

56228-41

1/10/2013

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Chemical Safety and Pollution Prevention
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

56228-41

Date of Issuance:

JAN 10 2013

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

Gonacon - Equine

Name and Address of Registrant (include ZIP Code):

U.S. Department of Agriculture, Animal and Plant Health Inspection Service
Environmental Services, Unit 149
4700 River Road
Riverdale, MD 20737

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.

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:

1. 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.
2. Make the following label change before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No 56228-41."

Signature of Approving Official:

Date:

JAN 10 2013

Meredith Laws, Chief
Insecticide-Rodenticide Branch, Registration Division (7505P)

3. Submit one copy of your final printed labeling before you release the product for shipment.

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, please contact Autumn Metzger at 703-305-5314 or metzger.autumn@epa.gov.

A stamped copy of the label is enclosed for your records.

Meredith Laws, Chief
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Keep away from humans, domestic animals and pets. Wear protective gloves when handling. If pregnant, do not handle or administer product. 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.

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

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:
 -long sleeved shirt and long pants
 -gloves
 -shoes plus socks

DIRECTIONS FOR USE

Restricted Use Pesticide

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.

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 not 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.

GonaCon™ - Equine is used to manage fertility in reproductively mature female wild or feral horses (*Equus caballus*) and burros (*Equus asinus*).

Use caution to prevent accidental self-injection when administering GonaCon™ - Equine to wild or feral horses and burros.

Pregnant women should not be involved in the handling or injection of GonaCon™. Do not ingest. Avoid contact with eyes.

Do not apply this product to food or feed.

Applicators: Additional State regulations and/or permitting may apply to the use of this product in wild or feral horses and burros. All applicable State authorities must be contacted prior to use. GonaCon™ renders vaccinated reproductively mature female wild or feral horses and burros infertile for a minimum of one year following vaccination.

(See right panel for application instructions)

RESTRICTED USE PESTICIDE

DUE TO NON-TARGET INJECTION HAZARD

For use by employees of USDA APHIS Wildlife Services and Veterinary Services, U.S. Bureau of Land Management, U.S. Fish and Wildlife Service, U.S. National Park Service, U.S. Department of Defense, Federally recognized Indian Tribes, State agencies responsible for wild or feral horse and burro management, public and private wild horse sanctuaries, or persons working under their authority.

GONACON™ - EQUINE

For managing fertility in female wild or feral horses (*Equus caballus*) and burros (*Equus asinus*)

ACTIVE INGREDIENT

Mammalian Gonadotropin Releasing Hormone 0.03%

OTHER INGREDIENTS 99.97%

TOTAL 100%

JAN 1 0 2013

Under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, this pesticide registered under

KEEP OUT OF REACH OF CHILDREN

CAUTION

Have the product container or label with you when calling a poison control center or doctor, or when going for treatment

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Keep preloaded GonaCon™ - Equine in a refrigerator (36 °F to 45 °F) until ready for use. In the field, keep preloaded GonaCon™ - Equine in a cooler on ice as long as possible prior to use.

PESTICIDE DISPOSAL: If not used within 6 months of manufacture when held under refrigeration (36°F to 45°F), or if not maintained on ice in the field, disable and dispose of unused GonaCon™ - Equine material and preloaded syringes as medical waste according to applicable Federal, State, and/or Local regulations.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill container. Disable and dispose of expired material, preloaded syringes or darts, used syringes, darts and needles as medical waste according to applicable Federal, State, and/or Local regulations.

APPLICATION INSTRUCTIONS

GonaCon™ can be administered at any time throughout the year and should not adversely affect an existing pregnancy, but should cause infertility of the vaccinated animal in the subsequent year and possibly longer.

Administer a single vaccination (2 ml) of GonaCon™ at least two to three months prior to the onset of breeding for full contraceptive effect. If longer contraceptive effect is desired, a second vaccination may be given 30 or more days after the first injection or during the following year with no known adverse health effects to the vaccinated animal. The effects of the vaccine may wear off during the second year or sometimes later and vaccinated females may once again become fertile. However, re-immunization with GonaCon™ can extend infertility.

There is a chance some vaccinated females will become permanently sterile. Accidental injection of males will result in infertility.

Two-milliliter (2 ml) doses of GonaCon™ are packaged in pre-loaded, 3-ml plastic syringes.

GonaCon™ can be administered by hand injection, jab stick or remote delivery (darting). Inject 2.0 ml of GonaCon™ by intramuscular injection (IM) into a large muscle mass (e.g., rump, neck).

Hand Injection: Inject IM 2 ml GonaCon™ using the packaged preloaded syringe and a 1.5-inch 18G or 19G stainless steel hypodermic needle.

Remote Darting: Recommended dart specifications for this use are a 2 cc dart with a 1.25- or 1.5-inch 14G gelatin barb needle. Transfer 2 ml GonaCon™ from the preloaded syringe into the dart. Deliver IM using an appropriate projection device.

If remote delivery is used, the applicator must make every attempt to recover all darts. If possible, all darts that are discharged and drop from the horses 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 content.

Syringes must be individually labeled with the following language:

Restricted Use: Injection Hazards
CAUTION
 GonaCon™ - Equine
 Active Ingredient: Gonadotropin Releasing Hormone (0.03%)
KEEP OUT OF REACH OF CHILDREN
 EPA Reg. No. 56228-XX, EPA Est. No. 26228-CO-1
 See Full Product Label for Application Instructions.
 Vaccine expires 6 months from _____.

UNITED STATES DEPARTMENT OF AGRICULTURE
 ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Riverdale, MD 20737-1237

EPA Est. No. 56228-CO-1

EPA Reg. No. 56228-XX

Net Contents: 2 milliliter (0.066 fl. ounce)

Batch Code No.: