

## Nomegestrol / Estradiol Formulation

Version 5.5      Revision Date: 16.10.2020      SDS Number: 17209-00016      Date of last issue: 23.03.2020  
Date of first issue: 30.09.2014

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### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Nomegestrol / Estradiol Formulation

#### Manufacturer or supplier's details

Company : Organon & Co.  
Address : Rua Treze de Maio, 1161  
Campinas, São Paulo, Brazil B-2220  
Telephone : 551-430-6000  
Emergency telephone : 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. HAZARDS IDENTIFICATION

#### GHS Classification in accordance with ABNT NBR 14725 Standard

Carcinogenicity : Category 1A  
Reproductive toxicity : Category 1A  
Specific target organ toxicity - repeated exposure : Category 1 (Liver, Bone, Blood, Endocrine system)  
Short-term (acute) aquatic hazard : Category 3  
Long-term (chronic) aquatic hazard : Category 1

#### GHS label elements in accordance with ABNT NBR 14725 Standard

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, Bone, Blood, Endocrine system) through prolonged or repeated exposure.  
H402 Harmful to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.

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Precautionary Statements : **Prevention:**  
P201 Obtain special instructions before use.  
P260 Do not breathe dust.  
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.

**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.	Classification	Concentration (% w/w)
Cellulose	9004-34-6		>= 10 -< 20
Estradiol	50-28-2	Acute toxicity (Oral), Category 5 Carcinogenicity, Category 1A Reproductive toxicity, Category 1A Specific target organ toxicity - repeated exposure (Liver, Bone, Blood, Endocrine system), Category 1 Short-term (acute) aquatic hazard, Category 2 Long-term (chronic) aquatic hazard, Category 1	>= 2,5 -< 5
17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate	58652-20-3	Acute toxicity (Oral), Category 5 Reproductive toxicity, Category 1A Short-term (acute) aquatic hazard, Category 2 Long-term (chronic) aquatic hazard, Category 1	>= 1 -< 2,5
Talc	14807-96-6		>= 1 -< 5

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Titanium dioxide	13463-67-7	Carcinogenicity (Inhalation), Category 2	>= 0,1 -< 1
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**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.
- 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.

**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 : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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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.

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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

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.  
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.

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- 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.
- 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
Cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
Estradiol	50-28-2	TWA	0.05 µg/m <sup>3</sup> (OEB 5)	Internal
Further information: Skin				
		Wipe limit	0.5 µg/100 cm <sup>2</sup>	Internal
17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate	58652-20-3	TWA	0,2 µg/m <sup>3</sup>	Internal
		Wipe limit	2 µg/100 cm <sup>2</sup>	Internal
Talc	14807-96-6	TWA (Respirable particulate matter)	2 mg/m <sup>3</sup>	ACGIH
Titanium dioxide	13463-67-7	TWA	10 mg/m <sup>3</sup> (Titanium dioxide)	ACGIH

- Engineering measures** : Minimize workplace exposure concentrations.  
Apply measures to prevent dust explosions.  
Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).  
If sufficient ventilation is unavailable, use with local exhaust ventilation.

**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.

# SAFETY DATA SHEET



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Filter type : Particulates type  
Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:  
Safety goggles

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.  
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : white

Odor : odorless

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

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 : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

# SAFETY DATA SHEET



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Relative density : No data available

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

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, dynamic : No data available  
Viscosity, kinematic : No data available

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 products : 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.

#### **Product:**

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg  
Method: Calculation method

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**Components:****Cellulose:**

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5,8 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

**Estradiol:**

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): > 300 mg/kg  
Application Route: Subcutaneous

**17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:**

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg  
LD50 (Mouse): > 2.000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): > 2.000 mg/kg  
Application Route: Intraperitoneal

**Talc:**

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg  
Remarks: Based on data from similar materials

**Titanium dioxide:**

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 6,82 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Talc:**

Species : Rabbit  
Result : No skin irritation

**Titanium dioxide:**

Species : Rabbit



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Result : No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Estradiol:**

Result : No eye irritation

**Talc:**

Species : Rabbit  
Result : No eye irritation

**Titanium dioxide:**

Species : Rabbit  
Result : No eye irritation

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Estradiol:**

Routes of exposure : Skin contact  
Species : Guinea pig  
Assessment : Does not cause skin sensitization.  
Result : negative

**Talc:**

Routes of exposure : Skin contact  
Species : Humans  
Result : negative

**Titanium dioxide:**

Test Type : Local lymph node assay (LLNA)  
Routes of exposure : Skin contact  
Species : Mouse  
Result : negative

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Cellulose:**

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

Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

**Estradiol:**

Genotoxicity in vitro : Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Test system: mammalian cells  
Result: positive

