

# **Etonogestrel / Ethinyl Estradiol Formulation**



Version Revision Date: SDS Number: Date of last issue: 23.03.2020 6.4 16.10.2020 16790-00018 Date of first issue: 29.09.2014

### **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Etonogestrel / Ethinyl Estradiol Formulation

Manufacturer or supplier's details

Company name of supplier : Organon & Co.

Address : Avenida 16 de Septiembre No. 301

Xaltocan - Xochimilco Mexico 16090

Telephone : 52 55 57284444 Emergency telephone : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

### **SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification** 

Carcinogenicity : Category 1A

Reproductive toxicity : Category 1A

Specific target organ toxicity

- repeated exposure

Category 1 (Liver, Blood)

**GHS** label elements

Hazard pictograms



Signal Word : Danger

Hazard Statements : H350 May cause cancer.

H360FD May damage fertility. May damage the unborn child. H372 Causes damage to organs (Liver, Blood) through

prolonged or repeated exposure.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/ protective clothing/ eye protection/

face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

Storage:



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P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste dis-

posal plant.

Other hazards

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
(17α)-13-Ethyl-17-hydroxy-11-methylene-	54048-10-1	>= 0.1 -< 1
18,19-dinorpregn-4-en-20-yn-3-one		
Ethinylestradiol	57-63-6	>= 0.1 -< 1

#### **SECTION 4. FIRST AID MEASURES**

General advice In the case of accident or if you feel unwell, seek medical

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled If inhaled, remove to fresh air.

Get medical attention.

In case of contact, immediately flush skin with soap and plenty In case of skin contact

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms

May cause cancer.

and effects, both acute and delayed

Protection of first-aiders

May damage fertility. May damage the unborn child.

Causes damage to organs through prolonged or repeated

exposure.

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation. First Aid responders should pay attention to self-protection.

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician Treat symptomatically and supportively.

### **SECTION 5. FIRE-FIGHTING MEASURES**



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Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical None known.

Unsuitable extinguishing

media

Specific hazards during fire

fighting

Hazardous combustion prod-

ucts

Exposure to combustion products may be a hazard to health.

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment :

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable

container for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

### **SECTION 7. HANDLING AND STORAGE**

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.



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Advice on safe handling : Do not get on skin or clothing.

Do not breathe dust, fume, gas, mist, vapors or spray.

Do not swallow.

Avoid contact with eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

assessment

Keep container tightly closed.

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

Conditions for safe storage : Keep in properly labeled containers.

Store locked up. Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents Organic peroxides

Explosives Gases

## **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
(17α)-13-Ethyl-17-hydroxy-11- methylene-18,19-dinorpregn-4- en-20-yn-3-one	54048-10-1	TWA	0.05 μg/m3 (OEB 5)	Internal
		Wipe limit	0.5 μg/100 cm <sup>2</sup>	Internal
Ethinylestradiol	57-63-6	TWA	0.01 μg/m3 (OEB 5)	Internal
		Wipe limit	0.1 µg/100 cm <sup>2</sup>	Internal

**Engineering measures** : Use closed processing systems or containment technologies

to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.



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All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

No open handling permitted.

Totally enclosed processes and materials transport systems

are required.

Operations require the use of appropriate containment technology designed to prevent leakage of compounds into

the workplace.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type Hand protection

Particulates type

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets,

disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

# **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : solid

Color : white

Odor : odorless

Odor Threshold : No data available

pH : Not applicable

Melting point/freezing point : Not applicable

Initial boiling point and boiling

range

Not applicable

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing,



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handling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

Not applicable

Lower explosion limit / Lower

flammability limit

Not applicable

Vapor pressure : Not applicable

Relative vapor density : Not applicable

Relative density : No data available

Density : 1 g/cm<sup>3</sup>

Solubility(ies)

Water solubility : insoluble

Partition coefficient: n-

octanol/water

Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle size : No data available

### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing,

handling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Hazardous decomposition

products

Oxidizing agents

No hazardous decomposition products are known.



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#### **SECTION 11. TOXICOLOGICAL INFORMATION**

### Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

### **Acute toxicity**

Not classified based on available information.

### **Components:**

### $(17\alpha)$ -13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

LD50 (Mouse): > 2,000 mg/kg

**Ethinylestradiol:** 

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg

LD50 (Mouse): 1,737 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

### Skin corrosion/irritation

Not classified based on available information.

