SAFETY DATA SHEET

Revision Date 16-Jul-2019 **Version** 1.01

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

Product identifier
Product Name femhrt

Other means of identification
Product Code FG00140
Synonyms Norethindrone acetate/ethinyl estradiol tablets

Recommended use of the chemical and restrictions on use
Recommended Use estrogen plus progestin indicated in a woman with a uterus for: • Treatment of Moderate to Severe Vasomotor Symptoms due to Menopause and Prevention of Postmenopausal Osteoporosis

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet
Manufacturer
Allergan plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525
E-mail address SDS@Allergan.com

Emergency telephone number
Emergency Telephone Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status
This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Serious eye damage/eye irritation	Category 1
Germ cell mutagenicity	Category 2
Carcinogenicity	Category 1A
Reproductive toxicity	Category 1B
Effects on or via lactation	Yes
Specific target organ toxicity (repeated exposure)	Category 2

Label elements

Emergency Overview

Danger

Hazard statements
H318 - Causes serious eye damage
H341 - Suspected of causing genetic defects
H350 - May cause cancer

H360 - May damage fertility or the unborn child
H362 - May cause harm to breast-fed children
H373 - May cause damage to organs through prolonged or repeated exposure

Appearance Tablet **Physical state** Solid **Odor** No information available

Chemical Name	Symptoms
Norethindrone Acetate	Common adverse effects from the therapeutic use of this product are weight gain, nausea, edema, and acne. These effects may also be experienced from occupational exposure. Additional effects include blood coagulation, swelling, changes in weight, jaundice, headache, migraine, mood swings, depression, insomnia, and optic nerve inflammation (which can lead to partial or complete vision loss).
Ethinyl Estradiol	The most common effects from therapeutic use of products containing Ethinyl Estradiol are headache, menstrual disorder, breast pain, abdominal pain, nausea, flu syndrome, acne, vaginal moniliasis, depression, diarrhea, asthenia, dysmenorrhea, back pain, infection, pharyngitis, inter-menstrual bleeding, migraine, vomiting, dizziness, nervousness, vaginitis, sinusitis, cystitis, bronchitis, gastroenteritis, allergic reaction, urinary tract infection, pruritus, emotional lability, rash, upperrespiratory infection. 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. Endometrial, breast, and certain liver cancers may occur at a higher incidence than the general population.
Donepezil HCL	The most common symptoms seen in therapeutic use include: nausea, diarrhea, insomnia, vomiting, muscle cramp, fatigue and anorexia.
Memantine Hydrochloride	Most common are dizziness, headache, confusion and constipation

Chemical Name	Medical Conditions Aggravated by Exposure
Norethindrone Acetate	In therapeutic use, dermatitis and other skin disorders as well as menstrual disorders, pre-diabetic and diabetic conditions, heart disease, liver disorders, and benign or malignant liver tumors may be aggracted by exposure to this product. Persons handling the product in the workplace may experience adverse reaction under the same conditions.
Ethinyl Estradiol	Pre-existing skin conditions may be aggravated by repeated overexposures to this compound. This compound should not be used when pregnant. The following preexistingconditions may be aggravated by therapeutic doses of this compound: adrenal gland problems, heart disease, high blood pressure, breast cancer, diabetes, kidney/eye/nerve/blood vessel disease, severe headaches/migraines, heart disease, liver conditions and gallbladder disease.
Donepezil HCL	When administered for therapeutic use, pre-existing asthma,ulcers, cardiac abnormalities, hepatic, bladder and neurological conditions may be aggravated by exposure
Memantine Hydrochloride	Contraindication include hypersensitivity to any component of this product hepatic impairment

Precautionary statements
P280 - Wear eye protection/ face protection
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician
P202 - Do not handle until all safety precautions have been read and understood

P281 - Use personal protective equipment as required
P405 - Store locked up
P201 - Obtain special instructions before use
P260 - Do not breathe dusts or mists
P263 - Avoid contact during pregnancy/while nursing
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P314 - Get medical advice/attention if you feel unwell
P501 - Dispose of contents/ container to an approved waste disposal plant

Other Information

Unknown Acute Toxicity 2% of the mixture consists of ingredient(s) of unknown toxicity

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	EINECS	Weight-%
Norethindrone Acetate	51-98-9	200-132-0	15 - 40*
Ethinyl Estradiol	57-63-6	200-342-2	10 - 30*
CALCIUM STEARATE NF	1592-23-0	216-472-8	10 - 30*
MICROCRYSTALLINE CELLULO(AVICEL PH102)	9004-34-6	232-674-9	3 - 7*
CORN STARCH NF	9005-25-8	232-679-6	1 - 5*
Donepezil HCL	120011-70-3	N/A	0.1 - 1*
Memantine Hydrochloride	41100-52-1	255-219-6	0.1 - 1*
Oleic Acid	112-80-1	204-007-1	<0.1*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

First aid measures

General advice If symptoms persist, call a physician. Do not breathe dust/fume/gas/mist/vapors/spray. Do not get in eyes, on skin, or on clothing.

