

Product Name: Norethindrone Acetate Tablets
Issued: Mar-15-2013

SAFETY DATA SHEET

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name: Norethindrone Acetate Tablets
Trade name: Lupaneta Pack
List Number: 1049
Lupaneta Pack kits: 1052; 1053

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

Recommended use: Pharmaceuticals

1.3 Details of the supplier of the safety data sheet

Supplier: AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
1-800-255-5162
+1-847-937-7433
Customer Service Telephone: 1-800-255-5162 (US and Canada only)
+1-847-937-7433
E-mail Address: AbbVie.SDS@abbvie.com

1.4 Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

Reproductive toxicity Category 1B
Carcinogenicity Category 2

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Risk Phrases: R40 - Limited evidence of a carcinogenic effect
R60 - May impair fertility
R61 - May cause harm to the unborn child

2.2 Label elements

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Section 2. Hazards identification



Signal Word: Danger

Hazard Statements:

- H351 - Suspected of causing cancer
- H360 - May damage fertility or the unborn child

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P405 - Store locked up
P501 - Dispose of contents/container to an approved waste disposal plant

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Lactose monohydrate 10039-26-6	70-90	NA		Not Hazardous*	No data available
Cellulose Microcrystalline 9004-34-6	5-20	232-674-9		Not Hazardous*	No data available
Norethindrone acetate 51-98-9	1-10	200-132-0	R40 R60, R61	Carc. 2 (H351) Repr. 1B (H360)	No data available
Magnesium Stearate 557-04-0	1-10	209-150-3		Not Hazardous*	No data available
Talc, Nonasbestos Containing 14807-96-6	1-10	238-877-9		Not Hazardous*	No data available

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

For the full text of the R-phrases mentioned in this Section, see Section 16
For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

4.1 Description of first aid measures

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Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms: Available information support the following: altered menstrual function, headaches, nausea, dizziness.

Medical Conditions Aggravated by Exposure: None known from occupational exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: Not determined

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8

6.2. Environmental precautions

Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

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Methods for Cleaning Up: Recover product and place in an appropriate container for disposal.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Lactose monohydrate 10039-26-6	Not Applicable	None
Cellulose Microcrystalline 9004-34-6	Not Applicable	None
Norethindrone acetate 51-98-9	Not Applicable	None
Magnesium Stearate 557-04-0	Not Applicable	None
Talc, Nonasbestos Containing 14807-96-6	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Cellulose Microcrystalline 9004-34-6	10 mg/m ³ total dust	TWA: 10 mg/m ³		20 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)	
Magnesium Stearate 557-04-0	10 mg/m ³ total dust				
Talc, Nonasbestos Containing 14807-96-6	2 mg/m ³ , respirable dust			10 mg/m ³ (TWA) 0.8 mg/m ³ (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Cellulose Microcrystalline 9004-34-6		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	20 mg/m ³ (STEL) 12 mg/m ³ (STEL) 20 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)
Talc, Nonasbestos Containing 14807-96-6	0.25 mg/m ³ (TWA)	2 mg/m ³ (TWA)	2 mg/m ³ (TWA)	3 mg/m ³ (STEL) 1 mg/m ³ (TWA)

8.2. Exposure controls

Product Name:	Norethindrone Acetate Tablets
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Engineering Controls:	No special provisions are required under normal product use conditions. Use inside a process enclosure when handling the bulk formulation.
Respiratory Protection:	Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.
Eyes:	Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.
Gloves:	Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.
Other PPE Data:	Wear appropriate body coverings if contact may occur.
Environmental Exposure Controls:	Not determined

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	White to off-white Oval tablet
Odor:	Not determined.
Odor Threshold:	Not determined
pH:	Not determined.
Boiling Pt. @ 760 mm Hg (°C):	Not determined.
Melting/Freezing Point (°C):	Not determined
Flash Point (°C):	Not determined.
Evaporation Rate at 20°C:	Not determined.
Flammability (Solid):	Not determined.
Lower Explosive Limit:	Not determined.
Upper Explosive Limit:	Not determined.
Vapor Pressure (mm Hg):	Not determined.
Vapor Density (Air = 1):	Not determined.
Specific Gravity:	Not determined.
Solubility(ies):	Not determined.
Partition coefficient: n-octanol/water	Not determined.
Autoignition Temp. (°C):	Not determined.
Decomposition temperature (°C):	Not determined.
Viscosity (centipoise):	Not determined.
Explosion Severity:	Not determined.
Oxidizer Properties:	Not determined.

9.2. Other information

Not determined

Section 10. Stability and reactivity

10.1. Reactivity

Not determined

Product Name: Norethindrone Acetate Tablets
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10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not determined.

10.4. Conditions to avoid

Not determined.

