1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Estradiol Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 199 Wenhai North Road
          HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone : 908-740-4000
Emergency telephone number : 86-571-87268110
E-mail address : EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview

<table>
<thead>
<tr>
<th>Appearance</th>
<th>gel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>clear, colourless</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
</tbody>
</table>

Highly flammable liquid and vapour. Causes serious eye irritation. May cause cancer. May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.

GHS Classification

<table>
<thead>
<tr>
<th>Flammable liquids</th>
<th>Category 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Category 2A</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Category 1A</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Category 1A</td>
</tr>
<tr>
<td>Specific target organ toxicity - repeated exposure</td>
<td>Category 1</td>
</tr>
<tr>
<td>Long-term (chronic) aquatic hazard</td>
<td>Category 1</td>
</tr>
</tbody>
</table>

GHS label elements
Estradiol Formulation

Hazard pictograms:
- Flammable (H225)
- Eye irritation (H319)
- May cause cancer (H350)
- May damage fertility (H360FD)
- May damage the unborn child (H360FD)
- Causes damage to organs through prolonged or repeated exposure (H372)
- Very toxic to aquatic life with long lasting effects (H410)

Signal word: Danger

Hazard statements:
- H225 Highly flammable liquid and vapour.
- H319 Causes serious eye irritation.
- 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.

Precautionary statements:

Prevention:
- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
- P233 Keep container tightly closed.
- P241 Use explosion-proof electrical/ventilating/lighting equipment.
- P242 Use only non-sparking tools.
- P243 Take precautionary measures against static discharge.
- P260 Do not breathe mist or vapours.
- P264 Wash skin thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response:
- P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P308 + P313 IF exposed or concerned: Get medical advice/attention.
- P337 + P313 IF eye irritation persists: Get medical advice/attention.
- P391 Collect spillage.

Storage:
- P403 + P235 Store in a well-ventilated place. Keep cool.
- P405 Store locked up.

Disposal:
- P501 Dispose of contents/container to an approved waste disposal plant.
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Estradiol Formulation

Version 1.5
Revision Date: 09/13/2019
SDS Number: 2678747-00006
Date of last issue: 2019/05/06
Date of first issue: 2018/04/12

Physical and chemical hazards
Highly flammable liquid and vapour.

Health hazards
Causes serious eye irritation. May cause cancer. May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

Environmental hazards
Very toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification
Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>&gt;= 40 - &lt;= 50</td>
</tr>
<tr>
<td>2,2',2''-Nitrilotriethanol</td>
<td>102-71-6</td>
<td>&lt;= 10</td>
</tr>
<tr>
<td>Estradiol</td>
<td>50-28-2</td>
<td>0.06</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air. Get medical attention.
In case of skin contact : In case of contact, immediately flush skin with 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 : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.
If swallowed : If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Causes serious eye irritation. May cause cancer. May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

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.
5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media:
- High volume water jet

Specific hazards during firefighting:
- Do not use a solid water stream as it may scatter and spread fire.
- Flash back possible over considerable distance.
- Vapours may form explosive mixtures with air.
- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides
- Nitrogen oxides (NOx)

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

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Remove all sources of ignition.
- Ventilate the area.
- 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.
- Prevent spreading over a wide area (e.g., by containment or oil barriers).
- 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:
- Non-sparking tools should be used.
- Soak up with inert absorbent material.
- Suppress (knock down) gases/vapours/mists with a water spray jet.
- For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- 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 deter-
7. HANDLING AND STORAGE

Handling
Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.
If advised by assessment of the local exposure potential, use only in an area equipped with explosion-proof exhaust ventilation.
Advice on safe handling: Do not get on skin or clothing.
Do not breathe vapours or spray mist.
Do not swallow.
Do not get in eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Non-sparking tools should be used.
Keep container tightly closed.
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.

Avoidance of contact: Oxidizing agents

Storage
Conditions for safe storage: Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Keep in a cool, well-ventilated place.
Store in accordance with the particular national regulations.
Keep away from heat and sources of ignition.

Materials to avoid: Do not store with the following product types:
Self-reactive substances and mixtures
Organic peroxides
Oxidizing agents
Flammable gases
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Poisonous gases
Explosives

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters
**Components**

<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>Ethanol</td>
<td>64-17-5</td>
<td>STEL</td>
<td>1,000 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>2,2',2''-Nitrilotriethanol</td>
<td>102-71-6</td>
<td>TWA</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Estradiol</td>
<td>50-28-2</td>
<td>TWA</td>
<td>0.05 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

- Wipe limit: 0.5 µg/100 cm²

**Engineering measures**

- Minimize workplace exposure concentrations.
- If sufficient ventilation is unavailable, use with local exhaust ventilation.
- If advised by assessment of the local exposure potential, use only in an area equipped with explosion-proof exhaust ventilation.

