SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Lynestrenol Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 855 Leandro N. Alem St., 8 Floor
Buenos Aires, Argentina  C1001AFB
Telephone: 908-740-4000
Emergency telephone: 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

SECTION 2. HAZARDS IDENTIFICATION

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:
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Starch</td>
<td>9005-25-8</td>
<td></td>
<td>&gt;= 20 - &lt; 30</td>
</tr>
<tr>
<td></td>
<td>Lynestrenol</td>
<td>52-76-6</td>
<td></td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
<tr>
<td></td>
<td>Talc</td>
<td>14807-96-6</td>
<td></td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td></td>
<td>Glycerine</td>
<td>56-81-5</td>
<td></td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td></td>
<td>Tocopherol</td>
<td>10191-41-0</td>
<td></td>
<td>&gt;= 0.1 - &lt; 1</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. 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.
Most important symptoms and effects, both acute and delayed: Rinse mouth thoroughly with water. May cause genetic defects. Suspected of causing cancer. May damage fertility. Suspected of damaging the unborn child. May cause 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

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 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.

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.

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>CMP</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
</tbody>
</table>

Further information: A4 - Not classifiable as a human carcinogen: Agents which cause concern that they could be carcinogenic for
SAFETY DATA SHEET

Lynestrenol Formulation

<table>
<thead>
<tr>
<th>TWA</th>
<th>10 mg/m³</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lynestrenol</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
</tr>
<tr>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Talc</td>
<td>CMP (Respirable fraction)</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>TWA</td>
<td>(Respirable fraction)</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Glycerine</td>
<td>CMP (Mist)</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>

Further information: The value is for particulate matter containing no asbestos and < 1% crystalline silica, lung.

Further information: Irritation

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

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: 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.

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.

### 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>
</tr>
<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>
</tbody>
</table>
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

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

**Glycerine:**
- Acute oral toxicity: LD50 (Rat): > 5.000 mg/kg
- Acute dermal toxicity: LD50 (Guinea pig): > 5.000 mg/kg

**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.

**Components:**

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

**Glycerine:**
- 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

**Glycerine:**
- Species: Rabbit
- Result: No eye irritation

**Tocopherol:**
- Species: Rabbit
  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

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

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

Test Type: Bacterial reverse mutation assay (AMES)
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

**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)
<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>80 weeks</td>
</tr>
<tr>
<td>Result</td>
<td>positive</td>
</tr>
<tr>
<td>Tumor Type</td>
<td>breast tumors</td>
</tr>
<tr>
<td>Carcinogenicity - Assessment</td>
<td>Limited evidence of carcinogenicity in animal studies</td>
</tr>
</tbody>
</table>

**Talc:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Glycerine:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Tocopherol:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>104 weeks</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Reproductive toxicity**

May damage fertility. Suspected of damaging the unborn child.

**Components:**

**Lynestrenol:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Fertility/early embryonic development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat, males</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Fertility</td>
<td>LOAEL: 20 mg/kg body weight</td>
</tr>
<tr>
<td>Remarks</td>
<td>Impaired spermatogenesis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Fertility/early embryonic development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat, females</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Fertility</td>
<td>LOAEL: 375 µg/kg</td>
</tr>
<tr>
<td>Result</td>
<td>Maternal toxicity observed., Effects on fertility.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rabbit</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Fertility</td>
<td>LOAEL: 1.300 µg/kg</td>
</tr>
<tr>
<td>Result</td>
<td>Effects on fertility., Postimplantation loss.</td>
</tr>
</tbody>
</table>
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

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

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**
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:**

**Glycerine:**
Species: Rat
NOAEL: 0.167 mg/l
LOAEL: 0.622 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 13 Weeks

Species: Rat
NOAEL: 8.000 - 10.000 mg/kg
Application Route: Ingestion
Exposure time: 2 y

Species: Rabbit
NOAEL: 5.040 mg/kg
Application Route: Skin contact
Exposure time: 45 Weeks

**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

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

Exposure time: 96 h

Exposure time: 48 h

Exposure time: 16 h
Method: DIN 38 412 Part 8
Remarks: Based on data from similar materials

Toxicity to microorganisms
NOEC (Pseudomonas putida): > 10.000 mg/l
Exposure time: 16 h
Method: DIN 38 412 Part 8
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates
EC50 (Daphnia magna (Water flea)): 1.955 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 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:

Glycerine:
Biodegradability
Result: Readily biodegradable.
Biodegradation: 92 %

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 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
Exposure time: 30 d  
Method: OECD Test Guideline 301D

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

**Bioaccumulative potential**

**Components:**

**Glycerine:**
Partition coefficient: n-octanol/water: log Pow: -1.75

**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.

### SECTION 15. REGULATORY INFORMATION

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

**Argentina. Carcinogenic Substances and Agents Registry:** Not applicable
Control of precursors and essential chemicals for the preparation of drugs.

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

Sources of key data used to compile the Material Safety Data Sheet:

Full text of other abbreviations

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **AR OEL**: Argentina. Occupational Exposure Limits
- **ACGIH / TWA**: 8-hour, time-weighted average
- **AR OEL / CMP**: TLV (Threshold Limit Value)

Abbreviations:

- AICS - Australian Inventory of Chemical Substances
- 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 Organization 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
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.