## **Components:**

# $(17\alpha)\text{-}13\text{-}Ethyl\text{-}17\text{-}hydroxy\text{-}11\text{-}methylene\text{-}18,19\text{-}dinorpregn\text{-}4\text{-}en\text{-}20\text{-}yn\text{-}3\text{-}one}:$

Species : Mouse

Result : No skin irritation

Species : Guinea pig
Result : No skin irritation

**Ethinylestradiol:** 

Remarks : No data available

### Serious eye damage/eye irritation

Not classified based on available information.

### **Components:**

**Ethinylestradiol:** 

Remarks : No data available



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### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

### Respiratory sensitization

Not classified based on available information.

### Components:

**Ethinylestradiol:** 

Remarks : No data available

### Germ cell mutagenicity

Not classified based on available information.

### Components:

### $(17\alpha)$ -13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:

Genotoxicity in vitro : Test Type: reverse mutation assay

Test system: Salmonella typhimurium

Result: negative

Test Type: in vitro test

Test system: Chinese hamster ovary cells

Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test

Species: Mouse

Application Route: Oral

Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

**Ethinylestradiol:** 

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Test system: Salmonella typhimurium

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Test system: Escherichia coli

Result: negative

Test Type: Chromosome aberration test in vitro

Test system: Human lymphocytes

Result: equivocal

Genotoxicity in vivo : Test Type: Chromosomal aberration

Species: Mouse

Cell type: Bone marrow Application Route: Oral

Result: positive

Test Type: Micronucleus test



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Species: Mouse Cell type: Bone marrow Application Route: Oral

Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Carcinogenicity

May cause cancer.

**Components:** 

 $(17\alpha)\text{-}13\text{-}Ethyl\text{-}17\text{-}hydroxy\text{-}11\text{-}methylene\text{-}18,19\text{-}dinorpregn\text{-}4\text{-}en\text{-}20\text{-}yn\text{-}3\text{-}one}:$ 

Species : Rat Application Route : Oral Activity duration : 2 y

0.5 mg/kg body weight

Result : negative

Species : Rat

Application Route : Subcutaneous

Activity duration : 2 y

: 0.02 mg/kg body weight

Result : negative

Carcinogenicity - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

**Ethinylestradiol:** 

Species : Rat, male and female

Application Route : Oral
Exposure time : 2 Years
Result : negative

Species : Monkey, female

Application Route : Oral Exposure time : 10 Years Result : negative

Carcinogenicity - Assess-

ment

: Positive evidence from human epidemiological studies

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

 $(17\alpha)$ -13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:

Effects on fertility : Test Type: Fertility

Species: Rat, female Application Route: Oral

Fertility: LOAEL: 0.012 mg/kg body weight

Result: Effects on fertility.



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Test Type: Fertility Species: Rabbit, female Application Route: Oral

Dose: 0.05 milligram per kilogram

Result: Effects on fertility.

Effects on fetal development : Species: Rat, female

Duration of Single Treatment: 14 d

General Toxicity Maternal: NOAEL: 1.8 mg/kg body weight

Result: No teratogenic effects.

Reproductive toxicity - As-

sessment

Positive evidence of adverse effects on sexual function and

fertility from human epidemiological studies.

**Ethinylestradiol:** 

Effects on fertility : Species: Hamster

Fertility: LOAEL: 6.3 mg/kg body weight

Result: Effects on fertility.

Effects on fetal development : Test Type: Four-generation reproduction toxicity study

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: > 0.006 mg/kg body weight

Result: Specific developmental abnormalities.

Test Type: Two-generation reproduction toxicity study

Species: Rat, male and female

Application Route: Oral

Developmental Toxicity: LOAEL: 0.005 mg/kg body weight

Result: Specific developmental abnormalities.

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of

adverse effects on development, based on animal

experiments.

# STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Causes damage to organs (Liver, Blood) through prolonged or repeated exposure.

### **Components:**

### **Ethinylestradiol:**

Target Organs : Liver, Blood

Assessment : Causes damage to organs through prolonged or repeated

exposure.



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### Repeated dose toxicity

### **Components:**

 $(17\alpha)$ -13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:

Species : Rat
LOAEL : 0.5 mg/kg
Application Route : Oral
Exposure time : 1 y

Target Organs : Reproductive organs, Endocrine system

Species : Dog

LOAEL : 0.625 mg/kg

Application Route : Oral Exposure time : 26 Weeks

Target Organs : Reproductive organs, Endocrine system

**Ethinylestradiol:** 

Species : Rat
NOAEL : 0.25 mg/kg
LOAEL : 0.5 mg/kg
Application Route : Oral
Exposure time : 2 Weeks
Target Organs : Liver

Species : Rabbit LOAEL : 0.015 mg/kg Application Route : Oral

Exposure time : 20 Weeks Target Organs : Liver

Species : Dog

NOAEL : 0.04 mg/kg LOAEL : 0.2 mg/kg Application Route : Oral Exposure time : 95 d Target Organs : Blood

Species : Rat, male and female

NOAEL : 0.0015 mg/kg LOAEL : 0.005 mg/kg

Application Route : Oral Exposure time : 2 y

Target Organs : Reproductive organs, Mammary gland, Liver, Uterus (includ-

ing cervix)

## **Aspiration toxicity**

Not classified based on available information.

