

SAFETY DATA SHEET



Etonogestrel / Ethinyl Estradiol Formulation



Version 4.10 Revision Date: 2020/10/16 SDS Number: 16782-00017 Date of last issue: 2020/03/23
Date of first issue: 2014/09/29

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Etonogestrel / Ethinyl Estradiol Formulation

Manufacturer or supplier's details

Company : Organon & Co.
Address : JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
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

2. HAZARDS IDENTIFICATION

GHS Classification

Carcinogenicity : Category 1A
Reproductive toxicity : Category 1A
Specific target organ toxicity - repeated exposure : Category 1 (Liver, Blood)
Long-term (chronic) aquatic hazard : Category 1

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.
H410 Very toxic to aquatic life with long lasting effects.

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.

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P264 Wash skin thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 P391 Collect spillage.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
(17 α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one	54048-10-1	≥ 0.3 -< 2.5
Ethinylestradiol	57-63-6	≥ 0.1 -< 0.25

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 : May cause cancer.

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and effects, both acute and delayed		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.
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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) 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.

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 deter-

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mine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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.
- 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.
- 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
(17 α)-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

- 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 | : | 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. |
| 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. |

9. PHYSICAL AND CHEMICAL PROPERTIES

- | | | |
|-----------------|---|-------------------|
| Appearance | : | solid |
| Colour | : | white |
| Odour | : | odourless |
| Odour Threshold | : | No data available |
| pH | : | Not applicable |

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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, 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 ³
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

10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	May form explosive dust-air mixture during processing, han-

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tions	dling 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 products	: No hazardous decomposition products are known.

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 α)-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 α)-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.

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Components:**Ethinylestradiol:**

Remarks : No data available

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

Germ cell mutagenicity

Not classified based on available information.

Components:**(17 α)-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

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

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

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Effects on fertility : Test Type: Fertility
Species: Rat, female
Application Route: Oral
Fertility: LOAEL: 0.012 mg/kg body weight
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 α)-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 α)-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

12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****(17 α)-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)): 0.0000027 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

M-Factor (Chronic aquatic toxicity) : 10,000

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:

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- Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 1.6 mg/l
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
- M-Factor (Chronic aquatic toxicity) : 100,000
- 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:****(17 α)-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:****(17 α)-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

Ethinylestradiol:

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 α)-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

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Ethinylestradiol, (17 α)-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 α)-13-Ethyl-17-hydroxy-11-methylene-18,19-dinorpregn-4-en-20-yn-3-one)
Class : 9
Packing group : III

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Labels : Miscellaneous
 Packing instruction (cargo aircraft) : 956
 Packing instruction (passenger aircraft) : 956
 Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
 (Ethinylestradiol, (17 α)-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.

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.

15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials

Type of Hazardous Materials Restricted to Import, Distribution and Supervision : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

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 : yyyy/mm/dd

Full text of other abbreviations

AIC - 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

SAFETY DATA SHEET



Etonogestrel / Ethinyl Estradiol Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 2020/03/23
4.10	2020/10/16	16782-00017	Date of first issue: 2014/09/29

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