



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 6, 2017

Kathleen M. Sanzo
Counsel for the Humane Society of the United States
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, D.C. 20004

Subject: Label Amendment – Adding sublabel B for deer
Product Name: Zonastate-H
EPA Registration Number: 86833-1
Application Date: 5/2/2017
Decision Number: 529061

Dear Ms. Sanzo:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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Decision No. 529061

with FIFRA section 6. If you have any questions, please contact Marianne Lewis by phone at (703) 308-8043, or via email at lewis.marianne@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to be 'MS' with a large loop and a horizontal line extending to the right.

Mark Suarez
Product Manager 07
Invertebrate & Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

RESTRICTED USE PESTICIDE

For retail sale to and use only by Certified Applicators or persons under their direct supervision of the following organizations and their designated wildlife management personnel and only for those uses covered by the Certified Applicator’s certification:

- Department of Interior and all its designated agents
- National Park Service, US Fish & Wildlife Service, Bureau of Land Management
- USDA and all its designated agents (i.e., U.S. Forest Service, Animal and Plant Health Inspection Service)
- State Agencies for agriculture/livestock & wildlife
- Federally recognized Indian Tribes
- Department of Defense
- Humane Society of the United States

Each Responsible Authority must sign a certification of use prior to the administration of the vaccine to any animals. The certification statement is attached to this label.

Sublabel A

ZONASTAT-H

Zonastat-H is a porcine zona pellucida immunocontraceptive vaccine indicated for use in limiting the populations of wild and feral horses (*Equus caballus*) and burros (*Equus asinus*).

Active Ingredients:

Porcine zona pellucida (ZP3)(0.1%)	0.071%
Porcine zona pellucida (ZP1, ZP2, ZP4)(0.1%)	0.029%
Other Ingredients:	<u>99.900%</u>
Total	100.000%

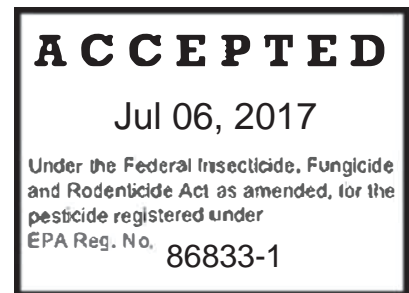
This product contains 100 µg of PZP per 0.04 oz (0.5 mL)

EPA Reg. No. 86833-x
EPA Est. No. 090192-MT-001

Net Contents: 0.5 mL

Humane Society of the United States
700 Professional Drive
Gaithersburg, MD 20879

Expiration date: xx-xx-xxxx



KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID	
IF ON SKIN OR CLOTHING	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. <u>Needle stick or cut:</u> clean wound immediately with soapy water and disinfect the wound with alcohol or other bactericidal solution. <u>Contact with Freund's Complete Adjuvant:</u> wipe skin clean with an ethanol soaked towelettes and wash with soapy water
IF INHALED	Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.
IF IN EYES	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. Accidental injection may cause infertility in women.	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Harmful if absorbed through skin. Harmful if inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Avoid breathing spray mist.

Personal Protective Equipment (PPE)

Mixers, loaders and applicators must wear:

- Long sleeved shirt and long pants
- Shoes
- Socks
- Chemical resistant gloves made out of: barrier laminate, butyl rubber ≥ 14 mils, nitrile rubber ≥ 14 mils, neoprene rubber ≥ 14 mils, natural rubber ≥ 14 mils, polyethylene, polyvinyl chloride ≥ 14 mils, or viton ≥ 14 mils

Environmental Hazards

Do not apply this product directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment rinse waters or rinsate.

DIRECTIONS FOR USE

Restricted Use Pesticide

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

Read this entire label and follow all use directions and precautions.

Restrictions

- Only for use on female wild and feral horses and burros
- All darts are to be recovered after delivery. Use neon orange or green darts to facilitate recovery.
- Do not expose children, pets, or other non-target animals to this product.
- Do not apply this product to food or feed.
- Do not apply this product to horses or burros being used as food.
- This product is only for use on female wild and feral horses and burros, which are defined as free-roaming horses or burros, privately or publicly owned, that are capable of doing environmental damage.

Product Information

When injected into a female wild and feral horse or burro, ZonaStat-D stimulates the production of anti-zona pellucida (ZP) antibodies. These antibodies bind to the native ZP glycoproteins surrounding the egg of the target female, alter their conformation, and block sperm attachment preventing conception.

