Document No: Alizin.Doc Revision E

SAFETY DATA SHEET

Product Name: Alizin Anti-Progesterone Injection Page: 1 of 5 Date of Issue 19 November, 2013

Section 1 - Identification of The Material and Supplier

Company: Virbac (Australia) Pty. Ltd

ABN 77 003 268 871

Address 361 Horsley Rd, Milperra, NSW 2214, Australia

Locked Bag 6000, Milperra Business Centre, NSW 1891, Australia

Telephone: (02) 9772 9772 or 1800 242 100

Fax: (02) 9772 9773

Emergency phone As above during business hours; answering machine after hours

Chemical nature: Aglepristone is an antiprogestagen active ingredient.

Trade Name: Alizin Anti-Progesterone Injection

APVMA Code: 52388

Product Code: ALIZN005, ALIZN010

Product Use: For the induction of abortion in the bitch from 0 to 45 days after mating.

For use only by a registered veterinarian.

Creation Date: July, 2002

This version issued: November, 2013 and is valid for 5 years from this date.

Section 2 - Hazards Identification

STATEMENT OF HAZARDOUS NATURE

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This product is classified as: Hazardous according to the criteria of SWA.

Not a Dangerous Good according to the Australian Dangerous Goods (ADG) Code.

Risk Phrases: R60, R61. May impair fertility. May cause harm to the unborn child.

Safety Phrases: S13, S20, S45, S53, S1/2. Keep away from food, drink and animal feeding stuffs. When using, do not eat or drink. In case of accident or if you feel unwell, contact a doctor or Poisons Information Centre immediately (show this SDS where possible). Avoid exposure - obtain special instructions before use. Keep locked up and out of reach of children.

SUSMP Classification: S4.

ADG Classification: None allocated. Not a Dangerous Good under the ADG Code.

UN Number: None allocated



GHS Signal word: DANGER

HAZARD STATEMENT:

H360: May damage fertility or the unborn child.

PREVENTION

P101: If medical advice is needed, have product container or label at hand.

P102: Keep out of reach of children.

P103: Read label before use.

P201: Obtain special instructions before use.

P202: Do not handle until all safety precautions have been read and understood.

P281: Use personal protective equipment as required.

RESPONSE

P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P308+P313: If exposed or concerned: Get medical advice.

P370+P378: Not combustible. Use extinguishing media suited to burning materials.

STORAGE

P405: Store locked up.

DISPOSAL

P501: Dispose of contents and containers as specified on the registered label.

Emergency: Virbac: 02 9772 9772 or 1800 242 100 (Business hours only)
Poisons Information Centre: 13 1126 from anywhere in Australia, (0800 764 766 in New Zealand)

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Emergency Overview

Physical Description & colour: Clear, yellow oily liquid.

Odour: No data.

Major Health Hazards: This product may be a hazard to women who are pregnant, intending to become pregnant, or whose pregnancy status is unknown. Care should be taken by veterinary surgeons or persons restraining dogs being treated (especially if they are in these categories) to avoid skin contact or accidental self injection.

Care should be taken by the veterinary surgeon when handling the product and the person restraining the animal to AVOID SELF-INJECTION.

Pregnant women and women of child-bearing age should avoid contact with this product.

Potential Health Effects

Inhalation

Short term exposure: Available data shows that this product is harmful, but symptoms are not available.

Long Term exposure: No data for health effects associated with long term inhalation.

Skin Contact:

Short term exposure: Available data shows that this product is harmful, but symptoms are not available.

Long Term exposure: No data for health effects associated with long term skin exposure.

Eye Contact:

Short term exposure: Available data shows that this product is not harmful.

Long Term exposure: No data for health effects associated with long term eye exposure.

Ingestion:

Short term exposure: Available data shows that this product is harmful, but symptoms are not available.

Long Term exposure: No data for health effects associated with long term ingestion.

Carcinogen Status:

SWA: No significant ingredient is classified as carcinogenic by SWA. **NTP:** No significant ingredient is classified as carcinogenic by NTP. **IARC:** No significant ingredient is classified as carcinogenic by IARC.

