

## Etonogestrel / Ethinyl Estradiol Formulation

Version 6.9      Revision Date: 16.10.2020      SDS Number: 16795-00017      Date of last issue: 23.03.2020  
Date of first issue: 29.09.2014

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**Section 1: Identification**

Product name : Etonogestrel / Ethinyl Estradiol Formulation

**Manufacturer or supplier's details**

Company : Organon & Co.

Address : 30 Hudson Street, 33rd floor  
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical

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**Section 2: Hazard 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 pro-  
longed 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/ vapours/ spray.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P281 Use personal protective equipment as required.

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**Response:**

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

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards which do not result in classification**

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)
(17 $\alpha$ )-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one	54048-10-1	$\geq 0.3$ -< 10
Ethinylestradiol	57-63-6	$\geq 0.1$ -< 0.3

**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 skin contact : In case of contact, immediately flush skin with soap and plenty 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 and effects, both acute and delayed : May cause cancer.  
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.

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Protection of first-aiders : 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.

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**Section 5: Fire-fighting measures**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances 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 firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

Hazchem Code : ZZ

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**Section 6: Accidental release measures**

Personal precautions, protective equipment and emergency 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.

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**Section 7: Handling and storage**

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- 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.
- Advice on safe handling : Do not get on skin or clothing.  
 Do not breathe dust, fume, gas, mist, vapours 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 labelled 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

## Section 8: Exposure controls/personal protection

## Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
(17 $\alpha$ )-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one	54048-10-1	TWA	0.05 $\mu\text{g}/\text{m}^3$ (OEB 5)	Internal
		Wipe limit	0.5 $\mu\text{g}/100 \text{ cm}^2$	Internal
Ethinylestradiol	57-63-6	TWA	0.01 $\mu\text{g}/\text{m}^3$ (OEB 5)	Internal
		Wipe limit	0.1 $\mu\text{g}/100 \text{ cm}^2$	Internal

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**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.  
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 : Particulates type

Hand protection

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

Colour : white

Odour : odourless

Odour 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

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Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, 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
Vapour pressure	:	Not applicable
Relative vapour 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
Auto-ignition 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

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**Section 10: Stability and reactivity**

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	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	:	Oxidizing agents
Hazardous decomposition	:	No hazardous decomposition products are known.

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**Section 11: Toxicological information**

Exposure routes : 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 $\alpha$ )-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-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 sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Ethinylestradiol:**

Remarks : No data available

**Chronic toxicity****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 assay  
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



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Test Type: Micronucleus test  
 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 $\alpha$ )-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one:**

Species : Rat  
 Application Route : Oral  
 Activity duration : 2 yr  
 : 0.5 mg/kg body weight  
 Result : negative

Species : Rat  
 Application Route : Subcutaneous  
 Activity duration : 2 yr  
 : 0.02 mg/kg body weight  
 Result : negative

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

**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 - Assessment : 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

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Result: Effects on fertility

Test Type: Fertility  
 Species: Rabbit, female  
 Application Route: Oral  
 Dose: 0.05 milligram per kilogram  
 Result: Effects on fertility

Effects on foetal 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 - Assessment : 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 foetal 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 - Assessment : 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 yr  
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 yr  
Target Organs                         : Reproductive organs, Mammary gland, Liver, Uterus (including 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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Inhalation : Symptoms: Headache, Dizziness, Abdominal pain, Nausea, Skin disorders, effects on menstruation, vaginitis, breast tenderness, mood swings, male reproductive effects, Sweating

**Ethinylestradiol:**

Ingestion : Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhoea, Headache, Dizziness, mood swings, Oedema, 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 toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.059 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210

NOEC (Oryzias latipes (Japanese medaka)): 0.000027 mg/l  
Exposure time: 183 d  
Method: OECD Test Guideline 229

Toxicity to daphnia and other aquatic invertebrates (Chronic 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/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

**Ethinylestradiol:**

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

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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 mg/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 toxicity)	: 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 (Chronic 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
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**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
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Partition coefficient: n-octanol/water	: log Pow: 3.5
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**Ethinylestradiol:**

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Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)  
 Bioconcentration factor (BCF): 264  
 Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : 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 environmental compartments : log Koc: 2.84  
 Method: FDA 3.08

**Ethinylestradiol:**

Distribution among environmental compartments : log Koc: 3.86

**Other adverse effects**

No data available

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**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.

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**Section 14: Transport information****International Regulations****UNRTDG**

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

**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) : 956  
 Packing instruction (passenger aircraft) : 956

# SAFETY DATA SHEET



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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, (17 $\alpha$ )-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.

### National Regulations

#### NZS 5433

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  
Hazchem Code                            :    2Z

### 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.

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## Section 15: Regulatory information

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

#### HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

#### HSW Controls

Certified handler certificate not required.  
Tracking hazardous substance not required.  
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

### The components of this product are reported in the following inventories:

AICS                                        :    not determined  
DSL                                         :    not determined

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IECSC : not determined

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**Section 16: Other information****Further information**Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Date format : dd.mm.yyyy

**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

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



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intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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