1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Lynestrenol Formulation

Manufacturer or supplier’s details
Company : Organon & Co.
Address : 30 Hudson Street, 33rd floor
         Jersey City, New Jersey, U.S.A 07302
Telephone : 551-430-6000
Emergency telephone number : 215-631-6999
E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Germ cell mutagenicity : Category 1B
Carcinogenicity : Category 2
Reproductive toxicity : Category 1A
Specific target organ toxicity - repeated exposure : Category 2 (Blood, Mammary gland, Uterus (including cervix), Ovary)

GHS label elements
Hazard pictograms : ⚠️
Signal word : Danger
Hazard statements : H340 May cause genetic defects.
H351 Suspected of causing cancer.
H360Fd May damage fertility. Suspected of damaging the unborn child.
H373 May cause damage to organs (Blood, Mammary gland, Uterus (including cervix), Ovary) through prolonged or repeated exposure.
Precautionary statements:

**Prevention:**
P203 Obtain, read and follow all safety instructions before use.
P260 Do not breathe dust.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
P318 IF exposed or concerned, get medical advice.

**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

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Lynestrenol</td>
<td>52-76-6</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Tocopherol</td>
<td>10191-41-0</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
</tbody>
</table>

### 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.
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

Specific extinguishing methods
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

Special protective equipment for firefighters
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items used 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.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Do not eat, drink or smoke when using this product.
- Take care to prevent spills, waste and minimize release to the environment.

**Conditions for safe storage**:
- Keep in properly labelled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

**Materials to avoid**:
- Do not store with the following product types:
  - Strong oxidizing agents

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Components with workplace control parameters**

<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>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Lynestrenol</td>
<td>52-76-6</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>TWA (Respirable part.)</td>
<td>2 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**

**Lynestrenol Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.4</td>
<td>10.10.2020</td>
<td>462438-00011</td>
<td>23.03.2020</td>
<td>15.01.2016</td>
</tr>
</tbody>
</table>

**Engineering measures**: Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies.

**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**

**Hand protection**

**Material**: Chemical-resistant gloves

**Remarks**: Consider double gloving.

**Eye protection**: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection**

**Hygiene measures**: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**: powder

**Colour**: No data available

**Odour**: No data available
## 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
Not applicable

## Evaporation rate
Not applicable

## Flammability (solid, gas)
May form explosive dust-air mixture during processing, handling or other means.

## Flammability (liquids)
No data available

## Upper explosion limit / Upper flammability limit
No data available

## Lower explosion limit / Lower flammability limit
No data available

## Vapour pressure
Not applicable

## Relative vapour density
Not applicable

## Relative density
No data available

## Density
No data available

## Solubility(ies)

### Water solubility
No data available

## Partition coefficient: n-octanol/water
Not applicable

## Auto-ignition temperature
No data available

## Decomposition temperature
No data available

## Viscosity

### Viscosity, kinematic
Not applicable

## Explosive properties
Not explosive

## Oxidizing properties
The substance or mixture is not classified as oxidizing.

## 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.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

Starch:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

Lynestrenol:
Acute oral toxicity: LD50: > 1,000 - 8,000 mg/kg
Acute toxicity (other routes of administration): LD50 (Mouse): 110 mg/kg
Application Route: Intraperitoneal

Talc:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Remarks: Based on data from similar materials

Tocopherol:
Acute oral toxicity: LD50 (Rat): > 4,000 mg/kg
Acute dermal toxicity: LD50 (Rat): > 3,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation:
Not classified based on available information.
SAFETY DATA SHEET
Lynestrenol Formulation

Version 3.4 Revision Date: 10.10.2020 SDS Number: 462438-00011 Date of last issue: 23.03.2020 Date of first issue: 15.01.2016

**Components:**

**Talc:**
Species: Rabbit
Result: No skin irritation

**Tocopherol:**
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components:**

**Starch:**
Species: Rabbit
Result: No eye irritation

**Talc:**
Species: Rabbit
Result: No eye irritation

**Tocopherol:**
Species: Rabbit
Method: OECD Test Guideline 405
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:**

**Starch:**
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

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

**Tocopherol:**
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Method: OECD Test Guideline 429
Result: positive
Assessment: Probability or evidence of low to moderate skin sensitisation rate in humans

Germ cell mutagenicity
May cause genetic defects.

