

86833-1

1/30/2012

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

86833-1

Date of Issuance:

JAN 30 2012

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Terms of Issuance:

Unconditional

ZonaStat-H

Name and Address of Registrant (include ZIP Code):

Humane Society of the United States
c/o Morgan, Lewis & Bockius LLP
1111 Pennsylvania Ave., NW
Washington, DC 20004

Attention: Kathleen M. Sanzo

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

Signature of Approving Official:

John Hebert
Product Manager (07)
Insecticide-Rodenticide Branch
Registration Division (7505P)

Date:

JAN 30 2012

Notice of Registration (continued)
EPA Reg. No. 86833-1

A. Submit and/or cite all data required for registration/reregistration of your product when the Agency requires all registrants of similar products to submit such data.

B. Make the following label changes before you release the product for shipment:

1. Revise your registration number to "EPA Reg. No. 86833-1",
2. Add "Department of Interior, and all its designated agents" before "National Park Service..." located in the first bullet of the certified applicators section,
3. Add a bullet in the certified applicators section that reads "USDA and all its designated agents (i.e., U.S. Forest Service, Animal and Plant Health Inspection Service),
4. Delete "Federal Land Management Agency" as there is no such entity,
5. Remove "Draft" from "Draft Package Insert for Zonastat-H", "DRAFT LABEL FOR ZONASTAT-H BAG", and "DRAFT LABEL FOR ZONASTAT-H VIAL".
6. Place a box around the restricted use section.
7. Revise "SEE OTHER PANEL FOR..." to read "SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS".
8. Add an "S" to ACTIVE INGREDIENT.
9. Under "Other ingredients" add "Total" and then add "100%" under "99.9%".
10. On page 4, change "Avoid contact with eyes" to read "Do not contact with eyes."
11. Revise the second sentence under the section title Application Rate to read "Efficacy is maintained by annual booster doses."
12. Revise "SEE PACKAGE INSERT FOR PRECAUTIONARY STATEMENTS" found on the label for the bag and vial to read "SEE PACKAGE INSERT FOR PRECAUTIONARY STATEMENTS AND DIRECTIONS FOR USE".
13. Remove "Store loaded darts in a cool dry area. In humid areas of the country, store in plastic sealable bags with a desiccant." from the Pesticide Storage paragraph of the Storage and Disposal section,
14. Add a reference to dart in the Pesticide Disposal section,
15. Create a second paragraph in the Pesticide Storage section that reads:

Notice of Registration (continued)
EPA Reg. No. 86833-1

“Storage: The vials containing PZP solution are stored frozen. The frozen PZP solution expires two years after freezing. After defrosting, the PZP solution expires after 24 hours. When transporting for use in the field, store the PZP solution in a cooler with ice packs. If transportation of the PZP solution takes longer than 8 hours, store the PZP solution on dry ice in the cooler. Store loaded darts in a cool dry place. In humid areas of the country, store in plastic sealable bags with a desiccant.”

- C. Submit one (1) copy of final printed labeling for the record before you release the product for shipment.

A copy of your label stamped “Accepted with Comments in EPA Letter Dated January 30, 2012” is enclosed for your records.

Reference to Website on Label

Should you wish to add a reference to the company's website on your label, 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 Assurance.

Confidential Statement of Formula

The acceptable Confidential Statement of Formula (CSF) for this product is dated September 12, 2011 (Basic Formulation). All other versions are obsolete.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

If you have any questions or comments regarding this letter, please contact Jennifer Gaines by phone (703-305-5967) or e-mail (gaines.jennifer@epa.gov).

Enclosures: 1. Stamped Label

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DRAFT PACKAGE INSERT FOR ZONASTAT-H

FRONT PANEL

ACCEPTED
with COMMENTS
In EPA Letter Dated
JAN 30 2012
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
86833-1

RESTRICTED USE PESTICIDE

For retail sale to and use 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 Applicators certification:

- National Park Service, Bureau of Land Management, U.S. Fish & Wildlife Service, and Federal Land Management Agency
- State departments of agriculture/livestock and wildlife, and their designated agents
- Federally recognized Indian tribes, and their designated agents
- Department of Defense and its designated agents
- Public and private wild horse sanctuaries and reserves
- Humane Society of the United States and designated agents.

Each Responsible Authority for wild horses and/or burros intended to be treated with ZONASTAT-H must sign a certification of use prior to the administration of the vaccine to any animals. The certification statement is attached to this Package Insert.

ZONASTAT-H

Product information: 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*).

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

HAVE LABEL WITH YOU WHEN OBTAINING TREATMENT ADVICE

If on skin: 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.

If inhaled: Move the person to fresh air.
If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
Call a poison control center or doctor for treatment advice.

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DRAFT

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.
 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. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

SEE OTHER PANEL FOR PRECAUTIONARY STATEMENTS

RESTRICTED USE PESTICIDE

ZONASTAT-H

ACTIVE INGREDIENT:

- Porcine zona pellucida (ZP3)(0.1%)..... 0.071%
- Porcine zona pellucida (ZP1, ZP2, ZP4)(0.1%).....0.029%
- Other ingredients..... 99.9%

Batch Code:

EPA Registration No. TBD

If pregnant, take precaution when preparing, loading, and recovering darts to not self-inject.

Humane Society of the United States
2100 L Street NW
Washington, DC 20037
202-452-1100

Net Contents 0.5 mL
Single dose

BACK PANEL

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Keep away from humans, domestic animals, and pets. Wear protective gloves when handling. If pregnant, take necessary precautions when preparing, loading, and recovering darts to not self-inject. Accidental injection may cause infertility in women. Wash all implements used for handling or applying product with detergent and water. Do not use these implements for mixing, holding, or transferring food or feed.

In the event of an accidental needle stick or cut, clean wound immediately with soapy water and disinfect wound with alcohol or other bactericidal solution. In the event of accidental contact with Modified Freund's Complete Adjuvant, wipe skin clean with an ethanol soaked towelette and wash with soapy water.

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 by cleaning of equipment or disposal of wastes.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- long sleeved shirt and long pants
- gloves
- shoes plus socks

USE INFORMATION

When injected into a female horse or burro, ZonaStat-H 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, thereby preventing conception.

USE RESTRICTIONS

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. A copy of this label must be in the possession of the user at the time that the product is applied.

READ THIS LABEL: Read this entire label and follow all use directions and precautions.

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IMPORTANT: Do not expose children, pets, or other non-target animals to this product. To help prevent accidents:

- 1) Keep children out of areas where this product is used.
- 2) Store product in use in a location out of reach of children and pets.
- 3) Apply product only according to the directions authorized.
- 4) Dispose of product container and spoiled or unused product as specified in the "STORAGE AND DISPOSAL" section on this label.

ZonaStat-H is for use only in 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.

Caution is required to prevent accidental self-injection when administering ZonaStat-H.

Pregnant women should take necessary precautions when preparing , loading , and recovering darts to not self-inject. Do not ingest. Avoid contact with eyes.

Do not apply this product to food or feed. Do not apply ZonaStat-H to horses or burros being used as food.

DIRECTIONS FOR USE

Mixing PZP Solution and Adjuvant:
This activity takes place in the field.

Equipment Needed:

- 2 BD #2311 glass syringes, 5.0 cc, graduated at 0.2 cc, with Luer-Loc
- BD 1.5-inch 18 g disposable sterile needle
- Vial of Adjuvant (supplied separately)
- Vial of PZP Solution
- Luer-Loc connector

FOR HAND DELIVERY

- BD 3cc disposable plastic syringe with Luer-Lok
- BD 1.5-inch 18 g disposable sterile needle

BACK PANEL (Continued)

FOR JAB-STICK DELIVERY

- Dan-Inject® Fiskars Combi-Click Jab Stick
- BD 3cc disposable plastic syringe with Luer-Lok
- Monoject 1.5-inch 14 g disposable sterile needle

FOR REMOTE (DART) DELIVERY

- BD 2.0 inch 18 g disposable sterile needle

1.0-cc C-type or P-type Pneu-Dart dart with 1.25-inch or 1.5-inch barbless needle

Procedures:

1. Examination gloves must be worn during mixing and loading of PZP solution.
2. Attach the Luer-Lok connector to one of the glass syringes.
3. Place the 1.5-inch needle on the second glass syringe.
4. Draw out 0.5 cc of adjuvant (supplied separately).
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.

FOR HAND DELIVERY (INJECTION), attach a 2.0 or 3.0cc 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 Monoject 14g 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, 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 Blow Gun with a 13 mm barrel (for use at ranges of 5-20 meters)
 - Pneu-Dart® model 193 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)
- The applicator must make every attempt to recover all darts. If possible, all darts that are discharged and drop from the horse at the shooting site must be recovered before another darting occurs. In exceptional situations, such as an onset of inclement weather, loss of daylight, applicator safety concerns, or other urgent circumstances, the site of a lost dart may be noted and marked, and recovery efforts made at a later time. Examine all fired darts after recovery to determine if the charge fired and the plunger fully expelled its vaccine contents.

Application Rate:

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

Initial Priming Dose

The initial treatment (priming dose) of ZonaStat-H consists of 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 the mating season.

Booster Dose

A booster dose of ZonaStat-H consists of 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 two 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.

PACKAGING

Packaging:

PZP antigen dissolved in phosphate buffered saline solution is packaged in screw-top, non-refillable plastic vials containing single 0.5 mL doses.

Adjuvant is provided separately for the initial priming dose and the booster dose. The adjuvant is provided in multidose bottles.

STORAGE AND DISPOSAL

Pesticide Storage:

Keep vials of PZP antigen (i.e., PZP + phosphate buffer solution) frozen until ready for use. When transporting for use in the field, keep PZP antigen stored in a cooler, with ice packs. 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. In humid areas of the country, store in plastic sealable bags with a desiccant.

Pesticide Disposal:

If the PZP solution is not used within 24 hours of defrosting, or if not properly stored while in the field, dispose of unused ZonaStat-H material and loaded syringes as medical waste according to applicable Federal, State, and/or Local regulations.

Container Disposal:

Non-refillable container. Do not reuse or refill container. Dispose of expired material, preloaded syringes, used syringes, darts, and needles as medical waste according to applicable Federal, State, and/or Local regulations.

Storage:

The vials containing PZP solution are stored frozen. The frozen PZP solution expires two years after freezing. After defrosting, the PZP solution expires after 24 hours. When transporting for use in the field, the PZP should be stored in a cooler with ice packs. The cooler should contain dry ice if transportation of the PZP takes longer than 8 hours.

The adjuvant should be refrigerated +2°C to +8°C, but not frozen.

Store loaded darts in a cool dry area. In humid areas of the country, it is recommended that they be stored in plastic sealable bags with a desiccant.

Disposal:

Used darts: Used darts should be disposed of in a sharps container, and further disposed of in accordance with state laws regarding disposal of medical waste.