



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 2, 2017

James McFadden, Ph.D.
Directory, Regulatory Affairs
Wellmark International
1501 E. Woodfield Rd., Suite 200W
Schaumburg, IL 60173

Subject: Notice of Extension of Conditional Registration until November 2, 2019
Product Name: RF2187 CDSO Plus II
EPA Registration Number: 2724-829
Application Date: August 17, 2017
Decision Number: 532757, 535182

Dear Dr. McFadden:

This letter is in reference to your request to extend the conditional, time-limited registration for the above-referenced registration. The above-referenced registration contains conditions calling for the registration to expire after two years. Additionally, your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information for the above-referenced registration.

The Agency has found your company to be in compliance with the terms and conditions for the subject product, and is therefore is granting the request to extend the two-year time-limited registration restriction. As such, the following change is being made to the terms and conditions for the product listed above:

- The two-year time-limited registration restriction has been extended. The new expiration date for the registration listed above is November 2, 2019.

Please note that the product is still subject to all other previously required conditions of registration. If your company wishes to remove the time limitations altogether, please submit to the Product Manager an amendment application for the product to change the terms and conditions of the registration. Please include with your submission a written rationale for the removal of the time limitation. As you remember, the Agency included this time limitation as a condition of registration for your product to allow for the post-market surveillance¹ of the product. Therefore, we recommend that you include in your rationale the following information, along with any additional information or analyses you think would be helpful to the Agency (e.g., tables, charts, information on stewardship activities, etc.):

- A summary and analysis of the incidents received associated with the product, including

¹ <http://www.epa.gov/pesticides/health/spot-on-meetings.html>

information on the following:

- A comprehensive analysis of incident rates per doses distributed;
- An analysis of historical incident trends since the products' release into the marketplace;
- An analysis of historical incident trends by weight range of animal, breed, weight range of product, etc...
- If the product is also registered in the European Union or Canada, information on incident rates per doses distributed and trends in those countries.

Please also note that requests to remove the expiration date condition are not subject to PRIA fees and do not have to be submitted under PRIA. However, these would also not be considered 90-day fast-track submissions, as the Agency requires time to fully evaluate the information provided. After receiving these submissions, the Agency will consider the incidents received since the initial registration; review the information and rationale provided; and make a decision on the request.

If you have any questions, please contact Jennifer Gaines at 703-305-5967 or via email at gaines.jennifer@epa.gov.

Sincerely,

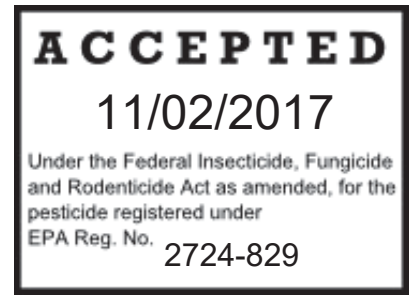
A handwritten signature in blue ink, appearing to read 'MW', enclosed in a thin black rectangular border.

Michael Wagman, Acting Product Manager 4
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

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

{This label has two sub-labels:
SUB-LABEL A – APPLICATOR DEVICE PACKAGE
SUB-LABEL B FOR REFILLPACKAGE}



{SUB-LABEL A – APPLICATOR DEVICE PACKAGE}

RF2187 CDSO Plus II

{Front Panel:}

Font size for word “Dog” in product name must be at least 75% the height of the largest letter in the primary brand name

Front Panel: For Use only on [Toy/Small (5-14 lbs.)], [Medium (15-30 lbs.)], [Large (31-60 lbs.)], [Extra Large (61-150 lbs.)] Dogs/Puppies 12 weeks of age or older

**[Flea & Tick [& Mosquito][Treatment] [and] Control only for Dogs/Puppies 12 weeks of age or older)]
DO NOT USE ON DOGS OR PUPPIES WEIGHING LESS THAN [5][15], [31], [61] {as appropriate for package size} LBS.**



Picture ,

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

{Each brand name product will be packaged in the weight classes designated below]
Weighing 5 to 14 lbs./15 to 30 lbs./31 to 60 lbs./61-150 lbs.}

ACTIVE INGREDIENTS:

Etofenprox	50.00%
Piperonyl Butoxide*	9.10%
N-octyl bicycloheptene dicarboximide (MGK 264)	0.91%
Pyriproxyfen	0.45%
(S)-Methoprene	0.23%
OTHER INGREDIENTS:	<u>39.31%</u>
TOTAL	100.00%

*(butyl carbityl)(6-propylpiperonyl) ether and related compounds

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See back/side panel for First Aid and additional precautionary statements.

For Dogs and Puppies Weighing:	Tubes per Package	Net Contents (Each tube)
5 to 14 lbs.	[6][3][1]	[0.204]/[0.102]/[0.034] fl. oz. total (1.0 ml.)
15 to 30 lbs.	[6][3][1]	[0.444]/[0.222]/[0.074] fl. oz. total (2.2 ml.)
31 to 60 lbs.	[6][3][1]	[[0.894]/[0.447]/[0.149] fl. oz. total (4.4 ml.)
61 to 150 lbs.	[6][3][1]	[1.482]/[0.741]/[0.247] fl. oz. total (7.3 ml.)