**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 vapour type

**Eye/face protection**

- Wear the following personal protective equipment:
  - Safety goggles

**Skin and body protection**

- Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
- Wear the following personal protective equipment:
  - If assessment demonstrates that there is a risk of explosive atmospheres or flash fires, use flame retardant antistatic protective clothing.
  - Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

**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. Take note that the product is flammable, which may impact the selection of hand protection. Wash hands before breaks and at the end of workday.

**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.

**9. PHYSICAL AND CHEMICAL PROPERTIES**
Estradiol Formulation

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>gel</td>
</tr>
<tr>
<td>Colour</td>
<td>clear, colourless</td>
</tr>
<tr>
<td>Odour</td>
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</tr>
<tr>
<td>Odour Threshold</td>
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<tr>
<td>pH</td>
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<td>Melting point/freezing point</td>
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<tr>
<td>Initial boiling point and boiling range</td>
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<tr>
<td>Flash point</td>
<td>13 °C</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</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>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
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</tr>
<tr>
<td>Solubility(ies)</td>
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</tr>
<tr>
<td>Water solubility</td>
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</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
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</tr>
<tr>
<td>Auto-ignition temperature</td>
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</tr>
<tr>
<td>Decomposition temperature</td>
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</tr>
<tr>
<td>Viscosity</td>
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</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>60000 - 85000 mm2/s</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.

Chemical stability: Stable under normal conditions.

Possibility of hazardous reactions:
- Highly flammable liquid and vapour.
  Vapours may form explosive mixture with air.
  Can react with strong oxidizing agents.

Conditions to avoid:
- Heat, flames and sparks.

Incompatible materials:
- Oxidizing agents

Hazardous decomposition products:
- No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Not classified based on available information.

Components:

Ethanol:
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
  Method: OECD Test Guideline 401

- Acute inhalation toxicity: LC50 (Rat): 124.7 mg/l
  Exposure time: 4 h
  Test atmosphere: vapour

2,2',2''-Nitrilotriethanol:
- Acute oral toxicity: LD50 (Rat): 6,400 mg/kg

Estradiol:
- Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg

- Acute toxicity (other routes of administration): LD50 (Rat): > 300 mg/kg
  Application Route: Subcutaneous

Skin corrosion/irritation:
Not classified based on available information.
Components:

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

2,2',2''-Nitrilotriethanol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

Ethanol:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

2,2',2''-Nitrilotriethanol:
Species: Rabbit
Result: No eye irritation

Estradiol:
Result: No eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Ethanol:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Result: negative

2,2',2''-Nitrilotriethanol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
# Estradiol Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
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<tr>
<td>1.5</td>
<td>09/13/2019</td>
<td>2678747-00006</td>
<td>2019/05/06</td>
<td>2018/04/12</td>
</tr>
</tbody>
</table>

### Estradiol:

**Exposure routes**: Skin contact  
**Species**: Guinea pig  
**Assessment**: Does not cause skin sensitisation.  
**Result**: negative

### Germ cell mutagenicity
Not classified based on available information.

### Components:

**Ethanol**:

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

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

**2,2',2''-Nitrilotriethanol**:

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

### Estradiol:

Genotoxicity in vitro: Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Test system: mammalian cells  
Result: positive

Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro  
Test system: mammalian cells  
Result: positive

Genotoxicity in vivo: Test Type: Chromosomal aberration  
Species: Rat  
Cell type: Bone marrow  
Result: negative

Genotoxicity in vivo: Test Type: Chromosomal aberration  
Species: Mouse  
Cell type: Bone marrow  
Result: negative
Carcinogenicity
May cause cancer.

Components:

2,2',2''-Nitrilotriethanol:
Species : Rat
Application Route : Skin contact
Exposure time : 103 weeks
Result : negative

Estradiol:
Species : Mouse
Application Route : Ingestion
Exposure time : 24 Months
LOAEL : 100 µg/kg
Result : positive
Target Organs : female reproductive organs

Species : Rat
Application Route : Subcutaneous
Exposure time : 13 weeks
LOAEL : 20 mg/kg body weight
Result : positive
Target Organs : Endocrine system

Carcinogenicity - Assessment : Positive evidence from human epidemiological studies

Reproductive toxicity
May damage fertility. May damage the unborn child.

