



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 20, 2019

Jesse Lollis
Tevra Brands, LLC
c/o Pyxis Regulatory Consulting Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332

Subject: Notification per PRN 98-10 – Addition of applicator icons
Product Name: TEVRA PERMETHRIN + METHOPRENE SPOT ON FOR DOGS
EPA Registration Number: 92413-12
Application Date: 18-July-2019
Decision Number: 553450

Dear Jesse Lollis:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

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 have any questions, you may contact Dr. Breeden-Alemi at 703-347-0511 or via email at Breeden-Alemi.Julie@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Elizabeth Fertich". The signature is written in a cursive, flowing style.

Elizabeth Fertich
Product Manager 04
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

{Text in braces { } include notes to reviewer and location of text on label}
{Optional text appears in brackets []. Text in parentheses () to be included on label.}

{FRONT PANEL}

**DOG Spot ON
PERMETHRIN + METHOPRENE**

TEVRA Permethrin + Methoprene Spot On for Dogs

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

{A large clear picture of a dog in the respective weight range will be on the front panel of the label.
For small dogs, a picture of a dog approximately 15 lbs will be used for that category.}

{**ABNs:** Pet Rely for Dogs, Vetality PROTECT™ Topicals for Dogs, TevraPet PROACT™ Topicals for Dogs, PROACT™ Topicals for Dogs, PROTECT™ Topicals for Dogs, PetRely for Dogs, Tevrapet ProAct for Dogs, ProAct for Dogs}

{Only one of the following marketing claims will be placed in a box on the front label as applicable to the specific size packaging}

{Small Dogs}

ONLY For Dogs weighing 7 to 32 lbs, over 12 weeks of age

{Medium Dogs}

ONLY For Dogs weighing 33 to 66 lbs, over 12 weeks of age

{Large Dogs}

ONLY For Dogs weighing 67 lbs and over, over 12 weeks of age

ACTIVE INGREDIENTS

Permethrin* 45.0%
S-Methoprene..... 1.2%

OTHER INGREDIENTS 53.8%

TOTAL 100.0%

*Cis/trans ratio: Max 55% (±) cis and min 45% (±) trans

NOTIFICATION

92413-12

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

08/20/2019

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for Directions for Use and Precautionary Statements

NET [WEIGHT] {OR} [CONTENTS]

{Small Dogs 7-32 lbs}

[0.051][0.102][0.153][0.204][0.306][0.408][0.51][0.612] fl oz;

[ONE][TWO][THREE][FOUR][SIX][EIGHT][TEN][TWELVE] Applicators each containing 0.051 fl oz (1.5 mL)

{Medium Dogs 33-66 lbs}[0.101][0.202][0.303][0.404][0.606][0.808][1.01][1.21] fl oz;

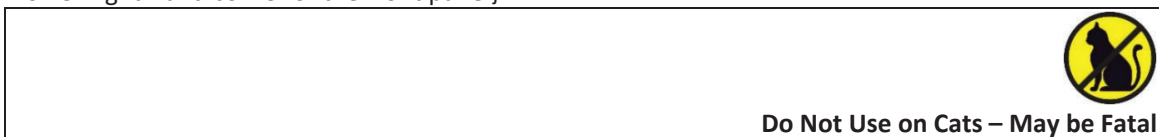
[ONE][TWO][THREE][FOUR][SIX][EIGHT][TEN][TWELVE] Applicators each containing 0.101 fl oz (3.0 mL)

{Large Dogs 67 lbs and over}

[0.203][0.406][0.609][0.812][1.218][1.624][2.03][2.436] fl oz;

[ONE][TWO][THREE][FOUR][SIX][EIGHT][TEN][TWELVE] Applicators each containing 0.203 fl oz (6.0 mL)

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



{END FRONT PANEL}

{BACK/SIDE PANEL(S)}

[TEVRA Permethrin + Methoprene Spot On for Dogs]

[DOG SPOT ON]

[PERMETHRIN + METHOPRENE]

[[This product] [Brand Name] is an effective and easy to use product to prevent eggs from fleas on treated dogs from developing into biting adults and to prevent reinfestations on your [dogs] [puppies] weighing [7 to 32 lbs][33 to 66 lbs][67 lbs and over] and over 12 weeks of age. [This product] [Brand Name] kills and repels ticks and kills mosquitoes, lice, and Sarcoptes mites that may cause Sarcoptic mange on dogs. [This product] [Brand Name] provides protection against listed pests for [4 weeks][one month].

READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON DOGS AND PUPPIES WEIGHING [7 to 32 lbs][33 to 66 lbs][67 lbs and over] OVER 12 WEEKS OF AGE

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS. CAUTION. Wash thoroughly with soap and water after handling and before eating, drinking chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS. FOR EXTERNAL USE ON DOGS ONLY. Individual sensitivities, while rare, may occur after using any pesticide product on dogs. Certain medications can interact with pesticides. Do not treat your dog with more than one pesticide product at a time. Over-dosing your dog can result in serious illness and even death. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant, or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. If your dog is exhibiting signs of and/or is being treated for skin dermatitis, talk to your veterinarian before applying any topical flea and tick control product. Consult a veterinarian for advice on Sarcoptes mites. This product is not a substitute for prescribed Heartworm preventative.

{The following Side Effects text in a box will be placed in the lower right-hand corner of back panel immediately above the cat warning box}

Side Effects: Monitor your dog after application. [Some dogs may experience temporary startle effects when any product is applied.] Dogs may experience some temporary irritation at the site of product application such as redness, scratching or other signs of discomfort. If signs of sensitivity occur, bathe your dog with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-800-775-9416. If your dog has an unusual reaction to the initial application, consult a veterinarian before repeating application.

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



DO NOT USE ON CATS. May be toxic or potentially fatal if applied to or ingested by cats. Keep cats away from treated dogs for 24 hours. Accidental application to cats and/or grooming a recently treated dog may result in tremors and/or uncoordinated muscle movements. If this occurs, immediate veterinary care should be provided. If applied to a cat or ingested by a cat, contact your veterinarian immediately.

PHYSICAL OR CHEMICAL HAZARDS: Do not mix or allow coming into contact with an oxidizing agent. Hazardous chemical reaction may occur.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

To prevent harm to you and your dog, read the entire label before each use. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied. [Use entire contents of applicator on each dog.] Weigh your dog to be sure you are applying the right dose formulated for the weight of your dog.

Restrictions

- Do not use on cats or kittens – may be fatal.
- Do not use on rabbits or animals other than dogs.
- Do not allow children to apply this product.
- Do not get this product in your dog's eyes or mouth.
- Do not allow your dog to ingest this product.
- Do not use on puppies under 12 weeks of age or dogs less than [7] [33] [67] lbs.

- Do not split one applicator between dogs.
- Do not apply more often than once every 4 weeks.
- Do not bathe dog for at least 24 hours after application.
- Do not apply more than one applicator per treatment for one dog regardless of the dog's weight.

HOW TO OPEN: Remove applicator from the package. [Separate one applicator from the others.] Hold the applicator in a vertical upright position with the tip pointing up and away from the face and body. Cut off top of applicator with scissors.

HOW TO APPLY:

The dog must be dry at the time of application. The dog should be standing for the application. Part the hair between the shoulder blades until the skin is visible. Invert the applicator and place the open end of the applicator on the skin of the dog. Apply the entire contents of one applicator, [1.5 mL {OR} 0.051 fl oz.][3 mL {OR} 0.101 fl oz.] [6 mL {OR} 0.203], to the skin as a continuous stripe from the shoulder blades to the base of the tail. Take care that liquid does not run off the dog. Avoid contact with treated area until dry. Discard empty applicator as described in Storage and Disposal. The dog must remain dry for at least 24 hours after application.



FREQUENCY OF APPLICATION

Apply [this product] [Brand Name] once every month to control fleas, ticks, and chewing lice, and to kill mosquitoes and Sarcoptes mites that may cause Sarcoptic mange. Avoid contact with treated area until dry. Do not reapply for [1 month] [4 weeks].

{SIDE PANEL}

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Do not remove applicators from outer packaging until ready to use. Store in a cool, dry place out of reach of children. Protect from freezing and direct sunlight.