EPA Reg. No. 2724-829
 EPA Est. No. 2724-TX-1
 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.}

{Back/Other Panel}

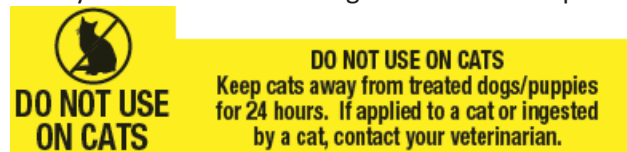
READ ENTIRE LABEL BEFORE EACH USE

IMPORTANT - USE ONLY ON DOGS OR ON PUPPIES 12 WEEKS OF AGE OR OLDER

DO NOT USE ON DOGS/PUPPIES WEIGHING LESS THAN [5][15][31][61] LBS.

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 [Brand name] at [phone number].

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



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

PRECAUTIONARY STATEMENTS

CAUTION

HAZARDS TO HUMANS

Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

DO NOT USE ON OTHER ANIMALS. Do not use on dogs or puppies less than 12 weeks old or weighing less than [5] [15], [31], [61] {as appropriate for package size} lbs. This product is not a substitute for prescribed heartworm preventative. Do not use this product on debilitated, aged, medicated, pregnant or nursing animals or on animals known to be sensitive to pesticide products without first consulting a veterinarian. Sensitivity, such as slight transitory redness of the skin at the site of application, may occur after using ANY pesticide product for pets. If signs

of sensitivity occur, bathe your pet with mild soap, rinse with large amounts of water, and consult a veterinarian immediately.

FIRST AID	
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 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 for treatment advice.
HOT LINE NUMBER: Have the product container or label with you when calling a poison control center, doctor or veterinarian, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-xxx-xxx.	

DIRECTIONS FOR USE WITH [brand][Smart Shield™] APPLICATOR

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on this product label. [If you choose to apply directly to dog without using the [brand][Smart Shield™] applicator device, read and follow the Directions for Use For Direct Application to Dog on this package.]

USE RESTRICTIONS:

For indoor use only

Do Not Allow Children to Apply this Product.

For external use only

Do not apply this product to puppies less than 12 weeks of age.

Do not apply to dogs/puppies weighing less than [5] [15], [31], [61] lbs.

Do not use more than one [tube] [vial][cartridge] per dog/puppy and d

Do not treat more than once per month.

Do not allow your dog/puppy to ingest this product.

Do not bathe your dog 48 hours prior to application.

In households with dogs and cats, the cat will often groom the dog as well as itself. Separate treated dogs from cats for 24 hours after treatment to [minimize][reduce potential] oral exposure to your cat.

<RF2187 CDSO Plus II> works by application directly to the dog's/puppy's skin, not to the hair. When applying, use [brand][Smart Shield™] applicator device tip to push aside dog's/puppy's hair to allow direct application to the skin.

<RF2187 CDSO Plus II> provides a unique [brand][Smart Shield™] applicator device that allows dog/puppy owners to treat their dogs/puppies more securely, and dispose of liquid cartridges [tubes][vials]with less mess.

{Note: Each package contains [cartridges]/[tubes]/[vials] for [1][3][6] application[s]}

{The application steps below may optionally be formatted as a paragraph, or by number or bullets to clarify the order, depending on the final physical layout of the label}

To apply the <RF2187 CDSO Plus II> treatment, use one disposable liquid [cartridge] [tube][vial][for each application] with the [brand][Smart Shield™] applicator device.

FOR [[TOY]/[SMALL]][[MEDIUM] SIZE DOGS/PUPPIES WEIGHING [5 TO 14 LBS.][15 TO 30 LBS.]

1. OPEN [icon]

Use finger scoop to lift open [color, e.g. green] door.

2. LOAD [icon] (2 alternate statements)

-[To Load, place tube [cartridge][vial] white side up into the open [brand][Smart Shield™] applicator with front of tube placed under tab on door]

-[To Load, place tube [cartridge][vial] white side up into the [open] applicator with tip end of tube placed under [color][U-shaped] tab on door]

[Ensure that tube [cartridge][vial] fits securely in the [brand][Smart Shield™] applicator.]

3. CLOSE [icon]

Gently close the [color, e.g. green] door [and] the tube [cartridge][vial] will snap open.

4. APPLY [icon]

The dog/puppy should be standing for easy application. To apply, use [front edge of [brand][Smart Shield™] applicator] [tip] to part hair and get next to dog's/puppy's skin. Press [circle] [[round] thumb pad] on [color-green] door [number][once] at each of two to three evenly placed spots between the shoulder and the base of the tail. 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/puppy. Do not spread <RF2187 CDSO Plus II> by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after treatment will help to distribute the material over the skin.

5. DISPOSE [icon]

[When finished, hold [brand][Smart Shield™] applicator device over trash.] To dispose of empty tube [cartridge][vial], open [color, e.g. green] door and drop empty tube [cartridge][vial] into trash or offer for recycling if available. [Close [brand][Smart Shield™] applicator device door and store in original package.]

