SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Lynestrenol / Ethinyl Estradiol Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name: Lynestrenol / Ethinyl Estradiol Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company: MSD
Innishannon
County Cork - Ireland
Telephone: 353 214329300
Telefax: 908-735-1496
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Germ cell mutagenicity, Category 1B
Carcinogenicity, Category 1A
Reproductive toxicity, Category 1A
Specific target organ toxicity - repeated exposure, Category 1
Long-term (chronic) aquatic hazard, Category 1

H340: May cause genetic defects.
H350: May cause cancer.
H360FD: May damage fertility. May damage the unborn child.
H372: Causes damage to organs through prolonged or repeated exposure.
H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms:

Signal word: Danger

Hazard statements:
H340 May cause genetic defects.
H350 May cause cancer.
**SAFETY DATA SHEET**

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**SDS Number:** 485504-00012

**Date of last issue:** 23.03.2020

**Date of first issue:** 21.01.2016

H360FD May damage fertility. May damage the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

**Precautionary statements**

**Prevention:**
- P201 Obtain special instructions before use.
- P260 Do not breathe dust.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
- P308 + P313 IF exposed or concerned: Get medical advice/ attention.
- P391 Collect spillage.

**Hazardous components which must be listed on the label:**

Lynestrenol
Ethinylestradiol

**2.3 Other hazards**

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**

**3.2 Mixtures Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. / EC-No. / Index-No. / Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lynestrenol</td>
<td>52-76-6 200-151-4</td>
<td>Acute Tox. 4; H302 Muta. 1B; H340 Carc. 2; H351 Repr. 1A; H360Fd STOT RE 1; H372 (Blood, Mammary gland, Uterus (including cervix), Ovary)</td>
<td>&gt;= 0.3 - &lt; 1</td>
</tr>
<tr>
<td>Ethinylestradiol</td>
<td>57-63-6 200-342-2</td>
<td>Acute Tox. 4; H302 Carc. 1A; H350 Repr. 1B; H360FD STOT RE 1; H372 (Liver, Blood) Aquatic Chronic 1; H410</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
</tr>
</tbody>
</table>
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M-Factor (Chronic aquatic toxicity): 100,000

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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. 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: May cause genetic defects. 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.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.
SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
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

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

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.

SECTION 6: Accidental release measures

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

6.2 Environmental precautions
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.

6.3 Methods and material for containment and cleaning up
Methods for 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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
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.

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.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

### Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>OELV - 8 hrs (TWA) (Respirable dust)</td>
<td>4 mg/m3</td>
<td>IE OEL</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>Ethinylestradiol</td>
<td>57-63-6</td>
<td>TWA</td>
<td>0.01 µg/m3 (OEB 5)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used.

### Exposure controls

#### 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

**Eye protection**: Wear the following personal protective equipment:
- Safety goggles
- Equipment should conform to I.S. EN 166

**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.

**Skin and body protection**

Select appropriate protective clothing based on chemical
resistance data and an assessment of the local exposure
potential. Skin contact must be avoided by using impervious protective
clothing (gloves, aprons, boots, etc).

**Respiratory protection**

If adequate local exhaust ventilation is not available or expo-
sure assessment demonstrates exposures outside the rec-
ommended guidelines, use respiratory protection.

Equipment should conform to I.S. EN 143

**Filter type**

Particulates type (P)

---

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic 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**: No data available
- **Flammability (solid, gas)**: May form explosive dust-air mixture during processing, han-
dling or other means.
- **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**: No data available
- **Solubility(ies)**
  - **Water solubility**: No data available
  - **Partition coefficient: n-octanol/water**: No data available
9.2 Other information

Flammability (liquids): No data available
Molecular weight: No data available
Particle size: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact
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Acute toxicity
Not classified based on available information.

Components:

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

Ethinylestradiol:
Acute oral toxicity: LD50 (Rat): 1,200 mg/kg
LD50 (Mouse): 1,737 mg/kg
Acute inhalation toxicity: Remarks: No data available
Acute dermal toxicity: Remarks: No data available

Skin corrosion/irritation
Not classified based on available information.