Components:

Ethanol:
Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

2,2',2''-Nitrilotriethanol:
Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative

Effects on foetal development : Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 421
Estradiol Formulation

Result: negative

**Estradiol:**

**Effects on fertility**

Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Fertility: LOAEL: 0.5 mg/kg body weight  
Result: Effects on fertility

Test Type: One-generation reproduction toxicity study  
Species: Rat  
Duration of Single Treatment: 90 d  
Fertility: LOAEL: 0.69 mg/kg body weight  
Result: Effects on fertility

Test Type: Two-generation study  
Species: Mouse  
Application Route: Oral  
Fertility: LOAEL: 0.1 mg/kg body weight  
Result: Effects on fertility

**Effects on foetal development**

Test Type: Embryo-foetal development  
Species: Mouse, female  
Application Route: Subcutaneous  
Teratogenicity: LOAEL: 4 mg/kg body weight  
Symptoms: Malformations were observed.  
Result: positive, Teratogenic effects

Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Subcutaneous  
Teratogenicity: LOAEL: 2.5 µg/kg body weight  
Symptoms: Reduced body weight  
Result: positive, Embryotoxic effects and adverse effects on the offspring were detected.

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 0.2 mg/kg body weight  
Symptoms: Early Resorptions / resorption rate, Reduced number of viable fetuses, Reduced body weight  
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

**Reproductive toxicity - Assessment**

May damage fertility. May damage the unborn child.

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Causes damage to organs through prolonged or repeated exposure.
Components:

2,2',2''-Nitrilotriethanol:
Assessment : No significant health effects observed in animals at concentrations of 200 mg/kg bw or less.
No significant health effects observed in animals at concentrations of 0.2 mg/l/6h/d or less.

Estradiol:
Target Organs : Liver, Bone, Blood, Endocrine system
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Ethanol:
Species : Rat
NOAEL : 1,280 mg/kg
LOAEL : 3,156 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

2,2',2''-Nitrilotriethanol:
Species : Rat
NOAEL : >= 1,000 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Species : Rat
NOAEL : >= 0.5 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 28 Days
Method : OECD Test Guideline 412

Species : Rat
NOAEL : 125 mg/kg
Application Route : Skin contact
Exposure time : 90 Days

Estradiol:
Species : Rat
LOAEL : >= 0.17 mg/kg
Application Route : Ingestion
Exposure time : 90 d
Target Organs : Mammary gland, Ovary, Uterus (including cervix), Liver, Bone, Endocrine system, Blood, Testis

Aspiration toxicity
Not classified based on available information.
Experience with human exposure

**Components:**

**Estradiol:**
- **Inhalation:** Symptoms: tingling, Nose bleeding
- **Skin contact:** Symptoms: Skin irritation, Redness, pruritis
- **Ingestion:** Symptoms: Headache, Gastrointestinal disturbance, Dizziness, Vomiting, Diarrhoea, water retention, liver function change, changes in libido, breast tenderness, menstrual irregularities

12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Ethanol:**
- **Toxicity to fish:** LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l
  Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Ceriodaphnia (water flea)): > 1,000 mg/l
  Exposure time: 48 h
- **Toxicity to algae/aquatic plants:** ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l
  Exposure time: 72 h
  EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l
  Exposure time: 72 h
- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):** NOEC (Daphnia magna (Water flea)): 9.6 mg/l
  Exposure time: 9 d
- **Toxicity to microorganisms:** EC50 (Pseudomonas putida): 6,500 mg/l
  Exposure time: 16 h

**2,2',2''-Nitrilotriethanol:**
- **Toxicity to fish:** LC50 (Pimephales promelas (fathead minnow)): 11,800 mg/l
  Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Ceriodaphnia dubia (water flea)): 609.88 mg/l
  Exposure time: 48 h
- **Toxicity to algae/aquatic plants:** ErC50 (Desmodesmus subspicatus (green algae)): 512 mg/l
  Exposure time: 72 h
  Test substance: Neutralised product
  EC10 (Desmodesmus subspicatus (green algae)): 26 mg/l
  Exposure time: 72 h
  Test substance: Neutralised product
- **Toxicity to daphnia and other aquatic invertebrates:** NOEC (Daphnia magna (Water flea)): 16 mg/l
### Estradiol Formulation