Components:

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

Lynestrenol:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Result: positive
Test Type: sister chromatid exchange assay
Result: positive
Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Mouse
Application Route: Intraperitoneal injection
Result: positive
Test Type: sister chromatid exchange assay
Species: Mouse
Application Route: Intraperitoneal injection
Result: positive
Test Type: dominant lethal test
Species: Mouse
Application Route: Intraperitoneal
Result: positive

Germ cell mutagenicity - Assessment: Positive result(s) from in vivo somatic cell mutagenicity tests in mammals. Evidence that the substance has potential to cause mutations to germ cells

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
## Tocopherol:

### Genotoxicity in vitro
- **Test Type:** Chromosome aberration test in vitro
- **Method:** OECD Test Guideline 473
- **Result:** negative
- **Remarks:** Based on data from similar materials

### Genotoxicity in vivo
- **Test Type:** Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
- **Species:** Mouse
- **Application Route:** Ingestion
- **Result:** negative
- **Remarks:** Based on data from similar materials

## Carcinogenicity

Suspected of causing cancer.

### Components:

#### Lynestrenol:
- **Species:** Mouse
- **Application Route:** Oral
- **Exposure time:** 80 weeks
- **Result:** positive
- **Tumor Type:** breast tumors, Liver
- **Remarks:** Benign and malignant tumor(s)

- **Species:** Rat
- **Application Route:** Oral
- **Exposure time:** 80 weeks
- **Result:** positive
- **Tumor Type:** breast tumors

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

#### Tocopherol:
- **Species:** Rat
- **Application Route:** Ingestion
- **Exposure time:** 104 weeks
- **Result:** negative
- **Remarks:** Based on data from similar materials
Reproductive toxicity
May damage fertility. Suspected of damaging the unborn child.

Components:

Lynestrenol:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat, males
Application Route: Oral
Fertility: LOAEL: 20 mg/kg body weight
Remarks: Impaired spermatogenesis

Species: Rat, females
Application Route: Oral
Fertility: LOAEL: 375 µg/kg
Result: Maternal toxicity observed., Effects on fertility

Species: Rabbit
Application Route: Oral
Fertility: LOAEL: 1,300 µg/kg
Result: Effects on fertility, Postimplantation loss.

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 0.1 mg/kg body weight
Result: Effects on foetal development

Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 0.1 mg/kg body weight
Result: Effects on foetal development, Postimplantation loss.

Reproductive toxicity - Assessment: Some evidence of adverse effects on development, based on animal experiments., 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

Tocopherol:
Effects on foetal development: Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials
STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs (Blood, Mammary gland, Uterus (including cervix), Ovary) through prolonged or repeated exposure.

Components:

Lynestrenol:
Target Organs: Blood, Mammary gland, Uterus (including cervix), Ovary
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Starch:
Species: Rat
NOAEL: >= 2,000 mg/kg
Application Route: Skin contact
Exposure time: 28 Days
Method: OECD Test Guideline 410

Tocopherol:
Species: Rat
NOAEL: 500 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Remarks: Based on data from similar materials

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Lynestrenol:
Ingestion: Target Organs: Uterus (including cervix)
Target Organs: breasts
Target Organs: ovaries
Target Organs: Blood
Symptoms: Headache, Nausea, Abdominal pain, Rash, Dizziness, Tremors, Sweating, Vomiting, migraine, acne, breast tenderness, gynecomastia, menstrual irregularities, ovarian cysts
Remarks: Used to prevent pregnancy
12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Talc:
Toxicity to fish: LC50 (Brachydanio rerio (zebrafish)): > 100,000 mg/l
Exposure time: 24 h

Tocopherol:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 23.53 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): 25.8 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

EC50 (Pseudokirchneriella subcapitata (green algae)): > 25.8 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms: EC50: > 937 mg/l
Exposure time: 30 min
Method: ISO 8192
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity): NOEC: > 100 mg/l
Exposure time: 28 d
Species: Oncorhynchus mykiss (rainbow trout)
Remarks: Based on data from similar materials

Persistence and degradability

Components:

Tocopherol:
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 20 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
SAFETY DATA SHEET

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Bioaccumulative potential
No data available

Mobility in soil
No data available

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
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Further information
Sources of key data used to compile the Safety Data Sheet

Date format : dd.mm.yyyy
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.

IN / EN