



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

EPA Reg. Number:

89459-114

Date of Issuance:

9/23/20

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
 Expires: 09/23/2022

Name of Pesticide Product:

RF2254 APM CDSO FOR DOGS

Name and Address of Registrant (include ZIP Code):

Dr. James McFadden
 Director, Regulatory Affairs
 Central Garden & Pet
 1501 East Woodfield Road
 Suite 200 West
 Schaumburg, Illinois 60173

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 conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

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

Signature of Approving Official:

Elizabeth Fertich, Product Manager 04
 Invertebrate & Vertebrate Branch 1, Registration Division, 7505P

Date:

9/23/20

2. This registration is time-limited and expires 09/23/2022.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
 - EPA Registration Number
 - Product name (brand name)
 - Lot #
 - Where purchased: internet, store, veterinarian
 - Active Ingredient(s)
 - Weight range for product
 - Date on which incident occurred (mm/dd/yyyy)
 - State in which the incident occurred (standard 2 letter abbreviation)
 - Registrant case #
 - Species: dog, cat, other (specify)
 - Breed: (as reported by pet owner)
 - Age: months or years
 - Sex: M, F, or neutered
 - Weight: pounds
 - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
 - Body System: neurological, dermatological, GI, respiratory, ocular, other
 - Major signs noted with separate column for each sign, using standard terminology
 - Time to Onset: (hours, days)
 - Treated by veterinarian: yes or no
 - First time product used: yes or no
 - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
 - Any known precondition
 - EPA Severity Code: death, major, moderate, minor
 - Outcome: died, recovered, still treated, unknown
4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
 - All incidents should be reported including all minor dermal and ocular irritation reports.
 - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

5. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 89459-114.”
6. Submit one copy of the 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 you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

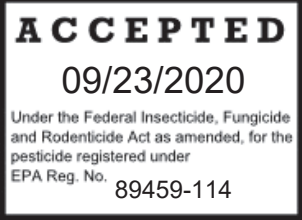
Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 12/06/2018

If you have any questions, please contact Vanessa Emerson by phone at 703-347-0360, or via email at emerson.vanessa@epa.gov.

Enclosure

{Text within braces { } denotes notes to reviewer.}
{Text within brackets [] denotes optional language.}
{Text within parentheses () is meant to be included on the label }



RF2254 APM CDSO For DOGS

{The word "dog" in product brand name will be 75% the height of the largest letter in primary brand name}

{One of the following statements will be placed in a box prominently on the front panel.}
[Small Dog size (0.5 ml / applicator) – Use only on dogs weighing 4-10 lbs and 8 weeks of age or older]
[Medium Dog size (1.3 ml / applicator) – Use only on dogs weighing 11-20 lbs and 8 weeks of age or older]
[Large Dog size (3.1 ml / applicator) – Use only on dogs weighing 21-55 lbs and 8 weeks of age or older]
[Extra-large Dog size (5.0 ml / applicator) – Use only on dogs weighing 56 lbs or more and 8 weeks of age or older]



{A large, clear picture of a dog in the weight range for the product as packaged will be included on the front panel in the final printed label.}

DO NOT USE ON CATS

{On the front panel of the product's packaging in BOLD will be "DO NOT USE ON CATS"}

ACTIVE INGREDIENTS:

Acetamiprid	9.5%
Permethrin	50.0%
S-Methoprene	5.0%
OTHER INGREDIENTS:	35.5%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN CAUTION

See back panel for First Aid and Additional Precautionary Statements

NET CONTENTS: [number] fl. oz. (total)

[number] each fl.\ oz.	[0.017 fl oz/0.5 ml-Small dog 4-10 lb]
	[0.044 fl oz/1.3 ml-Medium dog 11-20 lb,]
	[0.105 fl oz/3.1 ml-Large dog 21-55 lb,]
	[0.169 fl oz/5.0 ml-Extra large dog 56 lb or more]

EPA Reg. No. 89459-XXX
EPA Est. No. XXXX-XX-XX
Batch/Lot No.:



{A 1.5cm x 1.5cm cat prohibition icon will be in a box in the lower right hand corner of the front panel in yellow with black images.}

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

CAUTION:

HAZARDS TO HUMANS: Harmful if swallowed or absorbed through skin. Harmful if inhaled. Avoid breathing vapor. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.