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- **Aquatic Invertebrates (Chronic toxicity):** Exposure time: 21 d
- **Toxicity to microorganisms:** IC50: > 1,000 mg/l  
  Exposure time: 3 h  
  Method: OECD Test Guideline 209

### Estradiol:

- **Toxicity to fish:** LC50 (Oryzias latipes (Japanese medaka)): 3.9 mg/l  
  Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Daphnia magna (Water flea)): 2.7 mg/l  
  Exposure time: 48 h
- **Toxicity to algae/aquatic plants:** NOEC (Pseudokirchneriella subcapitata (green algae)): 1.7 mg/l  
  Exposure time: 72 h  
  Method: OECD Test Guideline 201
  - EC50 (Pseudokirchneriella subcapitata (green algae)): > 1.7 mg/l  
    Exposure time: 72 h  
    Method: OECD Test Guideline 201
- **Toxicity to fish (Chronic toxicity):** NOEC (Oryzias latipes (Japanese medaka)): 0.000003 mg/l  
  Exposure time: 160 d  
  Method: OECD Test Guideline 210
- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):** NOEC (Daphnia magna (Water flea)): 0.2 mg/l  
  Exposure time: 21 d
- **M-Factor (Chronic aquatic toxicity):** 1,000
- **Toxicity to microorganisms:** EC50: > 100 mg/l  
  Exposure time: 3 h  
  Test Type: Respiration inhibition  
  Method: OECD Test Guideline 209
  - NOEC: 100 mg/l  
    Exposure time: 3 h  
    Test Type: Respiration inhibition  
    Method: OECD Test Guideline 209

### Persistence and degradability

#### Components:

- **Ethanol:**
  - Biodegradability: Result: Readily biodegradable.  
    Biodegradation: 84%  
    Exposure time: 20 d

- **2,2’,2”-Nitrilotriethanol:**
Biodegradability : Result: Readily biodegradable.
Biodegradation: 96 %
Exposure time: 19 d

Estradiol:
Biodegradability : Result: rapidly degradable
Biodegradation: 84 %
Exposure time: 24 hrs

Bioaccumulative potential

Components:

Ethanol:
Partition coefficient: n-octanol/water : log Pow: -0.35

2,2',2"-Nitrilotriethanol:
Bioaccumulation : Species: Cyprinus carpio (Carp)
                   Bioconcentration factor (BCF): < 3.9
Partition coefficient: n-octanol/water : log Pow: -1.9

Estradiol:
Partition coefficient: n-octanol/water : log Pow: 4.01

Mobility in soil

Components:

Estradiol:
Distribution among environmental compartments : log Koc: 3.81

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
                         Empty containers retain residue and can be dangerous.
                         Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death.
                         If not otherwise specified: Dispose of as unused product.
14. TRANSPORT INFORMATION

International Regulations

**UNRTDG**
- **UN number**: UN 1170
- **Proper shipping name**: ETHANOL SOLUTION
- **Class**: III
- **Packing group**: II
- **Labels**: III

**IATA-DGR**
- **UN/ID No.**: UN 1170
- **Proper shipping name**: Ethanol solution
- **Class**: III
- **Packing group**: II
- **Labels**: Flammable Liquids
- **Packing instruction (cargo aircraft)**: 364
- **Packing instruction (passenger aircraft)**: 353

**IMDG-Code**
- **UN number**: UN 1170
- **Proper shipping name**: ETHANOL SOLUTION (Estradiol)
- **Class**: III
- **Packing group**: II
- **Labels**: III
- **EmS Code**: F-E, S-D
- **Marine pollutant**: Yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

**GB 6944/12268**
- **UN number**: UN 1170
- **Proper shipping name**: ETHANOL SOLUTION
- **Class**: III
- **Packing group**: II
- **Labels**: III

**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.

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases
Estradiol Formulation

Regulations on Safety Management of Hazardous Chemicals
Catalogue of Hazardous Chemicals : Listed
Identification of Major Hazard Installations for Hazardous Chemicals (GB 18218)
No. / Code Chemical name / Category Threshold quantity
W5.3 Flammable liquids 1,000 t

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

16. OTHER INFORMATION

Further information
Date format : yyyy/mm/dd

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit

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 Toxin; 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; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances; IC50 - Half maximal inhibitory concentration; IC50 - Half maximal inhibitory concentration; 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; 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; REACH - Regulation (EC) No
Estradiol Formulation

1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

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