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
             Shotton Lane
             NE23 3JU Cramlington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   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                      H340: May cause genetic defects.
   Carcinogenicity, Category 1A                             H350: May cause cancer.
   Reproductive toxicity, Category 1A                       H360FD: May damage fertility. May damage the unborn child.
   Specific target organ toxicity - repeated exposure, Category 1  H372: Causes damage to organs through prolonged or repeated exposure.
   Long-term (chronic) aquatic hazard, Category 1           H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms : [Images of hazard symbols]
   Signal word : Danger
   Hazard statements : H340 May cause genetic defects.
                        H350 May cause cancer.
Lynestrenol / Ethinyl Estradiol Formulation

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.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>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</td>
<td>&gt;= 0.3 - &lt; 1</td>
<td></td>
<td></td>
<td></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 Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 100,000</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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 and personal protective equipment recommendations.

6.2 Environmental precautions
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.

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. 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.

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 Explosives Gases
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Date of first issue: 21.01.2016

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>TWA (inhalable dust)</td>
<td>10 mg/m³</td>
<td>GB EH40</td>
</tr>
</tbody>
</table>

Further information: For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols. The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m⁻³ 8-hour TWA of inhalable dust or 4 mg.m⁻³ 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits. Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed ‘inhalable’ and ‘respirable’., Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4., Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with. Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used.

<table>
<thead>
<tr>
<th></th>
<th>TWA (Respirable dust)</th>
<th>GB EH40</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lynestrenol</td>
<td>52-76-6</td>
<td></td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
</tr>
<tr>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
</tr>
</tbody>
</table>

| Ethinylestradiol | 57-63-6               |         |
|                  | TWA                   | 0.01 µg/m³ (OEB 5) | Internal |
|                  | Wipe limit            | 0.1 µg/100 cm² | Internal |

8.2 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 BS 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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

- **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, handling or other means.
  - **Upper explosion limit / Upper flammability limit**: No data available
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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
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
Viscosity, dynamic : No data available
Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

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.
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Date of first issue: 21.01.2016

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

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

- Species: Monkey, female
  Application Route: Oral
  Exposure time: 10 Years
  Result: negative

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
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
Target Organs: 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: 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

Ethinylestradiol: Ingestion
Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhoea, Headache, Dizziness, mood swings, Oedema, liver function change, water retention, hair loss, gynecomastia, effects on menstruation

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

| ADN | : | UN 3077 |
|ADR | : | UN 3077 |
|RID | : | UN 3077 |
|IMDG| : | UN 3077 |
|IATA| : | UN 3077 |

14.2 UN proper shipping name

| ADN | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ethinylestradiol) |
|ADR | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ethinylestradiol) |
|RID | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ethinylestradiol) |
|IMDG| : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ethinylestradiol) |
|IATA| : | Environmentally hazardous substance, solid, n.o.s. (Ethinylestradiol) |

14.3 Transport hazard class(es)

| ADN | : | 9 |
|ADR | : | 9 |
|RID | : | 9 |
|IMDG| : | 9 |
|IATA| : | 9 |

14.4 Packing group

<table>
<thead>
<tr>
<th>ADN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group : III</td>
</tr>
<tr>
<td>Classification Code : M7</td>
</tr>
<tr>
<td>Hazard Identification Number : 90</td>
</tr>
</tbody>
</table>
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Labels : 9

ADR
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

IMDG
Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

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.
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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 - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
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 (EC) No 850/2004 on persistent organic pollutants: Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable

<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>100 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

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

Lynestrenol / Ethinyl Estradiol Formulation

Version 3.2
Revision Date: 09/13/2019
SDS Number: 485503-00010
Date of last issue: 24.04.2019
Date of first issue: 21.01.2016

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
Carc. : Carcinogenicity
Muta. : Germ cell mutagenicity
Repr. : Reproductive toxicity
STOT RE : Specific target organ toxicity - repeated exposure
GB EH40 : UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA : Long-term exposure limit (8-hour TWA 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; AICS - Australian Inventory of Chemical Substances; 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; 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; ICACO - 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); ISQ - 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
Sources of key data used to : Internal technical data, data from raw material SDSs, OECD
Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Code</th>
</tr>
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<tbody>
<tr>
<td>Muta. 1B</td>
<td>H340</td>
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<tr>
<td>Carc. 1A</td>
<td>H350</td>
</tr>
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<td>Repr. 1A</td>
<td>H360FD</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
</tr>
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</table>

Classification procedure:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Muta. 1B</td>
<td>Calculation method</td>
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<tr>
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<td>Calculation method</td>
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</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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.

GB / EN