FOR [LARGE][EXTRA LARGE] DOGS/PUPPIES WEIGHING [31 TO 60 LBS.][61 TO 150 LBS.]

1 OPEN [icon]

... Use finger scoop to lift open [color, e.g. green] door

2 LOAD [icon] {2 alternate statements}

-[To Load, place tube [cartridge][vial] white side up into the open [brand][Smart Shield™] applicator with front of tube placed under tab on door]

... [To Load, place tube [cartridge][vial] white side up into the [open] applicator with tip end of tube placed under [color][U-shaped] tab on door]

3 CLOSE [icon]

... Gently close the [color, e.g. green] door [and] the tube [cartridge][vial] will snap open.

4 APPLY [icon]

The dog should be standing for easy application. To apply, use [front edge of [brand][Smart Shield™] applicator][tip] to part hair and get next to dog's/puppy's skin. Press [circle] [[round] thumb pad] on [color][green] door [number-once] at each of four or five evenly placed spots between the shoulder to the base of the tail. 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/puppy. Do not spread <RF2187 CDSO Plus II> by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after treatment will help to distribute the material over the skin.

5 ...DISPOSE [icon]

[When finished, hold [brand][Smart Shield™] applicator device over trash.] To dispose of empty tube [cartridge][vial], open [color, e.g. green] door and drop empty tube [cartridge][vial] into trash or offer for recycling if available. [Close [brand][Smart Shield™] applicator device door and store in original package.]

<RF2187 CDSO Plus II> is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on dogs/puppies may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs/puppies with <RF2187 CDSO Plus II> rapidly kills fleas which may reduce the incidence of this condition. .]

[TREATMENT SCHEDULE			
Dosage: 1 [cartridge] [tube][vial] every 30 days per dog/puppy			
Dog/s/Puppy's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased <RF2187 CDSO Plus II> from: _____

NOTES: _____

Treatment table can be expanded based on package size. (6 months)]

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and pets.

CONTAINER DISPOSAL: Do not reuse empty cartridge [vial][tube]. If empty: Place in trash or offer for recycling if available. If partly 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:

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

[For more information call our (flea and tick) experts at 1-800-xxx-xxxx]

In case of emergency or for product information, call 1-800-xxx-xxxx or contact your veterinarian if your pet is experiencing an adverse event.

Wellmark International
 1501 E. Woodfield Road. 200W
 Schaumburg, Illinois 60173

[URL]

INDIVIDUAL TUBE TEXT

<RF2187 CDSO Plus II> [Brand Name]

For Use only on [toy/small (5-14 lbs)], [medium (15-30 lbs)], [large (31-60 lbs)], [Extra Large (61-150 lbs)] dogs/puppies & 12 wks [of age] or older

Etofenprox 50% PBO 9.1% MGK 264 0.91% Pyriproxyfen 0.45% S-Methoprene 0.23%

KEEP OUT OF REACH OF CHILDREN

CAUTION

For External Use Only

Read Entire Label Before Each Use

Range of volumes from [0.034 fl. oz. (1.0 ml)][0.074 fl. oz. (2.2 mL)][0.149 fl. oz. (4.4 mL)] to [0.247 fl. oz (7.3 ml)] {depending upon weight of dog}

EPA Reg. No. 2724-829

[EPA Est. No.]

[Batch/Lot No.]



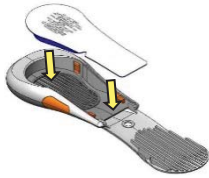
{Alternate Sets of ICONS for the RF2187 CDSO Plus II}

{ICON SET 1}

[OPEN]



[LOAD]



[CLOSE]



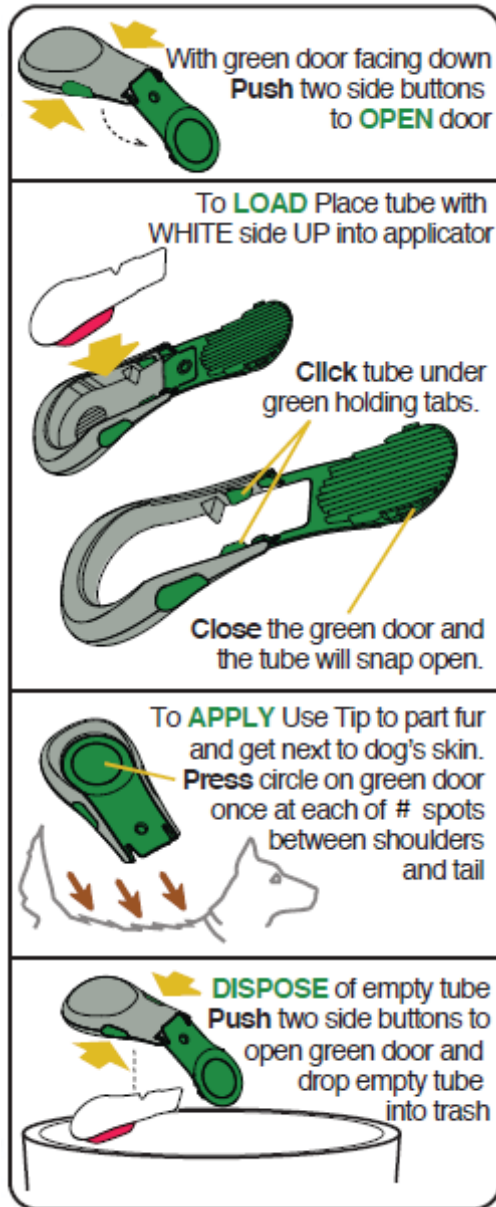
[APPLY]



