SAFETY DATA SHEET

Estradiol Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Estradiol Formulation

Manufacturer or supplier’s details

Company name of supplier : MSD
Address : Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone : 52 55 57284444
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Flammable liquids : Category 2
Eye irritation : Category 2A
Carcinogenicity : Category 1A
Reproductive toxicity : Category 1A
Specific target organ toxicity - repeated exposure : Category 1 (Liver, Bone, Blood, Endocrine system)

GHS label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H225 Highly flammable liquid and vapor.
H319 Causes serious eye irritation.
H350 May cause cancer.
H360FD May damage fertility. May damage the unborn child.
H372 Causes damage to organs (Liver, Bone, Blood, Endocrine system) through prolonged or repeated exposure.

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, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
SAFETY DATA SHEET

Estradiol Formulation

P270 Do not eat, drink or smoke when using this product.
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.
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.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards
Vapors may form explosive mixture with air.

SECTION 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>

SECTION 4. FIRST AID MEASURES

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

If inhaled : If inhaled, remove to fresh air. Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with 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.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media:
High volume water jet

Specific hazards during fire fighting:
- Do not use a solid water stream as it may scatter and spread fire.
- Flash back possible over considerable distance.
- Vapors 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 fire-fighters:
In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- 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:
Non-sparking tools should be used.
containment and cleaning up

Soak up with inert absorbent material.
Suppress (knock down) gases/vapors/mists with a water spray jet.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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 determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures : 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 vapors 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.

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.

Conditions for safe storage : Keep in properly labeled 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:
Strong oxidizing agents
Organic peroxides
Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures which in contact with water emit flammable gases
Explosives
Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Ingredients with workplace control parameters**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>VLE-CT</td>
<td>1,000 ppm</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></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>VLE-PPT</td>
<td>5 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></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 Internal

**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 vapor type

- **Hand protection**
  : Chemical-resistant gloves

- **Remarks**
  : Choose gloves to protect hands against chemicals depending on the concentration 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.

**Eye 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).

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
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<tbody>
<tr>
<td>Appearance</td>
<td>gel</td>
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<tr>
<td>Color</td>
<td>clear, colorless</td>
</tr>
<tr>
<td>Odor</td>
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<tr>
<td>Odor Threshold</td>
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<td>pH</td>
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<td>Melting point/freezing point</td>
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<td>Initial boiling point and boiling range</td>
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<tr>
<td>Flash point</td>
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<tr>
<td>Evaporation rate</td>
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<td>Flammability (solid, gas)</td>
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<tr>
<td>Flammability (liquids)</td>
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<td>Water solubility</td>
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<td>Partition coefficient: n-octanol/water</td>
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</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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Decomposition temperature: No data available
Viscosity
  Viscosity, kinematic: 60000 - 85000 mm²/s
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: No data available
Particle size: No data available

SECTION 10. STABILITY AND REACTIVITY
Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
  - Highly flammable liquid and vapor.
  - Vapors 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.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
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: vapor

2,2',2''-Nitrilotriethanol:
  Acute oral toxicity: LD50 (Rat): 6,400 mg/kg
  Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
**Estradiol Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
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<tbody>
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<td>2.3</td>
<td>09/13/2019</td>
<td>2678767-00006</td>
<td>06.05.2019</td>
<td>12.04.2018</td>
</tr>
</tbody>
</table>

**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 sensitization**

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
Not classified based on available information.

**Components:**

**Ethanol:**
- Test Type: Local lymph node assay (LLNA)
- Routes of exposure: Skin contact
- Species: Mouse
Result : negative

2,2',2''-Nitrilotriethanol:
Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

Estradiol:
Routes of exposure : Skin contact
Species : Guinea pig
Assessment : Does not cause skin sensitization.
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
                          Test Type: Bacterial reverse mutation assay (AMES)
                          Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)
                      Species: Mouse
                      Application Route: Ingestion
                      Result: equivocal

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

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

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
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Effects on fetal development

  Test Type: Reproduction/Developmental toxicity screening test
  Species: Rat
  Application Route: Ingestion
  Method: OECD Test Guideline 421
  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 fetal development

  Test Type: Embryo-fetal 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-fetal 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 (Liver, Bone, Blood, Endocrine system) 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,
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, Diarrhea, water retention, liver function change, changes in libido, breast tenderness, menstrual irregularities

SECTION 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: Neutralized product
EC10 (Desmodesmus subspicatus (green algae)): 26 mg/l
Exposure time: 72 h
Test substance: Neutralized product

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC (Daphnia magna (Water flea)): 16 mg/l
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

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

---

**SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods**

**Waste from residues:** Dispose of in accordance with local regulations.

**Contaminated packaging:** Empty containers should be taken to an approved waste handling site for recycling or disposal. 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.
SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 1170
Proper shipping name : ETHANOL SOLUTION
Class : 3
Packing group : II
Labels : 3

IATA-DGR
UN/ID No. : UN 1170
Proper shipping name : Ethanol solution
Class : 3
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 : 3
Packing group : II
Labels : 3
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.

Domestic regulation

NOM-002-SCT
UN number : UN 1170
Proper shipping name : ETHANOL SOLUTION
Class : 3
Packing group : II
Labels : 3

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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Federal Law for the control of chemical precursors, essential chemical products and machinery for
Not applicable
producing capsules, tablets and pills.

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

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

**SECTION 16. OTHER INFORMATION**

**Full text of other abbreviations**

- **ACGIH**: USA, ACGIH Threshold Limit Values (TLV)
- **NOM-010-STPS-2014**: Mexico, Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
- **ACGIH / TWA**: 8-hour, time-weighted average
- **ACGIH / STEL**: Short-term exposure limit
- **NOM-010-STPS-2014 / VLE-PPT**: Time weighted average limit value
- **NOM-010-STPS-2014 / VLE-CT**: Short term exposure limit value

**ABBREVIATIONS**

- AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Civil Aviation Organization; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemicals 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; 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 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

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

Revision Date: 09/13/2019

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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