Components:

Ethinylestradiol:
Remarks: No data available

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

Components:

Ethinylestradiol:
Remarks: No data available

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Ethinylestradiol:
Remarks: No data available

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

**Ethinylestradiol**:
- **Genotoxicity in vitro**
  - Test Type: Bacterial reverse mutation assay (AMES)
    - Test system: Salmonella typhimurium
    - Result: negative
  - Test Type: Bacterial reverse mutation assay (AMES)
    - Test system: Escherichia coli
    - Result: negative
  - Test Type: Chromosome aberration test in vitro
    - Test system: Human lymphocytes
    - Result: equivocal

- **Genotoxicity in vivo**
  - Test Type: Chromosomal aberration
    - Species: Mouse
    - Cell type: Bone marrow
    - Application Route: Oral
    - Result: positive
  - Test Type: Micronucleus test
    - Species: Mouse
    - Cell type: Bone marrow
    - Application Route: Oral
    - Result: negative
Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity
May cause 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

Ethinylestradiol:
Species: Rat, male and female
Application Route: Oral
Exposure time: 2 Years
Result: negative
Species: Monkey, female
Application Route: Oral
Exposure time: 10 Years
Result: negative
Carcinogenicity - Assessment: Positive evidence from human epidemiological studies

Reproductive toxicity
May damage fertility. May damage 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
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

Test Type: Embryo-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.

**Ethinylestradiol:**

Effects on fertility: Species: Hamster
Fertility: LOAEL: 6.3 mg/kg body weight
Result: Effects on fertility

Effects on foetal development: Test Type: Four-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: > 0.006 mg/kg body weight
Result: Specific developmental abnormalities

Test Type: Two-generation reproduction toxicity study
Species: Rat, male and female
Application Route: Oral
Developmental Toxicity: LOAEL: 0.005 mg/kg body weight
Result: Specific developmental abnormalities

Reproductive toxicity - Assessment: Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

**STOT - single exposure**
Not classified based on available information.

**STOT - repeated exposure**
Causes damage to organs 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.

**Ethinylestradiol:**
- **Target Organs:** Liver, Blood
- **Assessment:** Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**Ethinylestradiol:**
- **Species:** Rat
  - **NOAEL:** 0.25 mg/kg
  - **LOAEL:** 0.5 mg/kg
- **Application Route:** Oral
- **Exposure time:** 2 Weeks
- **Target Organs:** Liver

- **Species:** Rabbit
  - **LOAEL:** 0.015 mg/kg
  - **Application Route:** Oral
  - **Exposure time:** 20 Weeks
- **Liver

- **Species:** Dog
  - **NOAEL:** 0.04 mg/kg
  - **LOAEL:** 0.2 mg/kg
  - **Application Route:** Oral
- **Exposure time:** 95 d
- **Target Organs:** Blood

- **Species:** Rat, male and female
  - **NOAEL:** 0.0015 mg/kg
  - **LOAEL:** 0.005 mg/kg
  - **Application Route:** Oral
- **Exposure time:** 2 yr
- **Target Organs:** Reproductive organs, Mammary gland, Liver, Uterus (including cervix)

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure**

**Components:**

**Lynestrenol:**
SECTION 12: Ecological information

12.1 Toxicity

**Components:**

**Ethinylestradiol:**

**Toxicity to fish**

- **LC50 (Lepomis macrochirus (Bluegill sunfish)):** 1.6 mg/l
- **Exposure time:** 96 h
- **Method:** OECD Test Guideline 203

**Toxicity to algae/aquatic plants**

- **EC50 (Pseudokirchneriella subcapitata (green algae)):** > 6.7 mg/l
- **Exposure time:** 72 h
- **Method:** OECD Test Guideline 201

- **NOEC (Pseudokirchneriella subcapitata (green algae)):** 6.7 mg/l
- **Exposure time:** 72 h
- **Method:** OECD Test Guideline 201

**Toxicity to microorganisms**

- **EC50 : > 1,000 mg/l**
- **Exposure time:** 3 h
- **Test Type:** Respiration inhibition
- **Method:** OECD Test Guideline 209

- **NOEC : 24.9 mg/l**
- **Exposure time:** 3 h
- **Test Type:** Respiration inhibition
- **Method:** OECD Test Guideline 209