# Experience with human exposure

### **Components:**

 $(17\alpha)$ -13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:



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Symptoms: Headache, Dizziness, Abdominal pain, Nausea, Inhalation

> Skin disorders, effects on menstruation, vaginitis, breast tenderness, mood swings, male reproductive effects, Sweating

**Ethinylestradiol:** 

Ingestion Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhea,

> Headache, Dizziness, mood swings, Edema, liver function change, water retention, hair loss, gynecomastia, effects on

menstruation

#### **SECTION 12. ECOLOGICAL INFORMATION**

### **Ecotoxicity**

### **Components:**

 $(17\alpha)$ -13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): 4.0 mg/l

> Exposure time: 96 h Method: FDA 4.11

LC50 (Lepomis macrochirus (Bluegill sunfish)): > 1.3 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 3.9 mg/l

Exposure time: 48 h Method: FDA 4.08

Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 0.059 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

NOEC (Oryzias latipes (Japanese medaka)): 0.0000027 mg/l

Exposure time: 183 d

Method: OECD Test Guideline 229

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 1.2 mg/l

Exposure time: 21 d

Toxicity to microorganisms

NOEC: 70.8 mg/l Exposure time: 3 h

Test Type: Respiration inhibition

Method: OECD Test Guideline 209

EC50: > 1,000 mg/lExposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

**Ethinylestradiol:** 

LC50 (Lepomis macrochirus (Bluegill sunfish)): 1.6 mg/l Toxicity to fish



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Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 6.7

mq/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 6.7

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 0.01 µg/l

Exposure time: 35 d

Method: OECD Test Guideline 210

NOEC (Zebrafish): 0.00031 µg/l

Exposure time: 339 d

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.75 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Toxicity to microorganisms EC50: > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 24.9 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

## Persistence and degradability

### **Components:**

(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:

Stability in water Hydrolysis: < 10 %(5 d)

Method: FDA 3.09

### Bioaccumulative potential

#### **Components:**

(17α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:

Bioaccumulation Species: Lepomis macrochirus (Bluegill sunfish)

> Bioconcentration factor (BCF): 128 Method: OECD Test Guideline 305

Partition coefficient: n-

log Pow: 3.5

octanol/water

**Ethinylestradiol:** 



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Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)

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Bioconcentration factor (BCF): 264 Method: OECD Test Guideline 305

Partition coefficient: n-

16.10.2020

octanol/water

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: log Pow: 4.15

Mobility in soil

**Components:** 

 $(17\alpha)$ -13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:

Distribution among environ- : log Koc: 2.84 mental compartments Method: FDA 3.08

ieritai compartinerits - Metriod. FDA 3.

Ethinylestradiol:

Distribution among environmental compartments

log Koc: 3.86

Other adverse effects

No data available

### **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

### **SECTION 14. TRANSPORT INFORMATION**

### International Regulations

**UNRTDG** 

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

956

(Ethinylestradiol, (17α)-13-Ethyl-17-hydroxy-11-methylene-

18,19-dinorpregn-4-en-20-yn-3-one)

Class : 9
Packing group : III
Labels : 9

IATA-DGR

UN/ID No. : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.

(Ethinylestradiol, (17 $\alpha$ )-13-Ethyl-17-hydroxy-11-methylene-

18,19-dinorpregn-4-en-20-yn-3-one)

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen: 956

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ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Ethinylestradiol, (17α)-13-Ethyl-17-hydroxy-11-methylene-

18,19-dinorpregn-4-en-20-yn-3-one)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

**Domestic regulation** 

NOM-002-SCT

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Ethinylestradiol,  $(17\alpha)$ -13-Ethyl-17-hydroxy-11-methylene-

18,19-dinorpregn-4-en-20-yn-3-one)

Class : 9
Packing group : III
Labels : 9

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### **SECTION 15. REGULATORY INFORMATION**

producing capsules, tablets and pills.

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for

Not applicable

The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined



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#### **SECTION 16. OTHER INFORMATION**

#### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation: DSL - Domestic Substances List (Canada): ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk, IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China: IMDG - International Maritime Dangerous Goods: IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety

Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

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The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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