Eye contact Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. If symptoms persist, call a physician.

Skin Contact Consult a physician if necessary. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation Remove to fresh air. Call a physician. If breathing is irregular or stopped, administer artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.

Ingestion Rinse mouth. Drink plenty of water. If symptoms persist, call a physician. Do NOT induce vomiting.

Chemical Name
Norethindrone Acetate

Note to physicians
Handle this material following standard medical practices and following the recommendations presented on the Package Insert. Naproxen sodium extended-release tablets are contraindicated in patients with known hypersensitivity to naproxen. Naproxen

	sodium extended-release tablets should not be given to patients who have experienced asthma, urticarial, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients. Naproxen sodium extended-release tablets are contraindicated for the treatment of per-operative pain in the setting of coronary artery bypass graft (CABG) surgery.
Ethinyl Estradiol	This material is contraindicated in womon who have the following conditions: Thrombophlebitis or thromboembolic disorders, history of deep vein thrombophlebitis or thromboembolic disorders, cerebrovascular or coronary artery disease (current or history), valvular heart disease with thrombogenic complications, uncontrolled hypertension, diabetes with vascular involvement, headaches with focal neurological symptoms (such as aura), major surgery with prolonged immobilization, known or suspected carcinoma of the breast or personal history of breast cancer, carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia, undiagnosed abnormal genital bleeding, cholestatic jaundice of pregnancy or jaundice with prior pill use, hepatic adenomas or carcinomas, or active liver disease, known or suspected pregnancy, hypersensitivity to component of the product. Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with the extent of smoking (in epidemiologic studies, 15 or more cigarettes per day was associated wit ha significantly increased risk) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke. The use of oral contraceptives is associated with increased risk of several serious conditions including venous and arterial thrombotic and thromboembolic events (such as myocardial infarction, thromboembolism, and stroke), hepatic neoplasia, gallbladder disease, and hypertension, although the risk of serious morbidity or mortality is very small in healthy women without underlying risk factors. The risk of morbidity and mortality increases significantly in the presence of other underlying risk factors such as certain inherited thrombophilias hypertension, hyperlipidemias, obesity and diabetes.
Donepezil HCL	Overdosage with cholinesterase inhibitors can result in cholinergic crisischaracterized by severe nausea, vomiting, salivation, sweating, bradycardia,hypotension, respiratory depression, collapse and convulsions. Increasingmuscle weakness is a possibility and may result in death if respiratorymuscles are involved. Tertiary anticholinergics such as atropine may beused as an antidote for ARICEPT overdosage. Intravenous atropine sulfatetitrated to effect is recommended: an initial dose of 1.0 to 2.0 mg IV withsubsequent doses based upon clinical response.
Memantine Hydrochloride	Conditions that raise urine pH may decrease urinary elimination of Memantine, resulting in increased plasma levels of memantine.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
Fire may produce irritating, corrosive and/or toxic gases.

Explosion data

Sensitivity to Mechanical Impact Not impact sensitive.

Sensitivity to Static Discharge Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions Prevent entry into waterways, sewers, basements or confined areas. Do not flush into surface water or sanitary sewer system. See Section 12 for additional ecological information.

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

Methods for cleaning up Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Advice on safe handling Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.

Storage Conditions Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children.

Incompatible materials None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines .

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL (ug/m³)
Norethindrone Acetate 51-98-9	N/A	N/A	N/A	0.5 ug/m^3
Ethinyl Estradiol 57-63-6	N/A	N/A	N/A	0.01 ug/m^3
CALCIUM STEARATE NF 1592-23-0	TWA: 10 mg/m³ inhalable particulate matter except stearates of toxic metals TWA: 3 mg/m³ respirable particulate matter except stearates of toxic metals	N/A	N/A	N/A
MICROCRYSTALLINE CELLULO(AVICEL PH102) 9004-34-6	TWA: 10 mg/m³	TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 15 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction (vacated) TWA: 5 mg/m³ (vacated) STEL: 10 mg/m³	TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust TWA: 1 mg/m³	N/A
CORN STARCH NF 9005-25-8	TWA: 10 mg/m³	TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 15 mg/m³	TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust	N/A

		total dust (vacated) TWA: 5 mg/m³ respirable fraction		
Donepezil HCL 120011-70-3	N/A	N/A	N/A	17
Memantine Hydrochloride 41100-52-1	N/A	N/A	N/A	67

