



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

EPA Reg. Number:

92413-12

Date of Issuance:

4/23/19

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
 Expires: 04/23/2021

Name of Pesticide Product:

TEVRA PERMETHRIN +
 METHOPRENE SPOT ON FOR
 DOGS

Name and Address of Registrant (include ZIP Code):

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

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)(C). 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)
 Office of Pesticide Programs

Date:

4/23/19

EPA Form 8570-6

2. This registration is time-limited and expires 04/23/2021.

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. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
6. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 92413-12.”
7. 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 12/20/18

If you have any questions, please contact Dr. Breeden-Alemi by phone at 757.347.0511, or via email at breeden-alemi.julie@epa.gov.

Enclosure

{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}

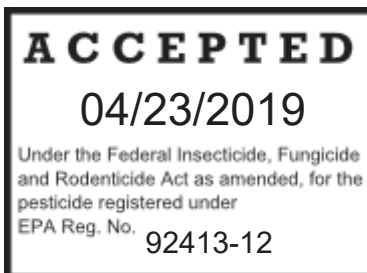
{Only one of the following marketing claims will be placed in a box on the front label as applicable to the specific size packaging}

| |
|---|
| <p><i>{Small Dogs}</i> ONLY For Dogs weighing 7 to 32 lbs, over 12 weeks of age</p> <p><i>{Medium Dogs}</i> ONLY For Dogs weighing 33 to 66 lbs, over 12 weeks of age</p> <p><i>{Large Dogs}</i> ONLY For Dogs weighing 67 lbs and over, over 12 weeks of age</p> |
|---|

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



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;

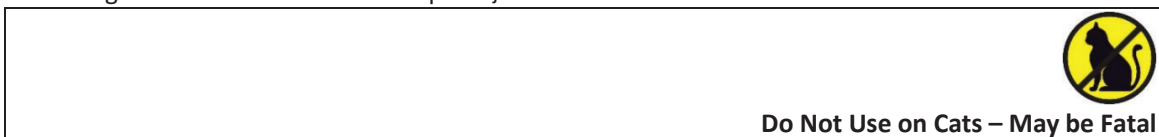
[ONE][TWO][THREE][FOUR][SIX][EIGHT][TEN][TWELVE] Applicators each containing 0.101 fl oz (3.0 mL)

{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 - RE
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 - RE
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:}

