



SAFETY DATA SHEET

Revision Date 02-Oct-2018

Version 10

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

Product identifier

Product Name Taytulla

Other means of identification

Product Code FG00079

Synonyms norethindrone acetate and ethinyl estradiol capsules and ferrous fumarate capsules), for oral use.

Recommended use of the chemical and restrictions on use

Recommended Use Contraceptive Agent

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)

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

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 Capsule

Physical state Solid

Odor No information available

Chemical Name
Ferrous Fumarate

Symptoms

Adverse reactions include vascular events, liver disease, serious cardiovascular events and stroke, irregular uterine bleeding, nausea, breast tenderness, headache.

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.

Chemical Name
Ferrous Fumarate

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 may experience aggravation upon 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 aggravated 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 preexisting conditions 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.

Precautionary statements

P202 - Do not handle until all safety precautions have been read and understood

P281 - Use personal protective equipment as required

P405 - Store locked up
 P280 - Wear protective gloves/protective clothing/eye protection/face protection
 P201 - Obtain special instructions before use
 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 44.8% 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-%
Sesame Oil	8008-74-0	232-370-6	10 - 30*
GELATIN TYPE A NF	9000-70-8	232-554-6	10 - 30*
Ferrous Fumarate	141-01-5	205-447-7	10 - 30*
Norethindrone Acetate	51-98-9	200-132-0	1 - 5*
Ethinyl Estradiol	57-63-6	200-342-2	0.1 - 1*

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

4. FIRST AID MEASURES

First aid measures

Eye contact Rinse immediately with plenty of water and seek medical advice.

Skin Contact Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation Remove to fresh air.

Ingestion Consult a physician if necessary.

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. This material is contraindicated in women 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,

Ethinyl Estradiol

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 with a 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.

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

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. Avoid generation of dust. Do not eat, drink or

smoke when using this product.

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

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/m ³)
Ferrous Fumarate 141-01-5	TWA: 1 mg/m ³ Fe	(vacated) TWA: 1 mg/m ³ Fe	TWA: 1 mg/m ³ Fe	1000 ug/m ³
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

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	Capsule
Color	No information available	Odor	No information available
Odor threshold	No information available		

Property

pH
Melting point/freezing point
Boiling point / boiling range
Flash point

Values

No information available
No information available
No information available
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 repeated 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	Contact with eyes may cause irritation.	Repeated or prolonged skin contact may cause allergic reactions with susceptible persons, Prolonged contact may cause redness and	If this compound is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT

	breathing fresh air.		irritation, Contact with the skin may cause mild irritation, which is alleviated upon rinsing. Prolonged or repeated skin contact may cause dermatitis (dry, red skin).	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.
--	----------------------	--	---	---

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Sesame Oil	N/A	> 2 g/kg (Rabbit)	N/A
Ferrous Fumarate	= 3850 mg/kg (Rat)	N/A	N/A
Norethindrone Acetate	6 gm/kg (rat)	N/A	N/A
Ethinyl Estradiol	= 960 mg/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 induces reproductive abnormalities, including polyovular follicles, over-independent vaginal epithelial stratification and cornification. Exposure to ethinylestradiol 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.

Chemical Name	STOT - single exposure	STOT - repeated exposure
Norethindrone Acetate	No information available.	Product may irritate exposed tissue, especially if 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 toxicity increases risk of cardiovascular disease, including myocardial infarction, cerebrovascular disease, thromboembolic disease, gallbladder disease, and certain cancers in some people.

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

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 44.8% 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) 12053 mg/kg

ATEmix (dermal) 4420 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

99.8% of the mixture consists of components(s) of unknown hazards to the aquatic environment

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

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 Listed

EINECS/ELINCS 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

IARC (International Agency for Research on Cancer)

Group 1 - Carcinogenic to Humans

Group 2B - Possibly Carcinogenic to Humans

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

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Ferrous Fumarate 141-01-5	-	-	X
Ethinyl Estradiol 57-63-6	-	X	X

16. OTHER INFORMATION

Revision Date 02-Oct-2018
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