NIOSH IDLH Immediately Dangerous to Life or Health

Other Information Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

Appropriate engineering controls

Engineering Controls The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

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

Skin and body protection During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Solid	**Appearance**	Tablet
Color	No information available	**Odor**	No information available
Odor threshold	No information available		

Property	**Values**
pH	No information available
Melting point/freezing point	No information available
Boiling point / boiling range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limit in Air	
Upper flammability limit:	No information available
Lower flammability limit:	No information available
Vapor pressure	No information available
Vapor density	No information available
Specific Gravity	No information available
Water solubility	No information available
Solubility in other solvents	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available

Explosive properties No information available
Oxidizing properties No information available

Other Information

Molecular weight No information available
VOC Content (%) No information available
Density No information available
Bulk density No information available

10. STABILITY AND REACTIVITY

Reactivity
Not defined As Reactive substance

Chemical stability
Stable under normal conditions.

Possibility of Hazardous Reactions
None under normal processing.

Conditions to avoid
Aerosol formation.

Incompatible materials
None known based on information supplied.

Hazardous Decomposition Products
None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute toxicity

Chemical Name	Inhalation	Eye contact	Skin Contact	Ingestion
Norethindrone Acetate	Inhalation of airborne dusts generated by this product may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.	Contact of this product with the eyes may cause moderate to severe irritation, redness, and tearing.	Contact with the skin may cause mild irritation, which is alleviated upon rinsing. Prolonged or reaped skin contact may cause dermatitis (dry, red skin).	Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause adverse symptoms. Symptoms of ingestion overexposure may include nausea, vomiting, and diarrhea.
Ethinyl Estradiol	Inhalation of airborne dusts generated by this product may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.	Contact with eyes may cause irritation.	Repeated or prolonged skin contact may cause allergic reactions with susceptible persons, Prolonged contact may cause redness and irritation, Contact with the skin may cause mild irritation, which is alleviated upon rinsing. Prolonged or reaped skin contact may cause dermatitis (dry, red skin).	If this compound 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.
Donepezil HCL	Inhalation of this compound may irritate the nose, throat, andlungs. No information is available on other possible effects.	Contact with the eyes of airborne dusts generated by this product may cause mild to moderate irritation, redness, and tearing.	Contact with the skin may cause irritation. Prolonged orrepeated skin contact may cause dermatitis (dry, red skin).	Ingestion is not a significant route of occupational overexposure.If swallowed, irritation of the gastrointestinal tract may occur with nausea,vomiting, and diarrhea.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Norethindrone Acetate	6 gm/kg (rat)	N/A	N/A
Ethinyl Estradiol	= 960 mg/kg (Rat)	N/A	N/A
CALCIUM STEARATE NF	> 10 g/kg (Rat)	N/A	N/A
MICROCRYSTALLINE CELLULO(AVICEL PH102)	> 5 g/kg (Rat)	> 2 g/kg (Rabbit)	> 5800 mg/m^3 (Rat) 4 h
Donepezil HCL	32.6 mg/kg (rat)	N/A	N/A
Memantine Hydrochloride	328 mg/kg Oral Rat (Female)	N/A	N/A
Oleic Acid	= 25 g/kg (Rat)	N/A	N/A

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Norethindrone Acetate	Not mutagenic in the standard battery of tests.	Suspected human carcinogen.	May cause irregular vaginal bleeding, decreased libido, and changes in cervical erosion and secretions.	Small amounts of progestin pass into the breast milk, resulting in steroid levels in infant plasma of 1 to 6% of the levels of maternal plasma. Lower infant weight gain, decreased milk production, and decreased composition of nitrogen and protein content of human milk have been associated with norethindrone and estrogenic agents.
Ethinyl Estradiol	Estradiol induced DNA breaks in hamster renal cells, but not in hepatocytes.	There is sufficient evidence in humans for the carcinogenicity of post-menopausal estrogen therapy. There is sufficient evidence in experimental animals for the carcinogenicity of estradiol and estrone.	Studies in mice show prenatal exposure of ethinylestradiol indcues reproductive abnormalities, including polyovular follicles, over-independent vaginal epithelial stratification and cornification. Exposure to ethinylestradoil also is linked to suppression of testicular testosterone levels, lower sperm head counts, lower weights of the testis, epididymis and prostate in rats.	Very small amounts are excreted in milk.
Donepezil HCL	Not mutagenic in the standard battery of tests.	Not suspected of being a human carcinogen.	This product does not contain any known or suspected reproductive hazards.	No information available
Memantine Hydrochloride	Not mutagenic in the standard battery of tests.	Animal studies in mice and rats have not shown carcinogenicity.	Studies in rats have not shown fertility impairment. Decreased pup weights and an increase in incompletely ossified vertebrae was observed at slightly maternally toxic doses with the NOEL of approximately 3 times the maximum recommended human therapeutic dose.	It is not known whether the drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this drug is administered to nursing mothers.
Oleic Acid	Not Suspected of being a	Not suspected of being a	Not suspected of being a	No information available