HAZARDS TO ANIMALS: DO NOT USE ON DOGS/PUPPIES LESS THAN 8 WEEKS OLD OR LESS THAN [4-10][11-20][21-55][56 and over] POUNDS. For external use only. Sensitivities may occur after using ANY pesticide product for dogs. If signs of sensitivity occur, consult a veterinarian immediately and bathe your dog with mild soap and rinse with large amounts of water. Consult a veterinarian before using this product on dogs on medication, debilitated, aged, pregnant or nursing dogs. This product is not a substitute for prescribed Heartworm preventative

DO NOT USE ON CATS. Keep cats away from treated dogs/puppies for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

FIRST AID.	
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If in eyes	<ul style="list-style-type: none"> • 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 Immediately for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor Immediately for treatment advice.
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor Immediately 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.	

Side Effects: Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or [phone number].

{A box labeled Side Effects will be immediately above the cat warning box on the back panel}



DO NOT USE ON CATS – MAY BE FATAL. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately.

{A 1.5 x 1.5cm cat prohibition icon and warning text in a box will be in the lower right hand corner of the back panel in yellow with black images and text.}

HOW RF2254 APM CDSO WORKS

This product is specifically designed to kill both flea adults, larvae, their eggs, RF2254 APM CDSO protects against mosquitoes on dogs, that may transmit heartworm.

{ The weight range on the label will correspond to the product in the package}

READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS AND PUPPIES [4-10][11-20][21-55][56 and over]LBS IN WEIGHT AND 8 WEEKS IN AGE

DIRECTIONS FOR USE - It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS:

- Do not apply more than once every month.
- Do not allow children to apply product.
- Do not use more than one tube per dog regardless of the dog's weight.
- Do not apply this product to animals other than dogs/puppies..
- Do not get this product in your dog's eyes or mouth.
- Do not allow your dog to ingest this product.
- Do not apply to dogs weighing less than [4][11][21][56] lbs. {The number selected will be the lower number in the weight range of the product's package.}
- Do not use on puppies less than 8 weeks old
- Do not spread by hand over the dog/puppy.
- Dog must be dry at time of application and remain dry for 24 hours after application.
- Use entire contents of one [applicator] [tube] on one dog.
- DO NOT USE ON CATS.
- Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.
- If applied to a cat or ingested by a cat, contact your veterinarian immediately.

RF2254 APM CDSO works by application directly to the dog's/puppy's skin, not to the hair. When applying, manually push aside dog's/puppy's hair to allow direct application to the skin.

The dog is to be dry and remain dry for 24 hours and be standing for application. To apply, use the tip of the tube [applicator] to part hair and get next to dog's skin.

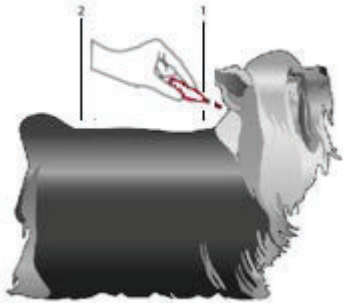
[1 step applicator]

To OPEN:

1. Bend at perforation and tear off first tube.
2. Hold tube upright away from face and body and use scissors to cut off the tip of the applicator.
3. Apply per the directions below.
4. Discard empty tube.

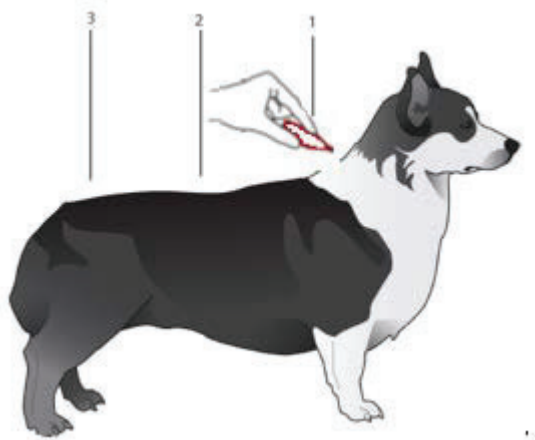
Only for Small dogs (4-10 lbs) and 8 weeks of age or older

Apply one-half of the tube's contents between the shoulders and one-half on the back near the base of the tail. {see the picture inset}. Do not apply an excessive amount of the solution at either spot that could cause some of the solution to run off the side of the dog. Do not spread [product] by hand over the dog. {The applicator is the CRP. The applicators are clear on one side with a white foil lidstock backing with black printing. No other color is allowed.}



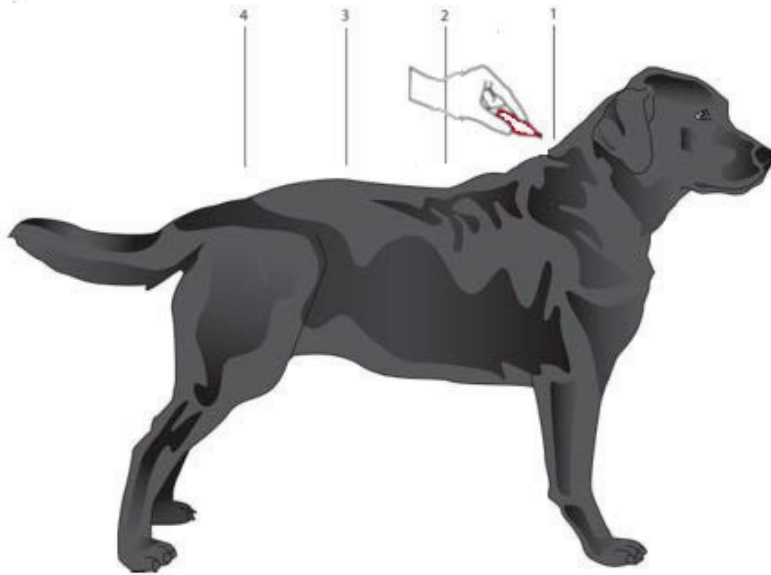
Only for Medium dogs (11-20 lbs) and 8 weeks of age or older.

Apply one-third of the tube's contents at each of three evenly placed spots between the shoulder to near the base of the tail {see the picture inset}. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog. Do not spread [product] by hand over the dog. {The applicator is the CRP. The applicators are clear on one side with a white foil lidstock backing with black printing. No other color is allowed.}



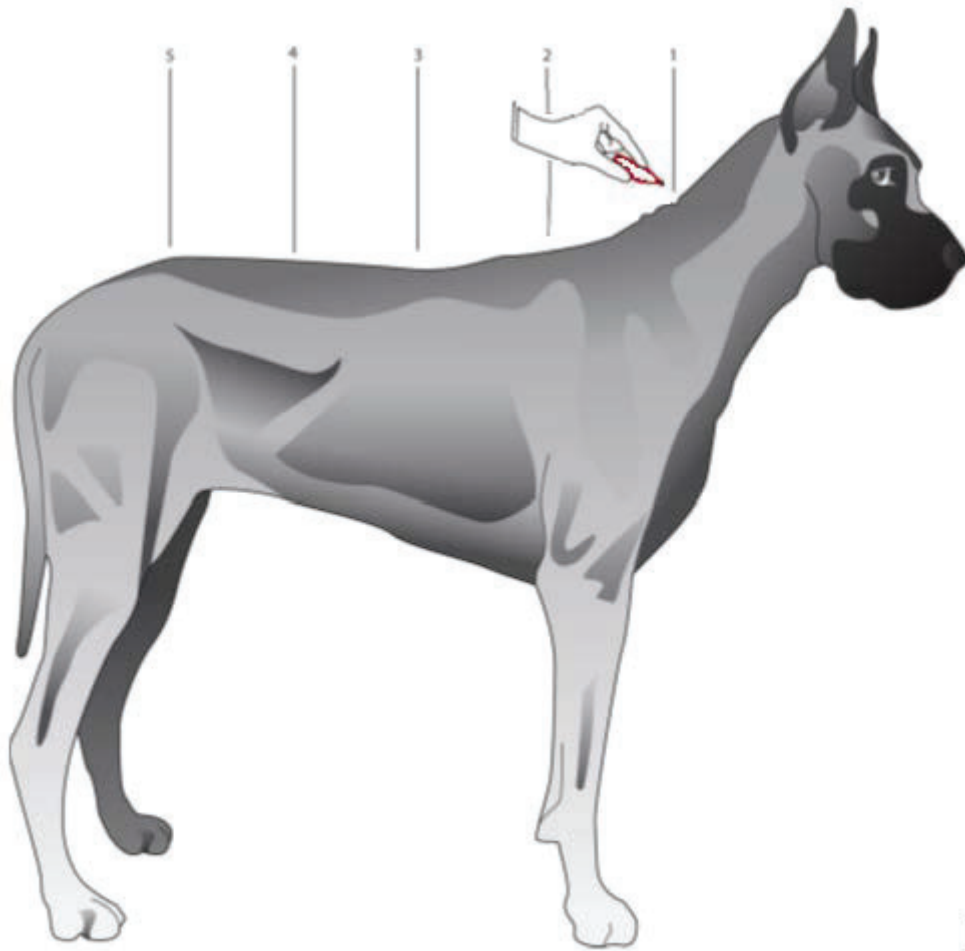
Only for Large dogs (21-55 lbs) and 8 weeks of age or older