Section 3 – Composition/Information on Ingredients

| Ingredients | CAS No | Conc,% | TWA (mg/m3) | STEL (mg/m3) |
|---------------------------------|-------------|--------|-------------|--------------|
| Aglepristone | 124478-60-0 | 3.29 | not set | not set |
| Other non hazardous ingredients | secret | to 100 | not set | not set |

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non hazardous ingredients are also possible.

The TWA exposure value is the average airborne concentration of a particular substance when calculated over a normal 8 hour working day for a 5 day working week. The STEL (Short Term Exposure Limit) is an exposure value that should not be exceeded for more than 15 minutes and should not be repeated for more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL. The term "peak "is used when the TWA limit, because of the rapid action of the substance, should never be exceeded, even briefly.

Section 4 - First Aid Measures

General Information:

You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia and is available at all times. Have this MSDS with you when you call.

Accidental Self Injection: If you meet any of the categories listed above under "Major Health Hazards" you should contact a Poisons Information Centre or doctor at one.

Otherwise if possible the application of gentle squeezing pressure with absorbent material (e.g. facial tissue) at the injection site will swab up unabsorbed material. Strong squeezing of the site should be avoided. The damaged area should be thoroughly cleansed and a topical antiseptic applied.

Inhalation: If inhalation occurs, contact a Poisons Information Centre, or call a doctor at once. Remove source of contamination or move victim to fresh air. If breathing is difficult, oxygen may be beneficial if administered by trained

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personnel, preferably on a doctor's advice. DO NOT allow victim to move about unnecessarily. Symptoms of pulmonary oedema can be delayed up to 48 hours after exposure.

Skin Contact: If skin contact occurs, contact a Poisons Information Centre, or call a doctor.

Eye Contact: First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor. **Ingestion:** If swallowed, do NOT induce vomiting. Wash mouth with water and contact a Poisons Information

Centre, or call a doctor.

Section 5 – Fire Fighting Measures

Fire and Explosion Hazards: There is no risk of an explosion from this product under normal circumstances if it is involved in a fire. Violent steam generation or eruption may occur upon application of direct water stream on hot liquids.

Only small quantities of decomposition products are expected from this products at temperatures normally achieved in a fire.

Fire decomposition products from this product are not expected to be hazardous or harmful.

Extinguishing Media: Not Combustible. Use extinguishing media suited to burning materials. **Fire Fighting:** If a significant quantity of this product is involved in a fire, call the fire brigade.

Flash point: Does not burn.

Upper Flammability Limit: No data.

Lower Flammability Limit: No data.

Autoignition temperature: No data.

Flammability Class: No data.

Section 6 - Accidental Release Measures

Accidental release: This product is sold in small packages, and the accidental release from one of these is not usually a cause for concern. For minor spills, refer to product label for specific instructions. No special protective clothing is normally necessary because of this product. However it is good practice to wear latex gloves when handling injectables. In the event of a major spill, prevent spillage from entering drains or water courses and call emergency services.

Section 7 - Handling and Storage

Handling: Keep exposure to this product to a minimum, and minimise the quantities kept in work areas. Check Section 8 of this MSDS for details of personal protective measures, and make sure that those measures are followed. The measures detailed below under "Storage" should be followed during handling in order to minimise risks to persons using the product in the workplace. Also, avoid contact or contamination of product with incompatible materials listed in Section 10.

Storage: This product is a Scheduled Poison. Observe all relevant regulations regarding sale, transport and storage of this class of poison. Make sure that containers of this product are kept tightly closed. Make sure that the product does not come into contact with substances listed under "Materials to avoid" in Section 10. Check packaging - there may be further storage instructions on the label.

Section 8 Exposure Controls and Personal Protection

The following Australian Standards will provide general advice regarding safety clothing and equipment:

Respiratory equipment: **AS/NZS 1715**, Protective Gloves: **AS 2161**, Occupational Protective Clothing: AS/NZS 4501 set 2008, Industrial Eye Protection: **AS1336** and **AS/NZS 1337**, Occupational Protective Footwear: **AS/NZS2210**.

SWA Exposure Limits TWA (mg/m³) STEL (mg/m³)

Exposure limits have not been established by SWA for any of the significant ingredients in this product.

Ventilation: No special ventilation requirements are normally necessary for this product. However make sure that the work environment remains clean and that dusts are minimised.