Equipment Needed:

For Mixing

glass syringes, 5.0 cc, graduated at 0.2 cc, with Luer-Loc

1.5 inch 18 g disposable sterile needle

Freund's Adjuvant

PZP Solution (PZP antigen dissolved in phosphate buffered saline solution)

Luer-Loc connector

For Hand Delivery

3 cc disposable plastic syringe w/Luer-Loc
1.5 inch 18 g disposable sterile needle

For Jab-Stick Delivery

Jab Stick
3 cc disposable plastic syringe with Luer-Loc
1.5 inch 14 g disposable sterile needle

For Remote Dart Delivery

2.0 inch 18 g disposable sterile needle
1.0 cc dart with 1.25 inch or 1.5 inch barbless needle

Application Rate:

For maximum efficacy, ZonaStat-H is administered as an initial priming dose followed by a booster dose at least two weeks later. Efficacy is maintained by annual booster doses.

Initial Priming Dose: Is 0.5 cc of the PZP Solution emulsified with 0.5 cc modified Freund's Complete Adjuvant. If followed by a booster dose, the priming dose may be administered at any time of the year. The priming dose alone is expected to reduce pregnancy rates by 55-70% for one year if administered one to three months prior to the onset of mating season.

Booster Dose: Is 0.5 cc of the PZP Solution emulsified in 0.5 cc modified Freund's Incomplete Adjuvant (which adjuvant?). Administration of a single booster treatment at least 2 weeks after the administration of the priming dose is expected to reduce pregnancy rates by 90-95% for one year. Efficacy in subsequent years is maintained by administering an annual booster dose.

Procedures:

Mixing

1. Gloves must be worn at all times
2. Attach the Luer-Lok connector to one of the glass syringes
3. Attach the 1.5 inch needle on the second glass syringe
4. Draw out 0.5 cc of adjuvant
5. Using the same syringe, draw up the 0.5 cc of PZP in phosphate buffered saline solution
6. Holding the syringe containing the vaccine very carefully (to prevent the plunger from slipping out), take off the needle and attach the syringe to the second syringe using the Luer-Lok connector.
7. Push the PZP solution-adjuvant mixture back and forth through the two syringes 100 times. The resulting emulsion will become thick and look white. THIS

PROCEDURE IS VERY IMPORTANT AND IS RELATED TO THE PRESENTATION OF THE ANTIGEN AND THE SUBSEQUENT EFFICACY OF THE PRODUCT.

8. Make sure that all of the emulsion is in one syringe.
9. Holding the syringe containing the emulsion very carefully, remove the other syringe, leaving the Luer-Lok on the syringe containing the emulsion.

Application:

For Hand Delivery Injection, attach a 2.0 or 3.0 cc plastic syringe to the glass syringe via the Luer-Lok, and inject the emulsion into the plastic syringe. After loading the plastic syringe, disconnect the glass syringe and connect an 18 g 1.5 inch needle to the plastic syringe containing the emulsion.

For Jab Stick Delivery, place the nose of the plastic syringe tightly into the Luer-Lok and inject the emulsion from the glass syringe into the plastic syringe. After filling the plastic syringe, remove the glass syringe and attach the 14 g 1.5 inch needle to the plastic syringe containing the emulsion. Place the plastic syringe into the jab stick.

For Remote Dart Delivery, attach the 18 g 2 inch needle to the glass syringe containing the emulsion. Insert the needle into the body of the dart through the dart needle, and inject the contents of the syringe into the dart. Apply a small amount of Vaseline to the dart tip.

After the antigen solution and adjuvant are emulsified in the field and loaded into the dart, remotely inject ZonaStat-H intramuscularly in the hip or gluteus or hamstring muscles using a syringe dart fired from a CO₂ or cartridge-powered projection system.

Use the Pneu-Dart 1.0 cc dart with a 1.25 inch or 1.5 inch barbless needle for delivery.

The darts can be delivered using any of the following rifles/projectors, depending on the logistical requirements of the particular targeted population:

- Dan-Inject CO₂ rifle (Wildlife Pharmaceuticals) with a 13 mm barrel (for use at ranges of 10 meters to 40 meters)
- Dan-Inject Pistol Grip CO₂ Gun with a 13 mm barrel (for use at ranges of 5 meters to 20 meters)
- Pneu-Dart model 193 or 196 rifle (for use at ranges of up to 50 meters)
- Pneu-Dart model 389 cartridge-fired rifle (for use at ranges of up to 50 meters)
- Pneu-Dart X-Caliber Gauged CO₂ Long Range Projector (for use at ranges up to 50 meters)