[DISPOSE]



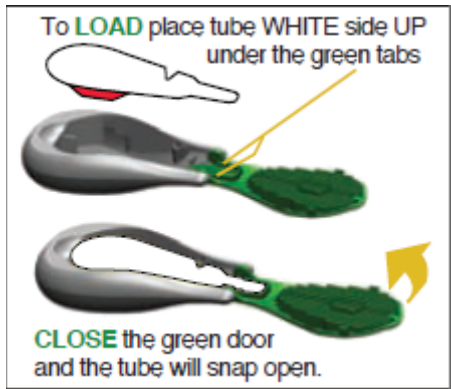
{**ICON SET 2**} {ALTERNATE ICONS FOR DIRECTIONS FOR USE (will be specific to dog's/puppy's size)}



{{“#Spots” is a variable dependent on size – see Directions For Use}

Door color may change based on brand.

(Alternate LOAD icon)}



{**ICON SET 3**} {ALTERNATE ICONS FOR DIRECTIONS FOR USE (will be specific to dog's/puppy's size)}



{ (“#Spots” is a variable dependent on size – see Directions For Use)
Door color may change based on brand.}

[2. DIRECTIONS FOR USE FOR DIRECT APPLICATION TO DOG/PUPPY]

{Optional if printed on applicator package}

USE RESTRICTIONS:

For Indoor Use Only

Do Not Allow Children to Apply this Product.

For external, use only

Do not apply this product to puppies less than 12 weeks of age.

Do not apply to dogs/puppies weighing less than [5][15][31][61] lbs. Do not use more than one [tube][vial][cartridge] per dog/puppy

Do not treat more than once per month.

Do not allow your dog/puppy to ingest this product.

Do not bathe your dog 48 hours prior to application.

In households with dogs and cats, the cat will often groom the dog as well as itself. Separate treated dogs from cats for 24 hours after treatment to [minimize][reduce potential] oral exposure to your cat.

<RF2187 CDSO Plus II> 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.

{Note: Application now assumes one [cartridge][tube][vial] per animal per application}

{Note: Each package contains [tubes]/[applicators] for [1][3][6] application[s]}

{The application steps below may optionally be formatted as a paragraph, or by number or bullets to clarify the order, depending on the final physical layout of the label}

To apply the <RF2187 CDSO Plus II> treatment, use one disposable liquid [cartridge] [tube][vial] for each application.

FOR [TOY/SMALL][MEDIUM] SIZE DOGS/PUPPIES WEIGHING [5 TO 14 LBS.][15 TO 30 LBS.]

1. [Bend at perforation and tear off first [tube][cartridge][vial].]
2. [Hold [tube][cartridge][vial] [and bend area of plastic at perforation, tear off and discard.]] Hold [tube][cartridge][vial] upright and snap tip back, away from face and body.
3. The dog/puppy should be standing for easy application. Apply <RF2187 CDSO> Plus II evenly to two to three spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube [cartridge][vial] on the skin and gently squeeze to expel a portion of the solution on the skin. 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/puppy.
4. Do not spread <RF2187 CDSO Plus II> by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin.
5. Discard empty [tube] [cartridge][vial] as described in Storage and Disposal

FOR [LARGE][EXTRA LARGE] DOGS/PUPPIES WEIGHING [31 TO 60 LBS.][61 TO 150 LBS.]

1. [Bend at perforation and tear off first [tube][cartridge][vial].]
2. [Hold [tube][cartridge][vial] [and bend area of plastic at perforation, tear off and discard.]] Hold [tube] [cartridge][vial] upright and snap tip back, away from face and body
3. The dog/puppy should be standing for easy application. Apply <RF2187 CDSO Plus II> evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube [cartridge][vial] on the skin and gently squeeze to expel a portion of the solution on the skin. 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/puppy.
4. Do not spread <RF2187 CDSO Plus II> by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin.
5. Discard empty [tube][cartridge][vial] as described in Storage and Disposal

<RF2187 CDSO Plus II> is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on dogs/puppies may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs/puppies with <RF2187 CDSO Plus II> rapidly kills fleas which may reduce the incidence of this condition.]

