Chronic1;H410	

NonHazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Sesame oil	232-370-6	8008-74-0	10 - 30	Not Listed	
Gelatin	232-554-6	9000-70-8	10 - 30	Not Listed	
Ferrous fumarate	205-447-7	141-01-5	10 - 30	Not Listed	

Full text of H- and EUH-phrases: see section 16

Additional information Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

- Inhalation** Remove to fresh air. Seek immediate medical attention/advice.
- Eye contact** Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
- Skin contact** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do

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not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO₂, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Contain the source of the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean spill area thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

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Advice on safe handling

Restrict access to work area. Avoid open handling. Ground and bond all bulk transfer equipment. Minimize dust generation. Use process containment, local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eyes, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical product used as. contraceptive agent.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

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

Norethindrone Acetate

Manufacturer OEL: 0.8 ug/m³, Skin

Ethinyl Estradiol

Manufacturer OEL: 0.04 ug/m³, Skin

Ferrous fumarate

ACGIH TLV	1 mg/m ³
Bulgaria	1.0 mg/m ³
Denmark	1 mg/m ³
Finland	1 mg/m ³
Ireland	1 mg/m ³
	STEL: 2 mg/m ³
Spain	1 mg/m ³
Switzerland	1 mg/m ³
OSHA PEL	(vacated) TWA: 1 mg/m ³ Fe
United Kingdom	TWA: 1 mg/m ³

Gelatin

Russia MAC: 10 mg/m³

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section. It is recommended that all operations be fully enclosed and no air recirculated.

Environmental exposure controls

No information available.

Personal protective equipment

Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Eye/face protection

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the

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standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Tablet
Color	Pink
Molecular formula (MF):	Mixture
Molecular weight	Mixture
Odor	No data available.
Odor threshold	No data available

Property

Values

pH	
Melting point / freezing point	No data available
Boiling point / boiling range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available

9.2. Other information

Liquid Density	No data available
Bulk density	No data available

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Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

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

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Long Term:

This material may cause adverse effects on fertility, the developing fetus, cardiovascular system, or blood. May cause effects in liver, cardiovascular system, gastrointestinal system. Based on clinical trials in humans, possible adverse effects following exposure to this compound may include: headache, nausea. The most common adverse effects seen during clinical use of oral contraceptives are menstrual irregularities. The use of oral contraceptives is associated with increased risks of myocardial infarction, thromboembolism, stroke, hepatic neoplasia, and gallbladder disease.

Known Clinical Effects:

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

Norethindrone Acetate

Rat Oral LD50 > 5010 mg/kg

Mouse Oral LD50 > 5010 mg/kg

Ethinyl Estradiol

Mouse Oral LD50 1737 mg/kg

Rat Oral LD50 1200 mg/kg

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Sesame oil		> 2 g/kg (Rabbit)	-
Ferrous fumarate	= 3850 mg/kg (Rat)	-	-
Ethinyl Estradiol	= 960 mg/kg (Rat)	-	-

Acute Toxicity Comments:

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

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

Norethindrone Acetate

Embryo / Fetal Development Rat No route specified 1 mg/kg/day LOEL Teratogenic

Embryo / Fetal Development Mouse No route specified 0.5 mg/kg/day LOEL Teratogenic

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Embryo / Fetal Development Rat No route specified 3.5 mg/kg/day Not Teratogenic

Ethinyl Estradiol

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

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

Norethindrone Acetate

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

Ethinyl Estradiol

Bacterial Mutagenicity (Ames) *Salmonella* Negative
Chromosome Aberration Human Lymphocytes Positive
Sister Chromatid Exchange Human Lymphocytes Positive
Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive
In Vivo Micronucleus Mouse Bone Marrow Positive

Norethindrone Acetate

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

Ethinyl Estradiol

80 Week(s) Mouse Oral, in feed 0.07 mg/kg/day LOEL Tumors, Pituitary gland
104 Week(s) Rat No route specified 0.07 mg/kg/day LOEL Malignant tumors, Liver
105 Week(s) Rat Oral, in feed 0.053 mg/kg/day NOEL Not carcinogenic

Carcinogenicity See below

Norethindrone Acetate

IARC Group 2B (Possibly Carcinogenic to Humans)

Ethinyl Estradiol

IARC Group 1 (Carcinogenic to Humans)

Section 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ethinyl Estradiol

Oncorhynchus mykiss (Rainbow Trout) LC50 96 hours 1.6 mg/l
Daphnia magna (Water Flea) EC50 48 5.7 mg/L
Algae EC50 0.84 mg/l

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

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12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

Chemical Name	PBT and vPvB assessment
Ferrous fumarate	The substance is not PBT / vPvB

12.6. Other adverse effects

Other adverse effects No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

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

Section 14: TRANSPORT INFORMATION

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

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

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Sesame oil		
CERCLA/SARA Section 313 de minimus %		Not Listed
California Proposition 65		Not Listed
TSCA		Present
EINECS		232-370-6
AICS		Present
Gelatin		
CERCLA/SARA Section 313 de minimus %		Not Listed
California Proposition 65		Not Listed
TSCA		Present
EINECS		232-554-6
AICS		Present
Ferrous fumarate		
CERCLA/SARA Section 313 de minimus %		Not Listed
California Proposition 65		Not Listed
TSCA		Present
EINECS		205-447-7
AICS		Present

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Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)

Schedule 5
Schedule 6
Schedule 2
Schedule 4

Norethindrone Acetate

CERCLA/SARA Section 313 de minimus %
California Proposition 65
EINECS
AICS

Not Listed
developmental toxicity 10/1/1991
200-132-0
Present

Ethinyl Estradiol

CERCLA/SARA Section 313 de minimus %
California Proposition 65

Not Listed
carcinogen 1/1/1988
developmental toxicity 4/1/1990 when mixed with Norethisterone
Present

TSCA

EINECS

AICS

Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)

200-342-2
Present
Schedule 4

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

H350 - May cause cancer
H360FD - May damage fertility. May damage the unborn child
H302 - Harmful if swallowed
H400 - Very toxic to aquatic life
H410 - Very toxic to aquatic life with long lasting effects

Prepared By Product Stewardship Hazard Communication
Global Environment, Health, and Safety Operations

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Reason for revision Updated Section 11 - Toxicology Information.

It is believed that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.