

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

July 11, 2024

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

Subject: Label Amendment – Combination of

two label amendments to add optional icons, modify label language and add deltamethrin ID

label language

Product Name: 4% Deltamethrin Collar for Dogs

EPA Registration Number: 92413-7

Application Dates: 10/10/2019, 2/23/2021, 1/12/2021

Case Numbers: 605846, 605830, 605804

Dear Ann Tillman:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

The alternate brand names: **ProLONG Flea & Tick collar for dogs, Tevrapet ProLONG Flea & Tick collar for Dogs, Vetality ProLONG Flea & Tick collar for Dogs** have been **removed** from the registration. Our records have been updated accordingly. This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the Registration Review of the above referenced product in connection with the Deltamethrin Interim Decision, and has concluded that your submission is acceptable.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you

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release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

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 FIFRA 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) lists 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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, you may contact Hester Dingle at 202-566-2596 or via email at dingle.hester@epa.gov.

Sincerely,

Jacquelyn Herrick, Product Manager 03 Invertebrate & Vertebrate Branch 1 Registration Division (7505T) Office of Pesticide Programs

Enclosure

{Text in braces { } includes notes to reviewer}

{Optional text appears in brackets []— the final product label may include some or all of the optional text on front, back, side panels. The CRP required text and format will not change.}

4% Deltamethrin Collar for Dogs

[ABNs:]

Vetality Protect for Dogs

Tevrapet ProAct Flea & Tick Collar for Dogs

ProAct Flea & Tick Collar for Dogs

Vetality Protect flea & tick collar for Dogs

Protect flea & tick collar for Dogs

Activate Flea & Tick Collar for Dogs

Avantect Flea & Tick Collar for Dogs

Firstact Flea & Tick Collar for Dogs

Firstect Flea & Tick Collar for Dogs

Tevrapet Activate for Dogs

Tevrapet Activate Flea & Tick Collar for Dogs

Activate for Dogs

Avantect for Dogs

Vetality Avantect for Dog

Vetality Avantect Flea & Tick Collar for Dogs

Tevrapet ProAct flea and tick collar for Dogs

Vetality Protect flea and tick Collar for Dogs

Protect for Dogs

ACCEPTED

07/11/2024

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 92413-7

ACTIVE INGREDIENT:

Deltamethrin	4.00%
OTHER INGREDIENTS	<u>96.00%</u>
Total	100.00%

DO NOT ALLOW CHILDREN TO PLAY WITH COLLAR **CAUTION**

See [Back] [Insert] [or] [Side] Label [Panel(s)] for Additional Precautionary Statements Net Weight: [[Small] 0.65oz. (18.4g)] [[Medium] 0.85oz. (24.1g)] [[Large] 0.97oz. (27.5g)] [Multi Packs] [[XX oz](XX g)]

> {Product Name} **READ ENTIRE LABEL BEFORE EACH USE** USE ONLY ON [DOGS] [MEDIUM DOGS] [SMALL DOGS] [SMALL BREEDS] [PUPPIES 12 weeks or older] DO NOT USE ON CATS

[PRODUCT INFORMATION]

[[Product Name] [This collar kills fleas and ticks for 6[six] months.] Use [Product Name] year round for most effective control. [Replace every 6[six] months.]

[[Product Name], containing deltamethrin insecticide, has been specially formulated using insecticide release technology. [Maximum effectiveness may not occur for 2-3 weeks after collar placement.] [If your dog is infested, consider shampooing your dog with an EPA registered [brand name] [flea and tick shampoo] to provide immediate relief from itching and biting before applying the [collar] [product name]. The collar works for six months to kill fleas (*Ctenocephalides sp.*) on the dog and to kill fleas that infest the dog from the surrounding environment. Collar will also kill ticks for 6[six] months. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*), and deer ticks (*Ixodes scapularis* and *Ixodes pacificus*), which may transmit Lyme disease. This collar should be worn continuously.] [Reapply a new collar every 6[six] months.]