PESTICIDE DISPOSAL AND CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. **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.

{END SIDE PANEL}

[WARRANTY

Read the entire Directions for Use and Warranty before using this Product. By using this product, user or buyer accepts the following warranty. The directions for use of this product must be followed carefully. It is impossible to eliminate all risks associated with the use of this product. Unintended consequences may result because of unknown factors. All such risks shall be assumed by the user or buyer. Tevra Brands is committed to providing high quality products. To the extent consistent with applicable law, Tevra Brands makes no warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond statements on this label. To the extent

consistent with applicable law, Tevra Brands, the manufacturer, or the Seller shall not be liable for indirect, special, incidental, or consequential damages. To the extent consistent with applicable law, the exclusive remedy of the user or buyer shall not exceed the purchase price paid.]

[Tevra Brands, LLC. is committed to providing high quality products. If you have questions or comments about this product, please write: Tevra Brands Pet Owner Response, 9100 F Street, Suite 200, Omaha, NE 68127]

In Case of Emergency, call: 1-800-775-9416
Non-Emergency, call: 1-844-276-3290

[Manufactured for the USA]

[Distributed by] [Manufactured for]:

Tevra Brands, LLC.
9100 F Street, Suite 200
Omaha, NE 68127

EPA Reg. No. 92413 - 12
EPA Est. No.
{date & label code; to be added at production}

{END BACK/SIDE PANEL(S)}

{Applicator Label}

{The volume used here will be consistent with the volume used in the net contents and within the DFU. mL to mL or oz to oz.}

Brand Name



{icon will be in black and white}

{7-32[33-66][67 and over] lbs as appropriate for packaging}
For Dogs [7-32 lbs][33-66 lbs] {or} [67 lbs and over] and older than 12 wks
Permethrin 45.0%, S-Methoprene 1.2%
{Appropriate volume for package will be included}
[1.5 mL][3 mL][6 mL]

KEEP OUT OF REACH OF CHILDREN

CAUTION: Read entire label before using. Use scissors to open.

For external use on Dogs only.

EPA Reg. No. 92413 - 12

Lot no.

{Optional Carton Text}

[Look at the Label [Look at the Label icon] [Easy] 6 Step [Easy] [Spot On] [Squeeze-On] [Topical]
Checklist

- [1] Read the label completely and follow directions
- [2] Weigh your dog
- [3] Do NOT use Dog products on Cats
- [4] Do NOT treat dog with more than one pesticide product at a time
- [5] Separate treated dogs from all other dogs and cats after treatment to avoid chance of ingestion
- [6] Do NOT split applicators between dogs [and use the ENTIRE contents of applicator].

[Brand Name]

[Brand Name] contains the Insect Growth Regulator (S-methoprene) which inhibits development of the immature stages of the fleas preventing them from reaching the biting adult stage.

{Optional Graphic: Flea life cycle diagram}



{Optional Marketing Statements}

Mosquitoes

1. KILLS AND REPELS MOSQUITOES [ON DOGS]
2. KILLS MOSQUITOES THAT MAY VECTOR HEARTWORM
3. PROTECTS AGAINST MOSQUITOES THAT MAY VECTOR HEARTWORM

Lice/Mites

4. ALSO KILLS DOG LICE AND SARCOPTES MITES

Fleas

5. KILLS AND REPELS ADULT FLEAS FOR 4 WEEKS [PER APPLICATION]!
6. KILLS AND REPELS [ADULT] FLEAS [FOR] 4 WEEKS [PER APPLICATION]!
7. KILLS, REPELS AND PREVENTS RE-INFESTATION OF FLEAS ON YOUR [DOG] [PUPPY WEIGHING [7-32 lbs] {OR} [33-66 lbs] {OR} [67 lbs and over] AND 12 WEEKS OR OLDER IN AGE][FOR 4 WEEKS!]
8. CONTROLS REINFESTATION OF FLEAS AND TICKS ON YOUR [DOG] [PUPPY WEIGHING [7-32 lbs] {OR} [33-66 lbs] {OR} [67 lbs and over] AND 12 WEEKS OR OLDER IN AGE]!
9. KILLS FLEA EGGS [& LARVAE]
10. PLUS KILLS FLEA EGGS AND LARVAE
11. PREVENTS FLEA EGGS FROM HATCHING!
12. PREVENTS FLEA EGGS FROM DEVELOPING INTO BITING ADULTS

Ticks

13. REPELS & KILLS TICKS ON DOGS
14. KILLS AND REPELS TICKS FOR 4 WEEKS [PER APPLICATION]!
15. KILLS AND REPELS THE DEER TICK (A VECTOR OF LYME DISEASE) FOR 4 WEEKS!
16. KILLS AND REPELS BROWN DOG TICKS [*Rhipicephalus sanguineus*] FOR 4 WEEKS [PER APPLICATION]!
17. KILLS AND REPELS TICKS INCLUDING THE BROWN DOG TICK AND DEER TICK (A VECTOR OF LYME DISEASE) FOR 4 WEEKS.
18. KILLS, REPELS AND PREVENTS REINFESTATION OF TICKS ON YOUR [DOG] [PUPPY] WEIGHING [7-32 lbs] {OR} [33-66 lbs] {OR} [67 lbs and over] AND 12 WEEKS OR OLDER IN AGE], INCLUDING BROWN DOG TICKS AND IXODES *SPP.* WHICH MAY BE VECTORS OF LYME DISEASE, FOR 4 WEEKS.

Multiple Infestations

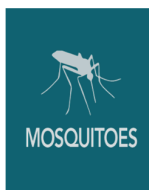
19. KILLS AND REPELS FLEAS AND TICKS FOR 4 WEEKS [PER APPLICATION]!
20. Kills & Repels fleas, flea eggs, ticks & mosquitoes [on dogs]
21. Kills lice & Sarcoptes mites [on dogs]
22. MONTHLY TOPICAL KILLS FLEAS, TICKS, MOSQUITOES AND FLEA EGGS
23. FLEA AND TICK CONTROL FOR DOGS AND PUPPIES 12 WEEKS OF AGE & OLDER, 7-32 lbs {OR} 33-66 lbs {OR} 67 lbs and over
24. FLEA, TICK & MOSQUITO TREATMENT
25. REPELS & KILLS FLEAS, TICKS & MOSQUITOES

- 26. KILLS & REPELS FLEAS, TICKS & MOSQUITOES
- 27. MONTHLY FLEA, TICK, [&] LICE [& SARCOPTES MITES] APPLICATION [TREATMENT]!
- 28. KILLS FLEAS, TICKS, MOSQUITOES, [&LICE [& SARCOPTES MITES] ON DOGS
- 29. TRIPLE PEST PROTECTION AGAINST
 - FLEAS
 - TICKS
 - MOSQUITOES
- 30. TRIPLE PEST PROTECTION AGAINST
 - FLEAS
 - TICKS
 - LICE
- 31. 3 Way Protection against fleas, ticks, lice
- 32. 3 Way Protection {icons shown below of flea, tick, louse will accompany this claim}
- 33. [FIVE][5]-IN-[ONE][1] PEST PROTECTION
 - FLEAS
 - TICKS
 - MOSQUITOES
 - LICE
 - SARCOPTES MITES
- 34. 5 Way Protection – {icons shown below of flea, tick, mosquito, Sarcoptes mites and louse will accompany this claim}
- 35. 5 Way Protection – against fleas, ticks, mosquitoes, lice and Sarcoptes mites

All Others

- 36. CITRUS SCENT
- 37. CONTAINS BITREX [A Bittering Agent]
- 38. BREAKS FLEA LIFE CYCLE! [ICON]
- 39. [1][2][3][4][6][8][10][12] MONTH SUPPLY [APPLICATIONS]
- 40. [QUICK DRYING,] [NON-GREASY,] [WATERPROOF]
- 41. Monthly Topical

{OPTIONAL GRAPHICS BELOW MAY APPEAR ON THE OUTER PACKAGING:}



1 
APPLICATOR

3 
APPLICATORS

4 
APPLICATORS