Test Type: Chromosome aberration test in vitro  
Test system: mammalian cells  
Result: positive

Test Type: Chromosomal aberration  
Test system: mammalian cells  
Result: positive

Genotoxicity in vivo : Test Type: Chromosomal aberration  
Species: Rat  
Cell type: Bone marrow  
Result: negative

Test Type: Chromosomal aberration  
Species: Mouse  
Cell type: Bone marrow  
Result: negative

**17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:**

Genotoxicity in vitro : Test Type: Ames test  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test  
Species: Rat  
Application Route: Oral  
Result: negative

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Test Type: In vivo micronucleus test  
 Species: Mouse  
 Application Route: Oral  
 Result: negative

**Talc:**

Genotoxicity in vitro : Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
 Result: negative

Genotoxicity in vivo : Test Type: Chromosome aberration test in vitro  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

**Titanium dioxide:**

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

Genotoxicity in vivo : Test Type: In vivo micronucleus test  
 Species: Mouse  
 Result: negative

**Carcinogenicity**

May cause cancer.

**Components:****Cellulose:**

Species : Rat  
 Application Route : Ingestion  
 Exposure time : 72 weeks  
 Result : negative

**Estradiol:**

Species : Mouse  
 Application Route : Ingestion  
 Exposure time : 24 Months  
 LOAEL : 100 µg/kg  
 Result : positive  
 Target Organs : female reproductive organs

Species : Rat  
 Application Route : Subcutaneous  
 Exposure time : 13 weeks  
 LOAEL : 20 mg/kg body weight  
 Result : positive  
 Target Organs : Endocrine system

Carcinogenicity - Assessment : Positive evidence from human epidemiological studies

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**17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:**

Species : Rat  
Application Route : oral (feed)  
Activity duration : 52 Weeks  
Dose : 10 mg/kg body weight  
Result : negative

Species : Mouse  
Application Route : oral (feed)  
Dose : 20 mg/kg body weight  
Result : positive  
Target Organs : Mammary gland, Pituitary gland

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

**Talc:**

Species : Mouse  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 2 Years  
Result : negative

**Titanium dioxide:**

Species : Rat  
Application Route : inhalation (dust/mist/fume)  
Exposure time : 2 Years  
Method : OECD Test Guideline 453  
Result : positive  
Remarks : The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in inhalation studies with animals.

**Reproductive toxicity**

May damage fertility. May damage the unborn child.

**Components:****Cellulose:**

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on fetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative

**Estradiol:**

Effects on fertility : Test Type: One-generation reproduction toxicity study

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Species: Rat  
 Application Route: Ingestion  
 Fertility: LOAEL: 0,5 mg/kg body weight  
 Result: Effects on fertility.

Test Type: One-generation reproduction toxicity study  
 Species: Rat  
 Duration of Single Treatment: 90 d  
 Fertility: LOAEL: 0,69 mg/kg body weight  
 Result: Effects on fertility.

Test Type: Two-generation study  
 Species: Mouse  
 Application Route: Oral  
 Fertility: LOAEL: 0,1 mg/kg body weight  
 Result: Effects on fertility.

- Effects on fetal development : Test Type: Embryo-fetal development  
 Species: Mouse, female  
 Application Route: Subcutaneous  
 Teratogenicity: LOAEL: 4 mg/kg body weight  
 Symptoms: Malformations were observed.  
 Result: positive, Teratogenic effects.
- Test Type: One-generation reproduction toxicity study  
 Species: Rat  
 Application Route: Subcutaneous  
 Teratogenicity: LOAEL: 2,5 µg/kg body weight  
 Symptoms: Reduced body weight  
 Result: positive, Embryotoxic effects and adverse effects on the offspring were detected.
- Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Subcutaneous  
 Developmental Toxicity: LOAEL: 0,2 mg/kg body weight  
 Symptoms: Early Resorptions / resorption rate., Reduced number of viable fetuses., Reduced body weight  
 Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Reproductive toxicity - Assessment : May damage fertility. May damage the unborn child.

**17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:**

Effects on fetal development : Test Type: Development  
 Species: Rat  
 Application Route: Oral  
 Result: negative

Test Type: Embryo-fetal development  
 Species: Rabbit  
 Application Route: Oral  
 Result: negative, No teratogenic effects.

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Reproductive toxicity - Assessment : Positive evidence of adverse effects on sexual function and fertility from human epidemiological studies.