	Mutagen.	human carcinogen.	reproductive hazard.	

Chemical Name	STOT - single exposure	STOT - repeated exposure
Norethindrone Acetate	No information available.	Product may irritate exposed tissue, especially is contact is prolonged.
Ethinyl Estradiol	Toxicity is unlikely following acute single exposure of excessive amounts.	Acute poisoning results in mild, self-limiting effects, usually involving the gastrointestinal tract (GI). Chronic toxiticty increases risk of cardiovascular disease, including myocardial infarction, cerebrovascular disease, thromboembolic disease, gallbladder disease, and certain cancers in some people.

Chronic toxicity May cause adverse liver effects. Contains a known or suspected reproductive toxin.
Target Organ Effects Central nervous system, Eyes, Gastrointestinal tract (GI), liver, Reproductive System, Respiratory system, Skin, Urinary Tract.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 2% of the mixture consists of ingredient(s) of unknown toxicity
The following values are calculated based on chapter 3.1 of the GHS document .
ATEmix (oral) 3504 mg/kg
ATEmix (dermal) 40040 mg/kg
ATEmix (inhalation-dust/mist) 116.1 mg/l

12. ECOLOGICAL INFORMATION

Ecotoxicity

63.9% of the mixture consists of components(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Crustacea
Oleic Acid 112-80-1	N/A	205: 96 h Pimephales promelas mg/L LC50 static	N/A

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient
Norethindrone Acetate 51-98-9	No information available	No information available	No information available	N/A
Ethinyl Estradiol 57-63-6	NOT READILY BIODEGRADABLE	No information available	Mobility in soil	3.67
Donepezil HCL 120011-70-3	This compound has not been tested for persistence or biodegradability	Based on the BCF, the potential for bioaccumulation in aquatic organisms is high.	This product has not been tested for mobility in soil	Log P = 4.708 (predict.)
Memantine Hydrochloride 41100-52-1	N/A	Based on the BCF, the potential for bioaccumulation in aquatic organisms is high.	Low mobility in soil	3.28

Other adverse effects No information available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging Do not reuse container. Dispose of contents/containers in accordance with local regulations.

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated

ICAO (air) Not regulated

IATA Not regulated

IMDG Not regulated

ADR Not regulated

ADN Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA	Not Listed
DSL/NDSL	Not Listed
EINECS/ELINCS	Not Listed

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

US Federal Regulations

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B)

Chemical Name	ACGIH	IARC	NTP	OSHA
Norethindrone Acetate 51-98-9	-	Group 2B	-	X
Ethinyl Estradiol 57-63-6	-	Group 1	-	X
MICROCRYSTALLINE CELLULO(AVICEL PH102) 9004-34-6	-	Group 1	Known	X

IARC (International Agency for Research on Cancer)
Group 1 - Carcinogenic to Humans
Group 2B - Possibly Carcinogenic to Humans
NTP (National Toxicology Program)
Known - Known Carcinogen
OSHA (Occupational Safety and Health Administration of the US Department of Labor)
X - Present

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute health hazard	Yes
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals

Chemical Name	California Proposition 65
Norethindrone Acetate - 51-98-9	Developmental
Ethinyl Estradiol - 57-63-6	Carcinogen Developmental
MICROCRYSTALLINE CELLULO(AVICEL PH102) - 9004-34-6	Carcinogen

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
MICROCRYSTALLINE CELLULO(AVICEL PH102) 9004-34-6	X	X	X
Oleic Acid 112-80-1	-	-	X
TALC USP(1656) 14807-96-6	X	X	X

16. OTHER INFORMATION

Revision Date 16-Jul-2019
Revision Note No information available

Disclaimer

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet