



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

July 15, 2024

Jim Warren
jim.e.warren@usda.gov
U.S. DEPARTMENT OF AGRICULTURE

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment - Only Indicated Changes Reviewed- Addition of application to Male Prairie Dogs
Product Name: GonaCon-Prairie Dogs
Admin Number: 56228-64
EPA Receipt Date: 12/19/2023
Action Case Number: 00496346

Dear Jim Warren:

The amended labeling 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 terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or 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 (1) copy of the final printed labeling before you release this 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.

The label submitted with the application has been stamped "Accepted Only Indicated Revisions Reviewed" and is enclosed for your records.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the 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 EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have questions, please contact Scott Campbell via email at campbell.scott@epa.gov.

Sincerely,

A handwritten signature in a cursive script that reads "Melissa Bridges".

Melissa Bridges, Product Manager 7
IVB3, RD
Office of Pesticide Programs

GONACON-PRAIRIE DOGS

An immun contraceptive vaccine for managing fertility in sub-adult or adult **female black-tailed, white-tailed, and Gunnison's** prairie dogs.

Intended for use by employees of USDA APHIS Wildlife Services or state wildlife management agency personnel, or persons working under their authority.

ACCEPTED

ONLY INDICATED

REVISIONS REVIEWED

07/15/2024

ACTIVE INGREDIENT:

Gonadotropin releasing hormone (GnRH): 0.032%

OTHER INGREDIENTS: 99.968%

TOTAL: 100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

56228-64

No label revisions other than those indicated were reported to the Agency.

HAVE LABEL WITH YOU WHEN SEEKING TREATMENT ADVICE. Have the product container or label with you when calling a poison control center or doctor or going for treatment. If you need immediate medical attention call the Poison Control Center at 1-800-222-1222 or a doctor. For non-emergency information concerning this product, call the National Pesticide Information Center at 1-800-858-7378.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Keep away from humans, domestic animals and pets. Do not ingest. Avoid contact with eyes. 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.

PERSONAL PROTECTION EQUIPMENT

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- 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
- Socks and shoes

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions are provided for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove PPE immediately after handling this product. As soon as possible, wash thoroughly and change into clean clothing. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

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.

ENDANGERED SPECIES CONSIDERATIONS

Notice: It is a Federal offense to use any pesticide in a manner that results in the death of a threatened or endangered species.

United States Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road, Unit 149
Riverdale, MD 20737
EPA Est. 56228-CO-1

Net Contents: 0.4 milliliter

Batch Code: _____

DIRECTIONS FOR USE

It is a violation of Federal and State 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 the entire label. This product must be used strictly in accordance with this label's precautionary statements and use directions, as well as with all applicable State and Federal laws and regulations.

PRODUCT INFORMATION

- Applicators should be aware that additional State regulations (including wildlife laws) and permitting may apply to the use of this product. All applicable State authorities must be contacted prior to use.
- GonaCon–Prairie Dogs **is intended to may** be used in combination with other population management techniques.
- GonaCon–Prairie Dogs should not affect existing pregnancy but should cause infertility of the vaccinated animal in the subsequent year.

USE RESTRICTIONS

- GonaCon–Prairie Dogs may only be used on the following target species:
 - Black-tailed prairie dogs (*Cynomys ludovicianus*);
 - White-tailed prairie dogs (*Cynomys leucurus*); and
 - Gunnison's prairie dogs (*Cynomys gunnisoni*).
- This product may only be used in prairie dog colonies that occur in urban/suburban areas, open spaces and natural areas, parks, campgrounds, airports, roadway medians, and other non-crop use sites. When a targeted prairie dog colony located primarily within these non-crop areas also extends into cropland, pastures, or rangeland, those portions of the colony may also be treated. Otherwise, this product may not be used for prairie dog colonies solely located within cropland, pastures, and rangeland used for grazing or animal feed production.
- **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 administered.
 - 2) **DO NOT** store in locations accessible to children, pets, and domestic animals.
 - 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.
- Caution is required to prevent self-injection when administering GonaCon–Prairie Dogs.
- **DO NOT** apply this product to food or feed.
- **DO NOT** administer more than a total of 2 vaccinations (0.4 mL each) per individual prairie dog per year.
- **DO NOT** administer an additional vaccine (0.4 mL) less than 90 days from the previous vaccination.
- **Accidental injection of males can result in infertility.**

APPLICATION INSTRUCTIONS

Administer a single vaccination (0.4 mL) of GonaCon–Prairie Dogs per **adult and sub-adult female** prairie dog at least two to three months prior to the onset of breeding for full contraceptive effect. **Vaccination strategies may be tailored to meet your management goals.**

Inject GonaCon–Prairie Dogs by intramuscular injection into a large muscle in the thigh using the packaged preloaded syringe and a 20- or 23-gauge stainless steel hypodermic needle. It is recommended that applicators mark the fur of vaccinated animals to ensure that they are not unintentionally reinjected during the same application period.

If a longer contraceptive effect is desired, a second vaccination may be given 90 days or more after the first injection or during the following years. There is a chance some vaccinated **prairie dogs females** will become permanently sterile.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Keep GonaCon–Prairie Dogs in a refrigerator (36 °F to 45 °F) until ready for use. In the field, keep GonaCon–Prairie Dogs 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, dispose of unused GonaCon–Prairie Dogs 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.

Syringe Label

GonaCon-Prairie Dogs

Syringe #__

KEEP OUT OF REACH OF CHILDREN

CAUTION: Injection Hazard

Active Ingredient: Gonadotropin Releasing Hormone 0.032%

See full product label for "DIRECTIONS FOR USE."

EPA Reg. No. 56228-64; EPA Est. No. 56228-CO-1

Net Contents: 0.4 ml; Lot: _____; Exp. date: _____