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

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

FIRST AID

IF SWALLOWED:

- 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 do so by the poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

IF ON SKIN OR CLOTHING:

- 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.

IF IN EYES:

- 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.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may contact 1-800-775-9416 for emergency medical treatment information.

DIRECTIONS FOR USE

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

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS 12 WEEKS AND OLDER

Do not use on puppies under 12 weeks. Do not use on cats.

Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your dog with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide and is not to be taken internally by humans or animals.

Do not open protective [pouch][package] until ready to use. Do not let children play with this collar. Dust forms on collar during storage. Do not get dust in mouth or eyes. Wipe collar with a damp paper towel or disposable cloth prior to applying. Place collar around dog's neck, adjust for fit, and buckle in place. The collar must be worn loosely to allow for growth of the dog and to permit the collar to move about the neck. Generally, a properly fitted collar is one that when fastened, will snugly slide over dog's head. Leave 2 or 3 inches for extra adjustment. Cut off and dispose of excess length. Wash hands after [installing] [placing] collar on dog. Replace collar every 6[six] months.

[OPTIONAL ALTERNATE DIRECTIONS FOR USE FOR INJECTION MOLDED COLLARS]

[[1.] Do not open until ready to use. Dust forms on collar during storage. Do not get dust in mouth or eyes. Take the collar out of the packaging and stretch to full length. [The tabs that held the collar in place [should][will] fall off when stretching; pull on any remaining tabs to remove them.]

[[2.] Wipe collar with a damp paper towel or disposable cloth prior to applying to remove dust on collar. Bend the buckle in half between the holes in the buckle, so that you can easily pass the end of the collar through both holes.]



[[3.] Place the collar around your dog's neck. Feed the collar through both holes [[ridges][notches] facing out]. Fit to the neck of the dog. The collar must be worn loosely to allow for growth of the dog and to permit the collar to move about the neck. Generally, a properly fitted collar is one that, when fastened, will snugly slide over dog's head [, and two fingers can be placed between the collar and dog's neck]. Leave [2 or 3] [1 or 2] extra inches for collar adjustment, cut off remaining excess collar and dispose of in the trash.]





[4.] Wash hands after [installing] [placing] collar on dog. Replace collar every 6[six] months.]

STORAGE AND DISPOSAL

Pesticide Storage: Store this product in a cool, dry place away from children and pets. **Pesticide Disposal and Container Handling:** Do not reuse container or used collar. Dispose of in trash. Do not dispose down-the-drain or sewer. Call your local solid waste agency for local disposal options.

[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 are believed to be adequate and 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. To the extent consistent with applicable law, 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.]

[Satisfaction guaranteed][If you are not satisfied, we will make it right with a replacement or refund.]

[If you have questions or comments about this product, please write: Tevra Brands Pet Owner Response, 9100 F Street, Suite 200, Omaha, Nebraska 68127]

In Case of Emergency, call: 1-800-775-9416

Non-Emergency, call 1-844-276-3290 {lot, date & label code}

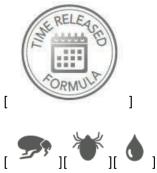
[Distributed by:][Manufactured by:] Tevra Brands, LLC. Omaha, Nebraska, 68127

[BAR CODE AREA] EPA Reg. No. 92413-7 EPA Est. No. XXXXX-XX-XXX

{END - BACK / SIDE PANEL}

{Each optional graphic below may or may not appear anywhere on the finished label}

[Fleas, Ticks, Waterproof-drop, hourglass]













{The following claims/text are optional and may or may not appear anywhere on the final printed labeling:}

{Note to reviewer: Whenever one of the claims below designated with "*" is used, the claims below will be located on the same panel so they can be read together.}

[Compare to Scalibor® Protector Band for Dogs [Tick and Flea Collar for Dogs], contains the same active ingredient.*]

[Compare to Scalibor® Protector Band for Dogs [Tick and Flea Collar for Dogs], contains the same active ingredient deltamethrin.*]

[Compare to the same active ingredient found in Scalibor® Protector Band for Dogs [Tick and Flea Collar for Dogs]*]

[[Brand Name] [This product] contains deltamethrin, the same active ingredient used in Scalibor® Protector Band for Dogs [Tick and Flea Collar for Dogs].*]

*Scalibor® is a registered trademark of [Merck Animal Health] [Intervet International B.V.]. [Brand Name] [This product] is not manufactured or distributed by [Merck Animal Health] [Intervet International B.V.].

