SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Lynestrenol Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil 13106-054
Telephone : 908-740-4000
Emergency telephone : 55 19 3758 2000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Germ cell mutagenicity : Category 1B
Carcinogenicity : Category 2
Reproductive toxicity : Category 1A
Specific target organ toxicity - repeated exposure : Category 1 (Blood, Mammary gland, Uterus (including cervix), Ovary)

GHS label elements in accordance with ABNT NBR 14725 Standard
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.
H372 Causes damage to organs (Blood, Mammary gland, Uterus (including cervix), Ovary) through prolonged or repeated exposure.

Precautionary Statements : Prevention:
P201 Obtain special instructions before use.
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protec-
tion/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>Acute toxicity (Oral), Germ cell mutagenicity,</td>
<td>&gt;= 20 &lt; 30</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Category 4, Germ cell mutagenicity, Category 1B,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Carcinogenicity, Category 2, Reproductive toxicity,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Category 1A, Specific target organ toxicity -</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>repeated exposure (Blood, Mammary gland, Uterus</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(including cervix), Ovary), Category 1</td>
<td></td>
</tr>
<tr>
<td>Lnestrenol</td>
<td>52-76-6</td>
<td>Acute toxicity (Oral), Germ cell mutagenicity,</td>
<td>&gt;= 5 &lt; 10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Category 4, Germ cell mutagenicity, Category 1B,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Carcinogenicity, Category 2, Reproductive toxicity,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Category 1A, Specific target organ toxicity -</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>repeated exposure (Blood, Mammary gland, Uterus</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(including cervix), Ovary), Category 1</td>
<td></td>
</tr>
<tr>
<td>Talc</td>
<td>14807-96-6</td>
<td>Acute toxicity (Oral), Skin sensitization, Sub-</td>
<td>&gt;= 1 &lt; 5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>category 1B</td>
<td></td>
</tr>
<tr>
<td>Tocopherol</td>
<td>10191-41-0</td>
<td>Acute toxicity (Oral), Skin sensitization, Sub-</td>
<td>&gt;= 0,1 &lt; 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>category 1B</td>
<td></td>
</tr>
</tbody>
</table>

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.
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 genetic defects. Suspected of causing cancer. May damage fertility. Suspected of damaging 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 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 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 and personal protective equipment.
Emergency procedures

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 spills 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.
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.

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.
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Lynestrenol Formulation

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

<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>Talc</td>
<td>14807-96-6</td>
<td>TWA (Respirable fraction)</td>
<td>2 mg/m³</td>
<td>ACGIH</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: Combined particulates and organic vapor type
  - Hand protection: Chemical-resistant gloves

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

Skin and body protection:
- Work uniform or laboratory coat.
  - Additional body garments should be used based upon the
task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Color</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
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<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
Explosive properties : Not explosive

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

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:

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg

Method: Calculation method

Components:

Starch:

Acute oral toxicity : LD50 (Mouse): > 5.000 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:
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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.

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:

Talc:
Species: Rabbit
Result: No eye irritation

Tocopherol:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

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

Tocopherol:
Test Type: Local lymph node assay (LLNA)
Routes of exposure: Skin contact
### Species
- **Mouse**

### Method
- **OECD Test Guideline 429**

### Result
- **positive**

### Assessment
- Probability or evidence of low to moderate skin sensitization rate in humans

### Germ cell mutagenicity
May cause genetic defects.

### Components:

#### 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

#### 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

Carcinogenicity - Assessment: Limited evidence of carcinogenicity in animal studies

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

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

Test Type: Fertility/early embryonic development
Species: Rabbit
Application Route: Oral
Fertility: LOAEL: 1.300 µg/kg

Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 0,1 mg/kg body weight
Result: Effects on fetal development.

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 0,1 mg/kg body weight
Result: Effects on fetal 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 fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

Tocopherol:
Effects on fetal development: Test Type: Embryo-fetal 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
Causes 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:

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

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

Toxicity to microorganisms
: EC50: > 937 mg/l
Exposure time: 30 min
Method: ISO 8192
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

Bioaccumulative potential
No data available

Mobility in soil
No data available

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
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 Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

ANTT
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. Ordinance No. 1274 on the control and monitoring of chemicals. : Not applicable

International Regulations

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information


Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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