1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Nomegestrol / Estradiol Formulation

Manufacturer or supplier’s details
Company: MSD
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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, Bone, Blood, Endocrine system)
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, Bone, Blood, Endocrine system) 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.
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Components</strong></td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Estradiol</td>
<td>50-28-2</td>
</tr>
<tr>
<td>17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate</td>
<td>58652-20-3</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

<table>
<thead>
<tr>
<th>General advice</th>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>If inhaled</td>
<td>If inhaled, remove to fresh air. Get medical attention.</td>
</tr>
<tr>
<td>In case of skin contact</td>
<td>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.</td>
</tr>
<tr>
<td>In case of eye contact</td>
<td>If in eyes, rinse well with water.</td>
</tr>
</tbody>
</table>
## SAFETY DATA SHEET

**Nomegestrol / Estradiol Formulation**

<table>
<thead>
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<td>09/13/2019</td>
<td>17221-00014</td>
<td>2019/05/03</td>
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</tr>
</tbody>
</table>

- **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.

### 5. FIREFIGHTING MEASURES

- **Suitable extinguishing media:**
  - Water spray
  - Alcohol-resistant foam
  - Carbon dioxide (CO2)
  - Dry chemical
- **Unsuitable extinguishing media:**
  - None known.
- **Specific hazards during firefighting:**
  - 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 (NOx)
- **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 and personal protective equipment recommendations.
- **Environmental precautions:**
  - Discharge into the environment must be avoided.
  - 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.

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. 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. 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Estradiol</td>
<td>50-28-2</td>
<td>TWA</td>
<td>0.05 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

Wipe limit 0.5 µg/100 cm² Internal
SAFETY DATA SHEET
Nomegestrol / Estradiol Formulation

<table>
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<tr>
<th>Component</th>
<th>CAS Number</th>
<th>Limit Value</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate</td>
<td>58652-20-3</td>
<td>TWA 0.2 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>Wipe limit 2 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>TWA (Respirable) 2 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals.

Further information: Chemicals with a limit value higher than the Allowable Exposure Limit (PEL) of OSHA and/or the recommended NIOSH limit value, Adopted in Year 1996, Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals. Chemical substance identity issued by other sources, and categorized as suspected of being a human carcinogen.

**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.
  - **Filter type**: Particulates type

**Hand protection**
- **Material**: Chemical-resistant gloves

**Remarks**
Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and 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**
- **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.
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Colour: white
Odour: odourless
Odour 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
Vapour pressure: No data available
Relative vapour density: No data available
Relative density: No data available
Density: 1 g/cm³
Solubility(ies)
  Water solubility: No data available
Partition coefficient: n-octanol/water: No data available
Auto-ignition 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

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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
  : Skin contact
  : Ingestion
  : Eye contact

Acute toxicity
Not classified based on available information.

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 
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 sensitisation
Skin sensitisation
Not classified based on available information.
Respiratory sensitisation
Not classified based on available information.

Components:
Estradiol:
Exposure routes : Skin contact
Species : Guinea pig
Assessment : Does not cause skin sensitisation.
Result : negative

Talc:
Exposure routes : Skin contact
Species : Humans
Result : negative

Titanium dioxide:
Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Result : negative

Germ cell mutagenicity
Not classified based on available information.

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

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

Estradiol:
Genotoxicity in vitro : Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Name: Nomegestrol / Estradiol Formulation

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**Nomegestrol / Estradiol Formulation**

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</table>

**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

- **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

17-Hydroxy-6-methyl-19-norpregna-4,6-diene-3,20-dione 17-acetate:
Species: Rat
Application Route: oral (feed)
Activity duration: 52 Weeks
Result: negative

Species: Mouse
Application Route: oral (feed)
Result: positive
Target Organs: Mammary gland, Pituitary gland

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

Nomegestrol / Estradiol Formulation

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 foetal 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
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 foetal development:
- Test Type: Embryo-foetal 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-foetal 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 foetal development:
- Test Type: Development
  Species: Rat
  Application Route: Oral
  Result: negative

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

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

Talc:
Effects on foetal development:
- Test Type: Embryo-foetal 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 : >= 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

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 yr


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, Diarrhoea, 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

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
  - 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
**SAFETY DATA SHEET**

Nomegestrol / Estradiol Formulation

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<thead>
<tr>
<th>M-Factor (Chronic aquatic toxicity)</th>
<th>1,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC50: &gt; 100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td></td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
</tr>
<tr>
<td></td>
<td>NOEC: 100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td></td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

**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 |

<table>
<thead>
<tr>
<th>M-Factor (Chronic aquatic toxicity)</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC50 (Natural microorganism): &gt; 2.8 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td></td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
</tr>
<tr>
<td></td>
<td>NOEC (Natural microorganism): 2.8 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td></td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

**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:
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
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.
(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
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
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

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
Date format : yyyy/mm/dd

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ID OEL : Indonesia. Occupational Exposure Limits
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.