

SAFETY DATA SHEET



Nomegestrol / Estradiol Formulation



Version 7.0 Revision Date: 06.04.2024 SDS Number: 17209-00023 Date of last issue: 26.09.2023
Date of first issue: 30.09.2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Manufacturer or supplier's details

Company : Organon & Co.
Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil 13106-054
Telephone : +55 (19) 3758-2000
Emergency telephone : +55 (11) 3173-4931
E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

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 |

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| | | | |
|------------------|------------|--|------------------|
| Talc | 14807-96-6 | | $\geq 1 - < 5$ |
| Titanium dioxide | 13463-67-7 | Carcinogenicity (Inhalation), Category 2 | $\geq 0,1 - < 1$ |

SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.
- In case of 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 (CO₂)
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_x)
- 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.

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.

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.

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- 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.
- Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
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 ³ | ACGIH |
| Estradiol | 50-28-2 | TWA | 0.05 µg/m ³ (OEB 5) | Internal |
| Further information: Skin | | | | |
| | | Wipe limit | 0.5 µg/100 cm ² | Internal |
| 17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate | 58652-20-3 | TWA | 0,2 µg/m ³ | Internal |
| | | Wipe limit | 2 µg/100 cm ² | Internal |
| Talc | 14807-96-6 | TWA (Respirable particulate matter) | 2 mg/m ³ | 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.

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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).

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

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Relative density : No data available

Density : 1 g/cm³

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 characteristics
Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous 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.

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:

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

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:

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Species : Rabbit
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 syn-
thesis 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 syn-
thesis 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
 : 10 mg/kg body weight
 Result : negative

Species : Mouse
 Application Route : oral (feed)
 : 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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| | |
|------------------------------------|---|
| Effects on fetal development | <p>Species: Rat Application Route: Ingestion Fertility: LOAEL: 0,5 mg/kg body weight Result: Effects on fertility.</p> <p>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.</p> <p>Test Type: Two-generation study Species: Mouse Application Route: Oral Fertility: LOAEL: 0,1 mg/kg body weight Result: Effects on fertility.</p> <p>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.</p> <p>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.</p> <p>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</p> |
| Reproductive toxicity - Assessment | <p>May damage fertility. May damage the unborn child.</p> |

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

| | |
|------------------------------|--|
| Effects on fetal development | <p>Test Type: Development Species: Rat Application Route: Oral Result: negative</p> <p>Test Type: Embryo-fetal development Species: Rabbit Application Route: Oral Result: negative, No teratogenic effects.</p> |
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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 : ≥ 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/m³
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

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 |

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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 aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h

||| Toxicity to algae/aquatic plants : EC50 (Skeletonema costatum (marine diatom)): > 10.000 mg/l
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-octanol/water : log Pow: 4,01

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

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

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

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

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| | | | |
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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 : Do not dispose of waste into sewer.
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

Environmentally hazardous : yes

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

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

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

Not applicable for product as supplied.

Domestic regulation

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.

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

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

AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 06.04.2024
Date format : dd.mm.yyyy

Further information

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Nomegestrol / Estradiol Formulation



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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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; TECI - Thailand Existing Chemicals Inventory; 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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