[TREATMENT SCHEDULE			
Dosage: 1 [cartridge] [tube][vial] every 30 days per dog/puppy			
Dog's/Puppy's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased <RF2187 CDSO Plus II> from: _____

NOTES:_____

Treatment table can be expanded based on package size. (6 months)]]

{SUB-LABEL B FOR REFILLPACKAGE}

{For use with [brand][Smart Shield™] applicator device or direct application to dog/puppy without [brand][Smart Shield™] applicator device}

{Front Panel:}

RF2187 CDSO Plus II

Font size for word “Dog” in product name must be at least 75% the height of the largest letter in the primary brand name

Front Panel: For Use only on [Toy/Small (5-14 lbs.)], [Medium (15-30 lbs.)], [Large (31-60 lbs.)], and [Extra Large (61-150 lbs.)] Dogs/Puppies 12 weeks of age or older

**[Flea & Tick [& Mosquito][Treatment] [and] Control only for Dogs/Puppies 12 weeks of age or older]
DO NOT USE ON DOGS/PUPPIES WEIGHING LESS THAN [5] [15], [31], [61] {as appropriate for package size} LBS.**



Picture ,

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

[Each brand name product will be packaged in the weight classes designated below]
Weighing [5 to 14 lbs.]/[15 to 30 lbs.]/[31 to 60 lbs.]/[61-150 lbs.]

ACTIVE INGREDIENTS:

Etofenprox	50.00%
Piperonyl Butoxide*	9.10%
N-octyl bicycloheptene dicarboximide (MGK 264)	0.91%
Pyriproxyfen	0.45%
(S)-Methoprene.....	0.23%

OTHER INGREDIENTS: 39.31%

TOTAL 100.00%

*(butyl carbityl)(6-propylpiperonyl) ether and related compounds

KEEP OUT OF REACH OF CHILDREN CAUTION

See back/other panel for First Aid and additional precautionary statements.

For Dogs and Puppies Weighing:	Tubes per Package	Net Contents (Each tube)
5 to 14 lbs.	[6][3][1]	0.204/0.102/0.034 fl. oz. total (1.0 ml.)
15 to 30 lbs.	[6][3][1]	0.444/0.222/0.074 fl. oz. total (2.2 ml.)
31 to 60 lbs.	[6][3][1]	0.894/0.447/0.149 fl. oz. total (4.4 ml.)
61 to 150 lbs.	[6][3][1]	1.482/0.741/0.247 fl. oz. total (7.3 ml.)

EPA Reg. No. 2724-829
EPA Est. No. 2724-TX-1
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.}

{Back/Other Panel}

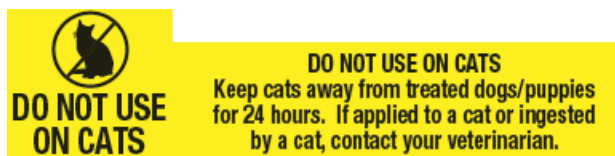
READ ENTIRE LABEL BEFORE EACH USE

IMPORTANT - USE ONLY ON DOGS OR ON PUPPIES 12 WEEKS OF AGE OR OLDER

DO NOT USE ON DOGS/PUPPIES WEIGHING LESS THAN [5] [15][31][61] LBS

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 [Brand name] at [phone number].

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



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

PRECAUTIONARY STATEMENTS

CAUTION

HAZARDS TO HUMANS

Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

DO NOT USE ON OTHER ANIMALS. Do not use on dogs or puppies less than 12 weeks old or weighing less than [5] [15], [31], [61] {as appropriate for package size} lbs. This product is not a substitute for prescribed heartworm preventative. Do not use this product on debilitated, aged, medicated, pregnant or nursing animals or on animals known to be sensitive to pesticide products without first consulting a veterinarian. Sensitivity, such as slight transitory redness of the skin at the site of application, may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap, rinse with large amounts of water, and consult a veterinarian immediately.

FIRST AID	
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 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 for treatment advice.
<p>HOT LINE NUMBER: Have the product container or label with you when calling a poison control center, doctor or veterinarian, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-xxx-xxx.</p>	

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Read and follow all directions and precautions on this product label.

[To apply the <RF2187 CDSO Plus II> treatment with the [Brand Name] [Smart Shield™] applicator, use one disposable liquid cartridge [tube][vial][for each application] with the [brand][Smart Shield™] applicator device.]

[Remove one refill tube [cartridge][vial] from the package and insert into opened [brand name] [Smart Shield™] applicator device. Make application according to label directions supplied with the [brand][Smart Shield™] applicator device.] If you need directions for application, please call 1-800-XXX-XXXX.

[However, if you choose to apply directly to dog/puppy without using the [brand][Smart Shield™] applicator device, read and follow the Directions for Use For Direct Application to Dog /Puppy on this package.]

(DIRECTIONS FOR USE FOR DIRECT APPLICATION TO DOG/PUPPY)

USE RESTRICTIONS

For Indoor Use Only

Do Not Allow Children to Apply this Product.

For external use only

Do not apply this product to puppies less than 12 weeks of age.

Do not apply to dogs/puppies weighing less than [5][15][31][61] lbs. Do not use more than one tube [vial][cartridge] per dog/puppy

Do not treat more than once per month.

Do not allow your dog/puppy to ingest this product.

Do not bathe your dog 48 hours prior to application.

In households with dogs and cats, the cat will often groom the dog as well as itself. Separate treated dogs from cats for 24 hours after treatment to [minimize][reduce potential] oral exposure to your cat.

<RF2187 CDSO Plus II> 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.

