



SAFETY DATA SHEET

A18318/03/AUS

OVURELIN INJECTION

SECTION 1 – IDENTIFICATION, CONTACTS

Bayer Australia Ltd 875 Pacific Highway Pymble NSW 2073	Emergency Telephone Number 1800 033 111 24 hour Emergency Service Australia Wide, Toll Free Contact Point (for non-emergency calls) Animal Health Division (02) 9391 6000
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Full Product Name	OVURELIN INJECTION
Other Names	Gonadorelin diacetate tetrahydrate
Product Use	FOR ANIMAL TREATMENT ONLY For use in oestrus synchronisation programs in combination with PGF2 α , prevention of delayed ovulation and improvement of postpartum fertility and for the treatment of cystic ovaries in cattle.
Creation Date	1 April 2013
Revision Date	24 August 2016

SECTION 2 – HAZARD IDENTIFICATION

Hazard Classification	NON- HAZARDOUS SUBSTANCE NOT CLASSIFIED AS DANGEROUS GOODS
GHS-Classification	Not classified
Signal Word	Not applicable
Hazard Statements	Not applicable
Precautionary statements	Not applicable

SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Components	Benzyl alcohol Concentration [Weight percent] 0.5 - >1 CAS-No.: 100-51-6 CAS name: Benzenemethanol GHS Classification: Acute Tox. 4 H332 Acute Tox. 4 H302
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SECTION 4 – FIRST AID MEASURES

Label Regulated First Aid Statement	If poisoning occurs contact a doctor or the Poisons Information Centre. Phone Australia 13 11 26.
Scheduled Poisons	S4
Inhalation	Move individual to fresh air. If breathing ceases, give artificial respiration. Seek medical attention if irritation occurs.
Skin contact	If skin contact occurs, wash thoroughly with soap and water. Remove any contaminated clothing. If sprayed in mouth rinse mouth with water ensuring mouthwash is not swallowed.
Eye contact	If in eyes, hold eyes open, flood with water for at least 15 minutes. If irritation continues seek medical advice.
Ingestion	Rinse mouth with water ensuring mouthwash is not swallowed. Do not induce vomiting. Drink water. Immediately seek medical attention.
Injected	If possible, gently squeeze pressure with an absorbent material (eg. facial tissues) at the injection site to swab up unabsorbed product. Strong squeezing of the site should be avoided. The damaged area should be thoroughly cleansed. Seek medical attention immediately.
Advice to doctor	In the case of accidental self-administration, headache, nausea, and mild abdominal pain and menstrual bleeding may occur. Injection site reactions (such as mild irritation, redness, bruising) may occur. Reproduction studies have been performed in mice, rats, and rabbits at doses up to 50 times the human dose, and have revealed no evidence of harm to the foetus due to gonadorelin. Treat symptomatically.

SECTION 5 – FIRE FIGHTING MEASURES

Extinguishing Media	This product is non-flammable. Thus extinguishing media should be selected on the basis of the material that is burning in surrounding fire being controlled.
Fire and Explosion Hazards	Should not present a significant explosive risk under normal circumstances if it is involved in a fire. Containers may burst when heated in an intense fire
Hazardous Combustion Products	Non Flammable. Only small quantities of decomposition products are expected from this product at temperatures normally achieved in a fire. This will occur after heating to dryness. Carbon dioxide, and if combustion is incomplete, carbon monoxide and smoke; water and sodium compounds.
Fire Fighting	Substance will not burn. Wear appropriate protective clothing and equipment depending on substances burning in the fire being controlled. If safe, remove containers from path of the fire.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Accidental Release	<p><u>Emergency Procedures:</u> Non applicable</p> <p><u>Method of Containment and Clean up Procedures:</u> Absorb small spills using inert material eg. sand, soil vermiculite, or another absorbent material eg. paper, and place in a sealed container for disposal in an authorised landfill. Contain large spills and transfer to an appropriate container for disposal. Place broken vials in a secure container for disposal. Use water and detergent to clean up all contaminated surfaces. Do not flush into drains or natural waterways or areas draining into potable water supplies. Use suitable protective equipment. Keep unnecessary persons away.</p>
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SECTION 7 – HANDLING AND STORAGE

Safe Handling	Limit all unnecessary personal contact. Avoid spraying or splashing the preparation. Avoid contact with eyes and skin. Do not smoke, eat or drink while handling or using the product. Observe good personal hygiene by washing hands before and after use. Wear eye protection (face visor or goggles) if accidental eye contact is possible.
Storage	Store below 25°C (Air conditioning) in the closed, original container, in a dry, well-ventilated area. Protect from sunlight. Containers should always be kept closed in storage and stored in original labeled container. Keep out of reach of children.