Apply one-quarter of the tube's contents at each of four evenly placed spots between the shoulder to near the base of the tail {see the picture inset}. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog. Do not spread [product] by hand over the dog. {The applicator is the CRP. The applicators are clear on one side with a white foil lidstock backing with black printing. No other color is allowed.}



Only for Extra-large dogs (56 lbs and heavier) and 8 weeks of age or older

Apply one-fifth of the tube's contents at each of five evenly placed spots between the shoulder to near the base of the tail {see the picture inset}. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog. Do not spread [product] by hand over the dog." {The applicator is the CRP. The applicators are clear on one side with a white foil lidstock backing with black printing. No other color is allowed.}



To minimize flea infestation, use appropriate products to:

1. Treat the indoor environment, especially where pets spend time resting
2. Treat the outdoor environment when necessary
3. Only use EPA-registered products that are labeled for these uses.

WHAT TO EXPECT:

This product is designed to spread across your dog's skin to kill adult fleas and flea eggs, over the entire dog. Kills and repels fleas for 30 days. Monthly treatments will ensure continuous protection against fleas

STORAGE AND DISPOSAL

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

Pesticide Storage: Do not open package until ready to use. Store in original, unopened container away from children. **Pesticide Disposal and Container Handling:** Nonrefillable container. Do not reuse or refill this container. **If empty:** Do not reuse tube. Place in trash or offer for recycling if available. **If partially filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

WARRANTY AND CONDITIONS OF SALE: To the extent consistent with applicable law, Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

Central Garden & Pet Company
1501 East Woodfield Road 200W
Schaumburg, Illinois 60173

PRECOR® Insect Growth Regulator is a registered trademark of Wellmark International.

For information [or in case of emergency] call, 1-800-XXX-XXXX

{TEXT FOR INDIVIDUAL TUBE/APPLICATOR}

<Product name>

Permethrin 50%, S-Methoprene 5.0%, Acetamiprid 9.5%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FOR EXTERNAL USE ON

DOGS ONLY

READ DIRECTIONS

BEFORE USING

EPA Reg No. 89459-xxx

Net Contents [0.017][0.044][0.105][0.169] fl. oz.



DO NOT USE ON CATS

For Use Only on [Small/Toy (4-10 lbs.)], [Medium (11-20 lbs.)], [Large (21-55 lbs.)] {and} [Extra Large (56 lbs and over)] Dogs/Puppies 8 weeks of age or older. {One of the weight ranges will be printed on the tube corresponding to the contents inside the tube.}

Alternative Marketing Claims:

- Kills flea eggs
- Kills fleas
- Kills flea larvae
- Repels fleas
-
- Kills and repels mosquitoes on dogs
-
-
- Quick drying formula

- Kills flea eggs, larvae and adults for one month
- Kills and repels fleas for one month
- Protects against mosquitoes on dogs that may transmit heartworm
- Kills and repels fleas and mosquitoes for one month
- with PRECOR® Insect Growth Regulator {IGR}
- PRECOR is Prevention {Protection}™
- PRECOR breaks the flea life cycle
- Prevents flea build-up on your dog/puppy by killing flea eggs before they hatch
- [Prevents flea infestations] [Halts flea infestations] by preventing flea egg hatch on your dog
- Ovicidal - kills flea eggs {before they hatch} for one month
- Works from head to tail
- Kills mosquitoes for one month
- Prevents all flea stages from developing