{Note: Application now assumes one [cartridge][vial][tube] per animal per application}
{Note: Each package contains [tubes][cartridges][vials] for [1][3][6] application[s]}

{The application steps below may optionally be formatted as a paragraph, or by number or bullets to clarify the order, depending on the final physical layout of the label}

To apply the <RF2187 CDSO Plus II> treatment, use one disposable liquid cartridge [tube][vial] for each application.

FOR [TOY/SMALL][MEDIUM] SIZE DOGS/PUPPIES WEIGHING [5 TO 14 LBS.][15 TO 30 LBS.]

1. [Hold [tube][cartridge][vial] [and bend area of plastic at perforation, tear off and discard.]] Hold [tube][cartridge][vial] upright and snap tip back, away from face and body.
2. The dog/puppy should be standing for easy application. Apply <RF2187 CDSO Plus II> evenly to two to three spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube [cartridge][vial] on the skin and gently squeeze to expel a portion of the solution on the skin. 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/puppy.
3. Do not spread <RF2187 CDSO Plus II> by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
4. Discard empty [tube] [cartridge][vial] as described in Storage and Disposal

FOR [LARGE][EXTRA LARGE] DOGS/PUPPIES WEIGHING [5 TO 14 LBS.][15 TO 30 LBS.]

1. [Hold [tube] [cartridge][vial] [and bend area of plastic at perforation, tear off and discard.]] Hold [tube] [cartridge][vial] upright and snap tip back, away from face and body
2. The dog/puppy should be standing for easy application. Apply <RF2187 CDSO Plus II> evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube [cartridge][vial] on the skin and gently squeeze to expel a portion of the solution on the skin. 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/puppy.
3. Do not spread <RF2187 CDSO Plus II> by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
4. Discard empty [tube] [cartridge][vial] as described in Storage and Disposal

RF2187 CDSO Plus II is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on dogs/puppies may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs/puppies with <RF2187 CDSO Plus II> rapidly kills fleas which may reduce the incidence of this

condition. .]

[TREATMENT SCHEDULE			
Dosage: 1 [cartridge] [tube][vial] every 30 days per dog/puppy			
Dog's/Puppy's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased <RF2187 CDSO Plus II> from: _____

NOTES: _____

Treatment table can be expanded based on package size. (up to 6 months)]]

{Precautionary/First Aid and Storage/Disposal) text as indicated on Sub-label A }

WARRANTY AND CONDITIONS OF SALE:

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx or contact your veterinarian if your pet is experiencing an adverse event.

Wellmark International
1501 East Woodfield Road 200W
Schaumburg, Illinois 60173

OPTIONAL TEXT FOR PACKAGE INSERTS
OPTIONAL INSERT 1

Dear Valued [Store Customer],

Thank you for your purchase of [Product Name]. [Brand] wants the best for your dog, and we are pleased to share with you some great tips on using the product for the best results.

- A. The [Product Name] comes in 4 different sizes so that the right amount of flea and tick protection is applied to your size dog/puppy. Weigh your dog/puppy before applying [Product Name] and be sure that the product you purchased is the right size for your dog/puppy. Do not apply this product to dogs/puppies younger than 12 weeks. If you have questions, please call 1-800-XXX-XXXX to talk to a product specialist.
- B. For best results, apply [Product Name] evenly to the dog's back in spots starting at the top of the back from the shoulders to the base of the tail. {one of two alternate statements} [Use two – three spots for toy/small or medium dogs] [Use four to five spots for large or extra large dogs.] At each spot, be sure to apply the product to your dog's skin, not to the surface of your dog's hair coat. For complete instructions on application, please read the package label.
- C. Sensitivities may occur after the use of any topically applied product. A dog's skin is a complex organ, and your dog's skin may be generally sensitive to topical products. Monitor your dog after application, and if you have questions about best results or if your dog experiences a reaction after application, please call 1-800-XXX-XXXX to talk to a product specialist.
- D. When applying [Product Name] make sure not to get this product in your dog's/puppy's eyes or mouth. If you are concerned that your dog may have an oral exposure to [Product Name] please call 1-800-XXX-XXXX to talk to a product specialist.
- E. In households with dogs and cats, the cat will often groom the dog as well as itself. Separate treated dogs from cats for 24 hours after treatment to minimize [reduce potential] oral exposure to your cat.
- F. Treatment of fleas on your dog does not address the 95-99% of the flea population that lives in your house and yard. So even after your dog is treated with [Product Name] and adult fleas are killed, flea eggs may continue to hatch in your home for up to two months. For best results, treat your yard and home for fleas with treatments that contain an Insect Growth Regulator, which kills flea eggs. Over time, treatment of your dog and its environment will eliminate fleas from your home.

OPTIONAL INSERT 2

STOP. Please read this insert/card and the entire instructions before using this product.

[Brand Name] wants the best for your dog/puppy, and we are pleased to share with you some great tips for using the product.

- Use [Product Name] only as directed.
- For best results, brush your dog's/puppy's coat 24 hours after application.
- Apply away from furniture and carpeting.
- Consult a veterinarian before using if your dog/puppy is aged, pregnant, nursing, or taking other medication.

[Contact a product specialist at 1-800-xxx-xxxx with any questions.]

OPTIONAL/ALTERNATE LABEL TEXT

Weighing [5 to 14]/[15 to 30]/[31 to 60]/[61-150] lbs.

[(S) Only (for) (Small) Puppies 5-14 lbs and 12 weeks of age or older]

[(M) Only (for) (Medium) Dogs 15-30 lbs. and 12 weeks of age or older]

[(L) Only (for) (Large) Dogs 31-60 lbs. and 12 weeks of age or older]

[(XL) Only (for) (Extra Large) Dogs 61-150 lbs. and 12 weeks of age or older]

MARKETING CLAIMS AND OTHER OPTIONAL STATEMENTS

Made in the USA

(Rapidly) (Quickly) eliminates fleas

Kills [(and) (&)] Repels] Mosquitoes, Prevent re-infestation(s) for (28 days)(30 days)(1 month) (4 weeks)

Kills [(and) (&)] Repels] Mosquitoes (before they bite) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas (that may transmit tapeworm) (for) (28 days) (30 days) (1 month) (4 weeks)(on dogs)

Kills fleas that may cause flea allergy dermatitis (and flea bite anemia) (for) (28 days) (30 days) (1 month) (4 weeks) (on dogs)

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Flea Eggs (and Flea Larvae) (for) (28 days) (30 days) (1 month) (4 weeks)

Prevents Flea Eggs from hatching

Kills Brown Dog Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (that may carry Lyme disease) (for) (28 days) (30 days) (1 month) (4 weeks)(on dogs)

Kills all biting stages of ticks

Kills [tick nymphs][and][kills][tick larvae]

Kills adult (brown dog) (deer) ticks, nymphs and larvae

Kills [adult] Fleas, Ticks, Flea eggs, (Flea larvae) (through contact)(after contact) (for) (28 days) (30 days) (1 month)(4 weeks)[on your dog]

Kills Fleas, Brown Dog Ticks, Deer Ticks, Flea Eggs, (Flea larvae) (through contact)(after contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills [X] kinds [types] of [pests][bugs]

Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

[Contains [*InfestStop™] [an Insect Growth Regulator (IGR) to kill flea eggs [and larvae]] and prevent flea development for (28 days) (30 days) (1 month) (4 weeks)]

[Breaks Flea Life Cycle for (28 days) (30 days) (1 month) (4 weeks)]

An important step in breaking the flea life cycle

[Controls flea reinfestation for (28 days) (30 days) (1 month) (4 weeks)]

[With [*InfestStop™][S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

*InfestStop/Infestop™ logo

[Plus][Contains][With] PRECOR® [vIGRen®][S-Methoprene][*InfestStop™], the first insect growth regulator for flea control

[(S)-Methoprene][*InfestStop™] Insect Growth Regulator (IGR) interrupts the development of the flea life cycle [at the egg stage]

[(S)-Methoprene][*InfestStop™] Insect Growth Regulator (IGR) prevents the development of flea eggs into adult fleas and [inhibits the development of flea eggs into adult fleas]

Flea control for dogs with [PRECOR®][vIGRen®] [*InfestStop™] Insect Growth Regulator (IGR)

[Kills][Prevents][Keeps] flea eggs from hatching for (28 days) (30 days) (1 month) (4 weeks)]

***(S)-Methoprene (Must occur on same panel wherever InfestStop™ is used)**

Helps [Keep][Prevent] Fleas & Ticks from [coming back][returning]
Kills flea eggs and flea larvae to help prevent future [re]-infestations
Kills all stages of the flea life cycle
Breaks the flea [and tick] life cycle(s)
Repels Mosquitoes (before they bite) (for) (28 days) (1 month) (4 weeks)
Repels Mosquitoes that may transmit West Nile virus (for) (28 days)(1 month) (4 weeks)(on dogs)
Repels Mosquitoes that may transmit heartworm (for) (28 days)(1 month) (4 weeks)(on dogs)
Once a month (Monthly) Flea and Tick (Prevention) (Treatment) (Control) (Solution)
(28 day) (30 day) (1 month) (4 weeks) Flea and Tick (Prevention) (Treatment) (Control) (Solution)
Prevents flea eggs from developing into biting [breeding] adults (for) (up to) (30 days) (1 month) (4 weeks)
[Quick drying] formula
Dries quickly
Stays on and doesn't rub off
Spreads with dog's skin oils
[Brand] works with the biology of your dog [by spreading through the oils of your dog's skin]
Kills fleas for 30 days (1 month) (4 weeks)
Prevents (and controls) re-infestation(s)
Proactive [pet] protection
Long lasting [formula]
Effective and convenient topical treatment
Easy spot on topical [Brand] [Smart Shield™] applicator
Kills fleas before they have a chance to lay eggs
New (Formula) (claim to be removed after 6 months)
Triple Active formula contains one adulticide and two insect growth regulators

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st/2nd/3rd/(Xth dose)
First/second/third (Xth month)
X-pack/X-tubes
Value pack
X month supply/X monthly treatment(s)
Includes (Brand) (Convenient) (easy to use) [Brand] [Smart Shield™] applicator
Easy (simple) to use (handle) (apply)
[brand] More life in their years