All darts are to be recovered after delivery. Use neon orange or green darts to facilitate recovery. Examine all fired darts after recovery to determine if the charge fired and the plunger fully expelled its contents.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal

Pesticide Storage: The frozen PZP antigen expires after two years. Keep vials of PZP antigen frozen until ready for use. When transporting for use in the field, keep PZP antigen stored in a cooler, with ice packs. Once defrosted the PZP antigen expires after 24 hours. If transportation takes longer than 8 hours, store PZP antigen on dry ice in the cooler. Keep adjuvant refrigerated at +2° C to +8° C, but not frozen, until ready to be mixed with the PZP antigen. Store loaded darts in a cool dry area.

Pesticide Disposal: For any unused product dispose of as medical waste according to Federal, State, and Local regulations.

Container Disposal: Non-refillable container. Do not reuse or refill container. Dispose of expired material, preloaded syringes, used syringes as medical waste according to applicable Federal, State, and Local regulations. All used darts and needles are to be placed in a Sharps container and disposed of as medical waste according to applicable Federal, State and Local regulations.

RESTRICTED USE PESTICIDE

For retail sale to and use only by Certified Applicators or persons under their direct supervision of the following organizations and their designated wildlife management personnel and only for those uses covered by the Certified Applicator’s certification:

- Department of Interior and all its designated agents
- National Park Service, US Fish & Wildlife Service, Bureau of Land Management
- USDA and all its designated agents (i.e., U.S. Forest Service, Animal and Plant Health Inspection Service)
- State Agencies for agriculture/livestock & wildlife
- Federally recognized Indian Tribes
- Department of Defense
- Humane Society of the United States

Each Responsible Authority for deer intended to be treated with Zonastat-D must sign a certification of use prior to the administration of the vaccine to any animals. The certification statement is attached to this label.

Sublabel B

ZONASTAT-D

Zonastat-D is a porcine zona pellucida immunocontraceptive vaccine indicated for use in limiting the populations of white tailed deer (*Odocoileus virginianus*) and other members of the family Cervidae.

Active Ingredients:

Porcine zona pellucida (ZP3)(0.1%)	0.071%
Porcine zona pellucida (ZP1, ZP2, ZP4)(0.1%)	0.029%
Other Ingredients:	<u>99.900%</u>
Total	100.000%

This product contains 100 µg of PZP per 0.04 oz (0.5 mL)

EPA Reg. No. 86833-x
EPA Est. No. 090192-MT-001

Net Contents: 0.5 mL

Humane Society of the United States
700 Professional Drive
Gaithersburg, MD 20879

Expiration date: xx-xx-xxxx

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CAUTION

FIRST AID	
IF ON SKIN OR CLOTHING	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. <u>Needle stick or cut:</u> clean wound immediately with soapy water and disinfect the wound with alcohol or other bactericidal solution. <u>Contact with Freund's Complete Adjuvant:</u> wipe skin clean with an ethanol soaked towelettes and wash with soapy water
IF INHALED	Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.
IF IN EYES	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. Accidental injection may cause infertility in women.	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Harmful if absorbed through skin. Harmful if inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Avoid breathing spray mist.

Personal Protective Equipment (PPE)

Mixers, loaders and applicators must wear:

- Long sleeved shirt and long pants
- Shoes
- Socks
- Chemical resistant gloves made out of: barrier laminate, butyl rubber ≥ 14 mils, nitrile rubber ≥ 14 mils, neoprene rubber ≥ 14 mils, natural rubber ≥ 14 mils, polyethylene, polyvinyl chloride ≥ 14 mils, or viton ≥ 14 mils

Environmental Hazards

Do not apply this product directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment rinse waters or rinsate.

DIRECTIONS FOR USE

Restricted Use Pesticide

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

Read this entire label and follow all use directions and precautions.

Restrictions

- Only for use on female deer
- All darts are to be recovered after delivery. Use neon orange or green darts to facilitate recovery.
- Do not expose children, pets, or other non-target animals to this product.
- Do not apply this product to food or feed.
- This product is only for use on female deer, which are defined as free-roaming deer, privately or publicly owned, that are capable of doing environmental damage.

Product Information

When injected into a female deer, ZonaStat-D stimulates the production of anti-zona pellucida (ZP) antibodies. These antibodies bind to the native ZP glycoproteins surrounding the egg of the target female, alter their conformation, and block sperm attachment.