SECTION 8 – EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure Limits	Exposure limits have not been established for this formulation.
Ventilation	Natural ventilation should be adequate under normal use conditions.
Eye Protection	Avoid contact with eyes. Wear suitable protective face shield glasses or goggles.
Skin Protection	Avoid skin contact. It is recommended to wear suitable gloves (preferably elbow-length) and long sleeved overalls when skin contact is likely. Wash hands or other exposed areas after handling and use.
Respirator	A respirator not required under normal conditions of use.

SECTION 9 – PHYSICAL & CHEMICAL PROPERTIES

Physical State	Liquid
Colour	Clear and colourless
pH	Not determined
Boiling point	~100°C at 100kPa
Flash point	Not applicable
Freezing point	~0°C
Solubility	Soluble in water

SECTION 10 – STABILITY & REACTIVITY

Chemical Stability	Stable under normal ambient and anticipated storage conditions of temperature and pressure
Conditions to Avoid	Long periods in direct sunlight. Long periods in ambient temperatures above 25°C
Incompatible Materials	No particular incompatibilities.
Hazardous Reactions	This product will not spontaneously polymerise.

SECTION 11 – TOXICOLOGICAL INFORMATION

Reproductive Effects	The intravenous administration of 60 mcg/kg/day of gonadorelin diacetate tetrahydrate to pregnant rats and rabbits during organogenesis did not cause embryotoxic or teratogenic effects.
Mutagenicity	None of the ingredients of the formulation have been shown to produce mutagenic effects in mammalian cells.
Carcinogenic Effects	None of the ingredients of the formulation are considered to be carcinogens.
Health Hazard Information	<p>ACUTE TOXOCITY</p> <p>Gonadorelin induces the release of lutenizing hormone, which may affect the reproductive system. May be harmful if swallowed. May cause headache, gastrointestinal disturbances, increased menstrual bleeding and hot flushes.</p> <p>Gonadorelin</p> <p>Rat Oral LD50: >600mg/kg</p>

SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity	There are no ecotoxicity or environmental data available. Environmental impacts are likely to be minor. Release into the environment should be avoided.
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SECTION 13 – DISPOSAL INFORMATION

After Intended Use	Dispose of empty container by wrapping with paper and putting in garbage.
After spill or accident	Dispose of sealed containers at an approved local waste disposal site.

SECTION 14 – TRANSPORT INFORMATION

UN No	None Allocated
UN Proper Shipping Name	None Allocated
Class & Subsidiary Risk	None Allocated
Packaging Group	None Allocated
Hazchem Code	None Allocated

SECTION 15 – REGULATORY INFORMATION

Poisons Schedule	S4
APVMA Registration	The product is registered by the APVMA.
Registration Number	63035
Labelling	All necessary directions, precautions and warnings for normal use of the product are included on the product label.

SECTION 16 – OTHER INFORMATION

Summary of Changes	GHS Update.
Acronyms	<p>ADG Code Australian Code for the Transport of Dangerous Goods by Road and Rail</p> <p>APVMA Australian Pesticides and Veterinary Medicines Authority</p> <p>CAS Chemical Abstracts Service Registry Number</p> <p>GHS Globally Harmonized System of Classification and Labelling of Chemicals</p> <p>HDPE High density polyethylene</p> <p>LDPE Low density polyethylene</p> <p>OECD Organisation for Economic Co-operation and Development</p> <p>STOT Specific Target Organ Toxicity</p> <p>SUSDP Standard for the Uniform Scheduling of Drugs and Poisons</p> <p>TWA Time Weighted Average – average airborne concentration of a particular substance when calculated over a normal eight-hour working day, for a five-day working week.</p> <p>UN Number United Nations number</p>
Disclaimer	<p>This Safety Data Sheet has been developed according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) Third revised edition. United Nations, 2009. The data, information and recommendations herein ("information") are represented in good faith and believed to be correct as of the date hereof. The purpose of this Safety Data Sheet is to describe product in terms of their safety requirements. Bayer Australia Limited makes no representation of merchantability, fitness for a particular purpose or application, or of any other nature with respect to the information or the product to which the information refers ("the product"). The information is supplied upon the condition that the persons receiving same will make their own determination as to its suitability for their purposes prior to use of the product. The physical data shown herein are typical values based on material tested. These values should not be construed as a guaranteed analysis of any specific lot or as guaranteed specification for the product or specific lots thereof. Due care should be taken to make sure that the use or disposal of this product and / or its packaging is in compliance with relevant Federal, State and Local Government regulations.</p>

END OF SDS