SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Ovurelin

ACVM number : A009949

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary medicine

1.3 Details of the supplier of the safety data sheet

Company
Bayer New Zealand Limited
3 Argus Place
0627 HILLCREST, AUCKLAND, NEW ZEALAND
NEW ZEALAND
Tel.: 0800 652 488
Fax: 0800 229 838
Mail: bhc-md-oeko@bayer.com

1.4 Emergency telephone number

In case of emergency: 0800 734 607 IXOM SH&E Shared services (24hr)

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Not a dangerous substance / mixture according to GHS.

GHS label elements
Not a dangerous substance / mixture according to GHS.

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&gt;= 0,01 -&lt; 0,1</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice : Take off all contaminated clothing immediately.

If inhaled : Remove to fresh air.
Call a physician immediately.

In case of skin contact: After contact with skin, wash immediately with plenty of soap and water. If skin reactions occur, contact a physician.

In case of eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

If swallowed: Clean mouth with water and drink afterwards plenty of water. Call a physician immediately.

Most important symptoms and effects, both acute and delayed: No information available.

Notes to physician: No information available.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media: High volume water jet

Specific hazards during firefighting: Fire may cause evolution of: Carbon monoxide (CO) Carbon dioxide (CO2)

Specific extinguishing methods: Prevent fire extinguishing water from contaminating surface water or the ground water system.

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. No special precautions required.

Environmental precautions: Do not flush into surface water or sanitary sewer system.

Methods and materials for containment and cleaning up: Cover spilled product with liquid-binding material (sand, silica gel, acid binder, universal binder, hybilat). Take up mechanically and fill into labeled, closable containers.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion: The product is not flammable.
Advice on safe handling: No special precautions required.

Hygiene measures: Cleanliness Guidelines (GMP) for manufacturing of drugs must be observed!

Conditions for safe storage: For storage suitable stores with adequate product-reception volume must be used. During handling local official regulations must be observed in order to avert impairment of water by the product. Keep tightly closed in a dry and cool place.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters
Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection: In the case of vapour formation use a respirator with an approved filter.

Hand protection
Material: Hand protection: protective gloves for chemicals made of Baypren, nitrile rubber or PVC wear

Remarks: Breakthrough time not tested; dispose of immediately after contamination. Advice: The gloves should not be reused.

Eye protection: Safety glasses

Protective measures: No special safety precautions are required during handling of pharmaceuticals in their intended finished form (tablets or liquid formulations) by chemists, the hospital's medical staff or patients. For the intake of ready for use pharmaceuticals or the external use on the skin please read the label and the package leaflet. Wear suitable protective equipment. The personal protective equipment is applicable for the handling of bulk material without packaging and for incidents if an exposure by the active ingredient or hazardous components can be expected.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: solution

Colour: colourless

 Decomposition temperature: No data available

Explosive properties: No statements available.

Oxidizing properties: No statements available.
SECTION 10. STABILITY AND REACTIVITY

Chemical stability: No data available
Possibility of hazardous reactions: None known.
Conditions to avoid: No data available
Incompatible materials: Oxidizing agents
Hazardous decomposition products: Carbon monoxide (CO)
Carbon dioxide (CO2)

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:
Acute oral toxicity: Acute toxicity estimate (ATE): > 5.000 mg/kg
Acute inhalation toxicity: Assessment: No adverse effect has been observed in acute toxicity tests.
Acute dermal toxicity: Acute toxicity estimate (ATE): > 5.000 mg/kg

Components:
Benzyl alcohol:
Acute oral toxicity: LD50 (Rat, male): 1.620 mg/kg
Assessment: The component/mixture is moderately toxic after single ingestion.
Acute inhalation toxicity: Assessment: The component/mixture is moderately toxic after short term inhalation.

Skin corrosion/irritation

Components:
Benzyl alcohol:
Species: Rabbit
Method: OECD 404
Result: No skin irritation
Serious eye damage/eye irritation

**Components:**

**Benzyl alcohol:**
Species: Rabbit
Result: Irritation to eyes, reversing within 7 days
Method: OECD 405

Respiratory or skin sensitisation

**Components:**

**Benzyl alcohol:**
Species: Guinea pig
Method: Magnusson and Kligmann maximization test
Result: Did not cause sensitisation on laboratory animals.

Chronic toxicity

Germ cell mutagenicity

**Components:**

**Benzyl alcohol:**
Genotoxicity in vitro
: Test Type: Ames test
Result: negative

Genotoxicity in vivo
: Result: No indication of mutagenic effects.

STOT - single exposure

**Components:**

**Benzyl alcohol:**
Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT - repeated exposure

**Components:**

**Benzyl alcohol:**
Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity

**Components:**

**Benzyl alcohol:**
Species: Rat
NOAEL: 400 mg/kg
Exposure time: 90-day
Further information

**Product:**
Pharmaceutic effects
Remarks: Hormone product

**Components:**

**Benzyl alcohol:**
Remarks: Dermal absorption possible
Remarks: If inhaled:
irritations
Shortness of breath
Cough
Remarks: If swallowed:
Vomiting
Nausea
Irritation of mucous membranes in the mouth, throat, gullet and gastro-intestinal tract after swallowing.
Remarks: Systemic toxicity
Headache
Nausea
CNS disorders
Ataxia (uncontrolled movements)
Unconsciousness
cessation of breathing

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**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Benzyl alcohol:**
Toxicity to fish: LC50 (Lepomis macrochirus (Bluegill sunfish)): 10 mg/l
Exposure time: 96 h
Test Type: Acute Fish toxicity

Toxicity to microorganisms: EC50 (Photobacterium phosphoreum): 71,4 mg/l
Exposure time: 0,5 h

**Persistence and degradability**

**Components:**

**Benzyl alcohol:**
Biodegradability: Result: rapidly biodegradable
Biodegradation: 92 - 96 %
Exposure time: 28 d
Method: OECD 301 C
Bioaccumulative potential

**Components:**

**Benzyl alcohol:**
Partition coefficient: n-octanol/water: log Pow: 1.05

**Mobility in soil**
No data available

**Other adverse effects**

**Product:**
Additional ecological information: Do not allow to enter surface waters or groundwater.

### SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

- **Waste from residues:** Dispose of as hazardous waste in compliance with local and national regulations.
- **Contaminated packaging:** Contaminated, empty containers are to be treated in the same way as the contents.

### SECTION 14. TRANSPORT INFORMATION

**International Regulations**

- **IATA-DGR:** Not regulated as a dangerous good
- **IMDG-Code:** Not regulated as a dangerous good
- **Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:** Not applicable for product as supplied.

**National Regulations**

### SECTION 15. REGULATORY INFORMATION

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

**HSNO Controls**
Approved handler certificate not required.
HSNO tracking not required.
Refer to EPA user guide to the HSNO control regulations for further information.

The components of this product are reported in the following inventories:
8 / 8

NZIoC : On the inventory, or in compliance with the inventory

SECTION 16. OTHER INFORMATION

Full text of other 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; CPR - Controlled Products Regulations; 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; IC50 - Half maximal inhibitory concentration; ICAO - 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); 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; 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

Date format : dd.mm.yyyy

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