**Toxicity to fish (Chronic toxicity)**

- **NOEC: 0.01 µg/l**
- **Exposure time:** 35 d
- **Species: Pimephales promelas (fathead minnow)**
- **Method:** OECD Test Guideline 210

- **NOEC: 0.00031 µg/l**
- **Exposure time:** 339 d
Species: Zebrafish

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC: 0.75 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)
- Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity): 100,000

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential

Components:

Ethinylestradiol:
- Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
- Bioconcentration factor (BCF): 264
- Method: OECD Test Guideline 305
- Partition coefficient: n-octanol/water: log Pow: 4.15

12.4 Mobility in soil

Components:

Ethinylestradiol:
- Distribution among environmental compartments: log Koc: 3.86

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product:
Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number
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<table>
<thead>
<tr>
<th>Version</th>
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<th>Date of last issue: 23.03.2020</th>
<th>Date of first issue: 21.01.2016</th>
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</thead>
<tbody>
<tr>
<td>3.4</td>
<td>485504-00012</td>
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</tbody>
</table>

### ADN
- **UN proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ethinylestradiol)
- **Transport hazard class(es)**: 9
- **Packing group**: III
- **Classification Code**: M7
- **Hazard Identification Number**: 90
- **Labels**: 9

### ADR
- **UN proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ethinylestradiol)
- **Transport hazard class(es)**: 9
- **Packing group**: III
- **Classification Code**: M7
- **Hazard Identification Number**: 90
- **Labels**: 9
- **Tunnel restriction code**: (-)

### RID
- **UN proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ethinylestradiol)
- **Transport hazard class(es)**: 9
- **Packing group**: III
- **Classification Code**: M7
- **Hazard Identification Number**: 90

### IMDG
- **UN proper shipping name**: Environmentally hazardous substance, solid, n.o.s. (Ethinylestradiol)
- **Transport hazard class(es)**: 9
- **Packing group**: III
- **Classification Code**: M7
- **Hazard Identification Number**: 90
- **Labels**: 9

### IATA
- **UN proper shipping name**: Environmentally hazardous substance, solid, n.o.s. (Ethinylestradiol)
- **Transport hazard class(es)**: 9
- **Packing group**: III
- **Classification Code**: M7
- **Hazard Identification Number**: 90
- **Labels**: 9
### Labels

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**IMDG**

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<th>EmS Code</th>
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<td>F-A, S-F</td>
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**IATA (Cargo)**

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<th>Packing instruction (cargo aircraft)</th>
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**IATA (Passenger)**

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<th>Packing instruction (passenger aircraft)</th>
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### 14.5 Environmental hazards

**ADN**

Environmentally hazardous : yes

**ADR**

Environmentally hazardous : yes

**RID**

Environmentally hazardous : yes

**IMDG**

Marine pollutant : yes

**IATA (Passenger)**

Environmentally hazardous : yes

**IATA (Cargo)**

Environmentally hazardous : yes

### 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

### SECTION 15: Regulatory information

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

**REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)**

: Not applicable

**REACH - Candidate List of Substances of Very High**

: Not applicable
Concern for Authorisation (Article 59).
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
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<td>200 t</td>
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Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements
H302 : Harmful if swallowed.
H340 : May cause genetic defects.
H350 : May cause cancer.
H351 : Suspected of causing cancer.
H360Fd : May damage fertility. Suspected of damaging the unborn child.
H360FD : May damage fertility. May damage the unborn child.
H372 : Causes damage to organs through prolonged or repeated exposure.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Lynestrenol / Ethinyl Estradiol Formulation

Version 3.4 Revision Date: 10.10.2020 SDS Number: 485504-00012 Date of last issue: 23.03.2020
Date of first issue: 21.01.2016

Carc.: Carcinogenicity
Muta.: Germ cell mutagenicity
Repr.: Reproductive toxicity
STOT RE: Specific target organ toxicity - repeated exposure
IE OEL: Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA): Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; IECSG - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:
Muta. 1B H340 Calculation method
Carc. 1A H350 Calculation method
Repr. 1A H360FD Calculation method
STOT RE 1 H372 Calculation method
Aquatic Chronic 1 H410 Calculation method

Classification procedure:
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.