SAFETY DATA SHEET

Estradiol Formulation

Section 1: Identification

Product name: Estradiol Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 33 Whakatiki Street - Private Bag 908
         Upper Hutt - New Zealand
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATATESTWARD@msd.com
Telefax: 908-735-1496

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

Section 2: Hazard identification

GHS Classification
Flammable liquids: Flam. Liq.2
Serious eye damage/eye irritation: 2A
Carcinogenicity: Carc.1A
Reproductive toxicity: Repr.1A
Specific target organ toxicity - repeated exposure: STOT RE1 (Liver, Bone, Blood, Endocrine system)

GHS label elements
Hazard pictograms:

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 (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/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.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P281 Use personal protective equipment as required.

Response:
P303 + P361 + P353 IF ON SKIN (or hair): Remove/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.

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.

Other hazards which do not result in classification:
Vapours 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>
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<tr>
<td>Estradiol</td>
<td>50-28-2</td>
<td>0.06</td>
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Section 4: First-aid measures
# SAFETY DATA SHEET

## 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>
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<tbody>
<tr>
<td>1.5</td>
<td>09/13/2019</td>
<td>2678769-00006</td>
<td>06.05.2019</td>
<td>12.04.2018</td>
</tr>
</tbody>
</table>

### General advice
- In the case of an 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 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.

**Hazchem Code**
- 2YE
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 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 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 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.
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.


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

Section 8: Exposure controls/personal protection

Components 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>WES-TWA</td>
<td>1,000 ppm 1,880 mg/m³</td>
<td>NZ OEL</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>WES-TWA</td>
<td>5 mg/m³</td>
<td>NZ OEL</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

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

Hand protection: Combined particulates and organic vapour type

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.

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

- Appearance: gel
- Colour: clear, colourless
- Odour: No data available
- Odour Threshold: No data available
- pH: 6.6 - 6.8
- Melting point/freezing point: No data available
- Initial boiling point and boiling range: No data available
- Flash point: 13 °C
- Evaporation rate: No data available
- Flammability (solid, gas): No data available
- Flammability (liquids): Not applicable
- Upper explosion limit / Upper flammability limit: No data available
- Lower explosion limit / Lower flammability limit: No data available
- Vapour pressure: 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 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.

### Section 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
SAFETY DATA SHEET

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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
Acute dermal toxicity: LD50 (Rabbit): > 2,000 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:
Exposure routes: Skin contact
Species: Guinea pig
Assessment: Does not cause skin sensitisation.
Result: negative

Chronic toxicity

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 vivo: 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
- 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

Speciess:
- 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
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 (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, 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

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: Neutralised 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
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.

**National Regulations**

**NZS 5433**
- UN number: UN 1170
- Proper shipping name: ETHANOL SOLUTION
- Class: 3
- Packing group: II
- Labels: 3
- Hazchem Code: 2YE
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

HSNO Approval Number
HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
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</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
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<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

Section 16: Other information

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>NZ OEL</td>
<td>New Zealand. Workplace Exposure Standards for Atmospheric Contaminants</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>ACGIH / STEL</td>
<td>Short-term exposure limit</td>
</tr>
<tr>
<td>NZ OEL / WES-TWA</td>
<td>Workplace Exposure Standard - Time Weighted average</td>
</tr>
</tbody>
</table>

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
SAFETY DATA SHEET

Estradiol Formulation

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