10.5 Incompatible materials

Not determined

10.6 Hazardous decomposition products

Carbon oxides, Nitrogen oxides (NOx)

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Clinical Route
Dermal: Yes
Inhalation: Unlikely

Acute Toxicity - Oral: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Lactose monohydrate 10039-26-6	LD50 >	10000	mg/kg, for a similar material	Rats
Cellulose Microcrystalline 9004-34-6	LD50 >	5000	mg/kg	Rats
Norethindrone acetate 51-98-9	LD50 >	5000	mg/kg	Rats Mice

Acute Toxicity - Dermal: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Cellulose Microcrystalline 9004-34-6	LD50 >	2000	mg/kg	Rabbits

Acute Toxicity - Inhalation: Data for component (s) given below.

Chemical Name	Test	Value	Units	Species
Cellulose Microcrystalline 9004-34-6	LC 50 >	5800	mg/m ³ , 4 hour	Rats
Magnesium Stearate 557-04-0	LC 50 >	2000	mg/m ³ , 1 hour	Rats

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: Not determined.

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Sensitization: Not determined.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Not determined.

Reproductive Effects: Active Ingredient : In animals adverse reproductive effects include: reduced fertility in females, fetal toxicity, fetal abnormalities.

Carcinogenicity: Data for component(s) given below.

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Norethindrone acetate 51-98-9	Liver Female Reproductive System	Rats	3-4	Oral	mg/kg	2 years
Talc, Nonasbestos Containing 14807-96-6	Lungs	Rats	18	Inhalation	mg/m ³ , 6 hours	2 years

Mutagenicity: Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Lactose monohydrate 10039-26-6	No Data.	Negative	No Data.	Negative
Cellulose Microcrystalline 9004-34-6				
Norethindrone acetate 51-98-9	No Data.	Negative	No Data.	Positive

Aspiration hazard: Not determined

Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

Section 12. Ecological information

12.1. Toxicity

Not determined.

12.2. Persistence and degradability

Not determined.

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined.

12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

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Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

Section 13. Disposal considerations

13.1 Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

Section 14. Transport information

ADR, DOT, ICAO/IATA, IMDG/IMO

Status: Not regulated

- 14.1. UN Number:** Not applicable
14.2. Proper shipping name: Not applicable
14.3. Hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazard: Not applicable
14.6. Special Provisions: Not applicable
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

Section 15. Regulatory Information

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

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Lactose monohydrate 10039-26-6	-	-	-	Not listed.	-
Cellulose Microcrystalline 9004-34-6	232-674-9	X	X	Not listed.	X
Norethindrone acetate 51-98-9	200-132-0	-	X	Not listed.	-
Magnesium Stearate 557-04-0	209-150-3	X	X	Not listed.	X
Talc, Nonasbestos Containing 14807-96-6	238-877-9	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Lactose monohydrate 10039-26-6	-	-	X	-	-	
Cellulose Microcrystalline 9004-34-6	Present	-	X	X	KE-05339	
Norethindrone acetate 51-98-9	-	7-(1)-266	-	X	KE-20747	

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Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Magnesium Stearate 557-04-0	Present	-	X	X	KE-26390	
Talc, Nonasbestos Containing 14807-96-6	Present	-	X	X	KE-32773	

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
TSCEA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
ISHL - Japan Industrial Safety and Health Law
IECSC - China Inventory of Existing Chemical Substances
AICS - Australian Inventory of Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Lactose monohydrate	70-90	Not Listed	Not Listed	Not Listed
Cellulose Microcrystalline	5-20	Not Listed	Not Listed	Not Listed
Norethindrone acetate	1-10	Not Listed	Not Listed	Not Listed
Magnesium Stearate	1-10	Not Listed	Not Listed	Not Listed
Talc, Nonasbestos Containing	1-10	Not Listed	Not Listed	Not Listed

SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Lactose monohydrate	70-90	No	Not Applicable	Not applicable
Cellulose Microcrystalline	5-20	No	Not Applicable	Not applicable
Norethindrone acetate	1-10	No	Not Applicable	Not applicable
Magnesium Stearate	1-10	No	Not Applicable	Not applicable
Talc, Nonasbestos Containing	1-10	No	Not Applicable	Not applicable

Immediate Health: Yes
Delayed Health: No
Fire: No
Sudden Pressure: No
Reactivity: No

RCRA Status: Not determined.

Proposition 65 Status: Chemicals known to the State of California to cause cancer or reproductive harm listed below.

Chemical Name	Percent	Proposition 65 Listed Materials
Norethindrone acetate	1-10	Cancer and Reproduction

WHMIS Hazard Class: Not determined.

NFPA Rating:
 Health: 1
 Fire: 1
 Reactivity: 0

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Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

Section 16. Other information

Risk Phrases: R40 - Limited evidence of a carcinogenic effect , R60 - May impair fertility, R61 - May cause harm to the unborn child

Full text of H-Statements referred to under sections 2 and 3

H351 - Suspected of causing cancer if inhaled, H360 - May damage fertility or the unborn child if inhaled

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