**Talc:**

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

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

**Components:****Estradiol:**

Target Organs : Liver, Bone, Blood, Endocrine system  
Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Cellulose:**

Species : Rat  
NOAEL :  $\geq 9.000$  mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

**Estradiol:**

Species : Rat  
LOAEL :  $\geq 0,17$  mg/kg  
Application Route : Ingestion  
Exposure time : 90 d  
Target Organs : Mammary gland, Ovary, Uterus (including cervix), Liver, Bone, Endocrine system, Blood, Testis

**17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:**

Species : Mouse  
NOAEL : 20 mg/kg  
Application Route : Oral  
Exposure time : 52 Weeks

Species : Rat  
NOAEL : 20 mg/kg  
Application Route : Oral  
Exposure time : 52 Weeks

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**Titanium dioxide:**

Species : Rat  
 NOAEL : 24.000 mg/kg  
 Application Route : Ingestion  
 Exposure time : 28 Days

Species : Rat  
 NOAEL : 10 mg/m<sup>3</sup>  
 Application Route : inhalation (dust/mist/fume)  
 Exposure time : 2 y

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Estradiol:**

Inhalation : Symptoms: tingling, Nose bleeding  
 Skin contact : Symptoms: Skin irritation, Redness, pruritis  
 Ingestion : Symptoms: Headache, Gastrointestinal disturbance, Dizziness, Vomiting, Diarrhea, water retention, liver function change, changes in libido, breast tenderness, menstrual irregularities

**17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:**

Ingestion : Symptoms: acne, amenorhea, Headache, Dizziness, Nausea, breast tenderness, changes in libido, insomnia, musculoskeletal pain, mood swings, muscle pain, muscle twitching

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Cellulose:**

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l  
 Exposure time: 48 h  
 Remarks: Based on data from similar materials

**Estradiol:**

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): 3,9 mg/l  
 Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2,7 mg/l  
 Exposure time: 48 h

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 1,7 mg/l  
 Exposure time: 72 h  
 Method: OECD Test Guideline 201

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EC50 (Pseudokirchneriella subcapitata (green algae)): > 1,7 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Oryzias latipes (Japanese medaka)): 0,000003 mg/l  
Exposure time: 160 d  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0,2 mg/l  
Exposure time: 21 d

M-Factor (Chronic aquatic toxicity) : 1.000

Toxicity to microorganisms : EC50: > 100 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

NOEC: 100 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

**17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:**

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 3,07 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,69 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Zebrafish): 0,0013 mg/l  
Exposure time: 27 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 3,65 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
Remarks: No toxicity at the limit of solubility.

M-Factor (Chronic aquatic toxicity) : 10

Toxicity to microorganisms : EC50 (Natural microorganism): > 2,8 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

NOEC (Natural microorganism): 2,8 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209



## Nomegestrol / Estradiol Formulation

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Remarks: No toxicity at the limit of solubility.

**Talc:**

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100.000 mg/l  
Exposure time: 24 h

**Titanium dioxide:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
aquatic invertebrates Exposure time: 48 h

Toxicity to algae/aquatic : EC50 (Skeletonema costatum (marine diatom)): > 10.000 mg/l  
plants Exposure time: 72 h

Toxicity to microorganisms : EC50: > 1.000 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209

**Persistence and degradability****Components:****Cellulose:**

Biodegradability : Result: Readily biodegradable.

**Estradiol:**

Biodegradability : Result: rapidly degradable  
Biodegradation: 84 %  
Exposure time: 24 hrs

**Bioaccumulative potential****Components:****Estradiol:**

Partition coefficient: n- : log Pow: 4,01  
octanol/water

**17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:**

Bioaccumulation : Species: Zebrafish  
Bioconcentration factor (BCF): 44

Partition coefficient: n- : log Pow: 3,7  
octanol/water

**Mobility in soil****Components:****Estradiol:**

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Distribution among environmental compartments : log Koc: 3,81

**17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:**

Distribution among environmental compartments : log Koc: 3,35  
Method: OECD Test Guideline 106

**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.  
(Estradiol, 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate)  
Class : 9  
Packing group : III  
Labels : 9

**IATA-DGR**

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Estradiol, 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate)  
Class : 9  
Packing group : III  
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.  
(Estradiol, 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate)  
Class : 9  
Packing group : III  
Labels : 9

# SAFETY DATA SHEET



## Nomegestrol / Estradiol Formulation



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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

#### ANTT

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Estradiol, 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate)  
Class : 9  
Packing group : III  
Labels : 9  
Hazard Identification Number : 90

### 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

National List of Carcinogenic Agents for Humans - (LINACH)

Group 2B: Possibly carcinogenic to humans  
17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate      58652-20-3  
Group 2B: Possibly carcinogenic to humans  
Titanium dioxide      13463-67-7

Brazil. List of chemicals controlled by the Federal Police : Not applicable

### International Regulations

#### 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

### Further information

Sources of key data used to compile the Material Safety : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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Data Sheet cy, <http://echa.europa.eu/>

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

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 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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