[Brand] [Smart Shield™] Applicator Claims

[Brand] [Smart Shield™] Applicator easily [quickly] gets through dog's fur, for on-skin application
[Brand] [Smart Shield™] Applicator easily [quickly] penetrates dog's fur, for on-skin application
[Brand] [Smart Shield™] Applicator glides [smoothly] through the dog's fur
[Brand] [Smart Shield™] Applicator easily gets through [penetrates] dog's fur to minimize (oily) residue
[Brand] [Smart Shield™] Applicator features rounded edges for on-skin application
[Brand] [Smart Shield™] Applicator features an angled tip to help guide the application
Direct to your dog's skin
You may bathe your dog 48 hours after application
To help remind you when you last applied treatment, simply write in the date when each dose is applied:
[New] contemporary design
[brand name] [Smart Shield™] [Applicator] helps to prevent getting liquid on [your] hands

[brand name] [Smart Shield™] [Applicator] tip parts hair to help [liquid][application] get down to [the][your][dog's/puppy's] skin
Ergonomically contoured [ergonomic][shape][design] for easy handling [ease of use] [easy use]
For use with [only][brand name][disposable][liquid dispensing] tubes [pods] [vials] [cartridges]
[brand name] [Smart Shield™] [applicator][has][provides][allows for][delivers] better grip
[brand name][provides] re-closable [re-sealable] packaging for [easy] storage
Closing [the][brand name] [Smart Shield™] [applicator] door automatically opens the [disposable][liquid dispensing] tube [pod][vial][cartridge]
[brand name] [Smart Shield™] [Applicator] [will not drip after opening]
[brand name] [Smart Shield™] [Applicator] Won't drip when set down as you go fetch the [your] dog/puppy
Includes unique [brand] [Smart Shield™] applicator
Puts the liquid on your dog/puppy – not your hands
Directs the liquid onto your dog [/puppy] – not your hands
[Brand] [Smart Shield™] [Applicator] provides a [more confident][secure] application
Directs the liquid onto your dog [/puppy] – away from your hands
Applies liquid to your dog's [/puppy's] skin – not yours
[Introducing] [Breakthrough] Convenient, easy to use ACCU-TIP [Brand] [Smart Shield™] [Applicator] [DISPENSER]
[Easy to use] Longer [Brand] [Smart Shield™] applicator tip for easy application to long-haired dogs/puppies
[Brand] [Smart Shield™] Applicator patent pending

Thermoform claims

New

New [disposable][liquid dispensing] tube [cartridge][vial][pod]
(Note tube/vial/cartridge/pod used interchangeably)
[New] [brand name][disposable][liquid dispensing] [tube][vial][pod] tip [helps][to] spread out liquid [on your][dog/puppy]
Unique [cartridge] [tube][vial][pod] with flow control
[no drip][no mess][application][tube][cartridge][vial][pod]

Promotional Package Copy

One month [dose] free
One free month supply [dose] included
Bonus pack
Free [brand] [Smart Shield™] [applicator][tube][vial][cartridge][pod][inside]
Designed not to drip when set on top of the counter, or table, or other flat surface.
For use with [brand] [Smart Shield™] applicator
[Brand][Smart Shield™] Applicator [device] not included
[brand] Refill Pack [brand] [Smart Shield™] [applicator [device] not included]
Free [brand] applicator
Free [brand][Smart Shield] applicator
[\$x] coupons Save [\$x]
[\$X] off
[X%] Off
[\$X] savings
[X] [applicator][tube][vial][cartridge][pod][inside]
Scan [QRcode][here] to learn more
Scan [QRcode][here] [for] [to sign up for] [our newsletter] [special offers] [promotions] [coupons] [more information][FAQ's] [helpful tips] [product tips] [monthly reminder][program]
Visit [website URL] [for] [to sign up for] [our newsletter] [special offers] [promotions] [coupons] [more information][FAQ's] [helpful tips] [product tips] [monthly reminder][program]
Win [a free] [prize] [by entering] [at website URL] [visit website URL] [see official rules] [no purchase necessary]
For official rules visit [website URL]
Game piece inside
Enter to win
Buy one [product x] get one [product x] free

Buy one [product x] get one [product x] [X%][off]
Buy one [product x] get one [product x] [\$x] [off]
X [%] [more] [months] [supply] [doses] [tubes] [of protection] [free]

Refill Claims

For use [only] with [brand name] [Smart Shield™] [Applicator]
([1][3][4][6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses
Easy to use [convenient] refills
[Can be used with] [Use with] [Brand Name][Smart Shield™] applicator
[Brand Name (e.g., Adams or Bio Spot, Smart Shield)] [Applicator] [Refills][Refill Pack]
[Refill Pack] [for][Brand Name] [Smart Shield™] Applicator
[tube][cartridge][vial][pod] refill pack [refills]
Refills [Refill Pack] available
New [refill][tube][cartridge][vial][pod] design

Applicator name options (applicator device is used in text)

Applicator
Tool
Device
Applicator Device
Application Tool

Thermoform name options (tube, cartridge and vial are used in the text)

Ampoule
Cartridge
Packet
Pod
Refill
Tube
Vial