

U.S. ENVIRONMENTAL PROTECTION AGENCY

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

56228-64

EPA Reg. Number:

Date of Issuance:

3/2/22

NOTICE OF PESTICIDE:

X Registration
Reregistration
(under FIFRA, as amended)

Unconditional

Term of Issuance:

Name of Pesticide Product:
GonaCon-Prairie Dogs

Name and Address of Registrant (include ZIP Code):

USDA APHIS Environmental and Risk Analysis 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 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/registration/registration review of your product when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official: Sincerely,	Date:
Gene Benbow, Product Manager 7 Invertebrate & Vertebrate Branch 3 Registration Division (7505P) Office of Pesticide Programs	3/2/22

- 2. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 56228-64."
- 3. Submit one copy of the revised final printed label for the record before you release the product for shipment.

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.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

Basic CSF dated 10/18/2021

If you have any questions, please contact Jasmin Jackson by phone at 202-566-2797, or via email at Jackson.Jasmin@epa.gov.

Enclosure: Registration Notice & Stamped Label

GONACON-PRAIRIE DOGS

An immunocontraceptive vaccine for managing fertility in sub-adult or adult female black-tailed prairie dogs.

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

ACTIVE INGREDIENT:

KEEP OUT OF REACH OF CHILDREN

CAUTION

ACCEPTED
03/02/2022
Under the Federal Insecticide, Fungicide

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under. EPA Reg. No. 50000 04

56228-64

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:	u.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 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 Iudovicianus);
 - 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 female prairie dog at least two to three months prior to the onset of breeding for full contraceptive effect.

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 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-XX; EPA Est. No. 56228-CO-1
Net Contents: 0.4 ml; Lot: ______; Exp. date: ______