Equipment Needed:

For Mixing

glass syringes, 5.0 cc, graduated at 0.2 cc, with Luer-Loc

1.5 inch 18 g disposable sterile needle

Freund's Adjuvant

PZP Solution (PZP antigen dissolved in phosphate buffered saline solution)

Luer-Loc connector

For Remote Dart Delivery

2.0 inch 18 g disposable sterile needle
1.0 cc dart with 1.25 inch barbless needle

Application Rate:

For maximum efficacy, ZonaStat-D is administered as an initial priming dose followed by a booster dose at least two weeks later. Efficacy is maintained by annual booster doses.

Initial Priming Dose: Is 1.0 cc of the PZP Solution/modified Freund's Complete Adjuvant emulsion. If followed by a booster dose, the priming dose may be administered at any time of the year. The priming dose alone is expected to reduce pregnancy rates by 55-70% for one year if administered one to three months prior to the onset of mating season.

Booster Dose: Is 0.5 cc of the PZP Solution emulsified in 0.5 cc modified Freund's Incomplete Adjuvant Administration of a single booster treatment at least 2 weeks after the administration of the priming dose is expected to reduce pregnancy rates by 90-95% for one year. Efficacy in subsequent years is maintained by administering an annual booster dose.

Procedures:

Mixing

1. Gloves must be worn at all times
2. Attach the Luer-Lok connector to one of the glass syringes
3. Attach the 1.5 inch needle on the second glass syringe
4. Draw out 0.5 cc of adjuvant
5. Using the same syringe, draw up the 0.5 cc of PZP in phosphate buffered saline solution
6. Holding the syringe containing the vaccine very carefully (to prevent the plunger from slipping out), take off the needle and attach the syringe to the second syringe using the Luer-Lok connector.
7. Push the PZP solution-adjuvant mixture back and forth through the two syringes 100 times. The resulting emulsion will become thick and look white. **THIS PROCEDURE IS VERY IMPORTANT AND IS RELATED TO THE PRESENTATION OF THE ANTIGEN AND THE SUBSEQUENT EFFICACY OF THE PRODUCT.**
8. Make sure that all of the emulsion is in one syringe.
9. Holding the syringe containing the emulsion very carefully, remove the other syringe, leaving the Luer-Lok on the syringe containing the emulsion.

Application:

For Remote Dart Delivery, attach the 18 g 2 inch needle to the glass syringe containing the emulsion. Insert the needle into the body of the dart through the dart needle, and inject the contents of the syringe into the dart. Apply a small amount of Vaseline to the dart tip.

After the antigen solution and adjuvant are emulsified in the field and loaded into the dart, remotely inject ZonaStat-D intramuscularly in the hip or gluteus or hamstring muscles using a syringe dart fired from a CO₂ or cartridge-powered projection system.

Use the Pneu-Dart 1.0 cc dart with a 1.25 inch barbless needle for delivery.

The darts can be delivered using any of the following rifles/projectors, depending on the logistical requirements of the particular targeted population:

- Dan-Inject CO₂ rifle with a 13 mm barrel (for use at ranges of 10 meters to 40 meters)
- Dan-Inject Pistol Grip CO₂ Gun with a 13 mm barrel (for use at ranges of 5 meters to 20 meters)
- Pneu-Dart model 193 or 196 rifle (for use at ranges of up to 50 meters)
- Pneu-Dart model 389 cartridge-fired rifle (for use at ranges of up to 50 meters)
- Pneu-Dart X-Caliber Gauged CO₂ Long Range Projector (for use at ranges up to 50 meters)

All darts are to be recovered after delivery. Use neon orange or green darts to facilitate recovery. Examine all fired darts after recovery to determine if the charge fired and the plunger fully expelled its contents.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal

Pesticide Storage: The frozen PZP antigen expires after two years. Keep vials of PZP antigen frozen until ready for use. When transporting for use in the field, keep PZP antigen stored in a cooler, with ice packs. Once defrosted the PZP antigen expires after 24 hours. If transportation takes longer than 8 hours, store PZP antigen on dry ice in the cooler. Keep adjuvant refrigerated at +2° C to +8° C, but not frozen, until ready to be mixed with the PZP antigen. Store loaded darts in a cool dry area.

Pesticide Disposal: For any unused product dispose of as medical waste according to Federal, State, and Local regulations.

Container Disposal: Non-refillable container. Do not reuse or refill container. Dispose of expired material, preloaded syringes, used syringes as medical waste according to applicable Federal, State, and Local regulations. All used darts and needles are to be placed in a Sharps container and disposed of as medical waste according to applicable Federal, State and Local regulations.