Eye Protection: Eye protection is not normally necessary when this product is being used. However, if in doubt, wear suitable protective glasses or goggles.

Skin Protection: Prevent skin contact by wearing impervious gloves, clothes and, preferably, apron. Make sure that all skin areas are covered. See below for suitable material types.

Protective Material Types: We suggest that protective clothing be made from the following materials: rubber.

Respirator: Not usually necessary.

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Section 9 - Physical and Chemical Properties:

Physical Description & colour: Clear, yellow oily liquid.

Odour: No data.

Boiling Point: Not available.

Freezing/Melting Point: No specific data. Liquid at normal temperatures. **Volatiles:** No specific data. Expected to be low at 100°C.

Vapour Pressure:No data.Vapour Density:No dataSpecific Gravity:No data.

Water Solubility: Completely soluble in water.

pH: No data.

Volatility: No data.

Odour Threshold: No data.

Evaporation Rate: No data.

Coeff Oil/water distribution: No data

Section 10 - Stability and Reactivity

Reactivity: This product is unlikely to react or decompose under normal storage conditions. However, if you have any doubts, contact the supplier for advice on shelf life properties.

Conditions to Avoid: This product should be kept in a cool place, preferably below 25°C.

Incompatibilities: strong oxidising agents.

Fire Decomposition: Only minor quantities of decomposition products are expected at temperatures normally achieved in a fire. Carbon dioxide, and if combustion is incomplete, carbon monoxide and smoke. Water. Carbon monoxide poisoning produces headache, weakness, nausea, dizziness, confusion, dimness of vision, disturbance of judgment, and unconsciousness followed by coma and death.

Polymerisation: This product is unlikely to undergo polymerisation processes.

Section 11 – Toxicological Information

Target Organs: There is no data to hand indicating any particular target organs.

Classification of Hazardous Ingredients

Ingredient Risk Phrases

No ingredient mentioned in the HSIS database is present in this product at hazardous concentrations.

Repeated or prolonged contact with the mixture may cause removal of natural oil from the skin resulting in non-allergic contact dermatitis and absorption through the skin.

Known human reproductive toxicant.

May damage fertility and the unborn child.

Section 12 – Ecological Information

Environment Australia has assessed data relating to this product and has concluded that, given the proposed use pattern, the relatively low amount proposed for use, the excretory pattern, and the restricted sale and administration, the use will not result in a significant environmental hazard.

Section 13 – Disposal Considerations

Disposal: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled sharps container. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

Section 14 – Transport Information

ADG Code: This product is not classified as a Dangerous Good. No special transport conditions are necessary unless required by other regulations.

Section 15 - Regulatory Information

AICS: All of the significant ingredients in this product are compliant with NICNAS regulations.

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Section 16 – Other Information

This MSDS contains only safety-related information. For other data see product literature.

Contact point: Technical Manager, QA Manager or R&D Director

Telephone (02) 9772 9772 or 1800 242 100

Fax (02) 9772 9773

Acronyms:

ADG Code Australian Code for the Transport of Dangerous Goods by Road and Rail, 7th Edition

AICS Australian Inventory of Chemical Substances
CAS number Chemical Abstracts Service Registry Number

Hazchem Number Emergency action code of numbers and letters that provide information to emergency

services especially firefighters

IARC International Agency for Research on Cancer
SWA Safe Work Australia, formerly ASCC and NOHSC

NOS Not otherwise specified

NTP National Toxicology Program (USA)

R-Phrase Risk Phrase

SUSMP Standard for the Uniform Scheduling of Medicines & Poisons

UN Number United Nations Number

THIS MSDS SUMMARISES OUR BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION OF THE PRODUCT AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE. EACH USER MUST REVIEW THIS MSDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THE WORKPLACE.

IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT THIS COMPANY SO WE CAN ATTEMPT TO OBTAIN ADDITIONAL INFORMATION FROM OUR SUPPLIERS OUR RESPONSIBILITY FOR PRODUCTS SOLD IS SUBJECT TO OUR STANDARD TERMS AND CONDITIONS, A COPY OF WHICH IS SENT TO OUR CUSTOMERS AND IS ALSO AVAILABLE ON REQUEST.

Please read all labels carefully before using product.

This MSDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice" (December 2011)

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