OR

*Scalibor® is a registered trademark of [Merck Animal Health] [Intervet International B.V.]. [Brand Name] [This product] is not manufactured or distributed by the makers of Scalibor® Protector [Band] [Brand] for Dogs.

Fleas

- [Flea [control] [prevention] for dogs [& puppies 12 weeks or older]]
- [Kills Fleas]
- [Kills [Adult] Fleas for 180 days[!]]
- [Kills [Adult] Fleas for 6[six] months[!]]

- [Provides long lasting (180 days) protection against fleas]
- [Provides long lasting (6[six] months) protection against fleas]
- [Prevents new flea infestations]
- [Kills adult fleas (before they lay eggs)]
- [Kills fleas that may cause flea bite anemia]
- [Kills fleas that may cause bartonellosis]
- [Kills [adult] fleas which may transmit tapeworms]
- [Kills [adult] fleas which may cause flea bite anemia]
- [Kills [adult] fleas which may reduce the incidence of Flea Allergy Dermatitis (FAD)]
- [Kills [adult] fleas that may cause [Flea Allergy Dermatitis (FAD)][and][flea bite anemia]]
- [Kills [adult] fleas which may be a source of flea allergy dermatitis][(and) flea bite anemia][(and)tapeworm]
- Breaks the flea life cycle

Ticks

- [Tick (control)(prevention) for dogs (& puppies 12 weeks or older)]
- [Kills Ticks]
- [Kills Ticks for 180 days[!]]
- [Kills Ticks for 6[six] months[!]]
- [Provides long lasting (180 days) protection against ticks]
- [Provides long lasting (6[six] months) protection against ticks]
- [Kills ticks that may transmit Lyme Disease]
- [Kills ticks that may transmit babesiosis]
- [Kills ticks that may transmit anaplasmosis]
- [Kills ticks (including deer ticks which may transmit Lyme disease)]
- [Kills the Ticks that may transmit Rocky Mountain Spotted Fever]
- [Kills ticks for 6[six] months, including Deer ticks (that may transmit Lyme disease and anaplasmosis), American dog ticks (that may transmit Rocky Mountain spotted fever and ehrlichiosis), and Brown dog ticks (that may transmit ehrlichiosis, anaplasmosis, bartonellosis, canine hemoplasmosis, babesiosis)]

Multiple Pests

- [Provides 180 days control of fleas [and] [&] ticks]
- [Provides 6[six] months control of fleas [and] [&] ticks]
- [Kills Fleas [and][&] Ticks]
- [Kills Fleas and Ticks for 180 days]
- [Kills Fleas and Ticks for 6[six] months]

Multiple Package Claims

- [Each Collar = 6[Six] months protection [against fleas & ticks]]
- [Two[2] Collars [provide][=]12[Twelve] months protection [against fleas & ticks]]
- [Twelve[12] month protection: apply one[1] collar every six[6] months]

Collar Fit Claims

- [For Dogs of all sizes]
- [Lock and Stay Design]
- [Click and Stay Design]
- [Pull and Click]
- [Clicks into place]
- [Click to Fit Design]

- [Modern Click to Fit Design]
- [Slide [to] [and] Fit [Design]]
- [Fit] [-] [and] Stay [Design]]
- [Slide Fit [and] Stay Design]
- [Right Fit [Design]]
- [Just Right Fit [Design]]
- [Fits Just Right [Design]]
- [Fits securely] [Stays in place]
- [Fits just right ... won't be too loose or too tight]
- [Comfort Fit [Design]]
- [Designed for Comfort]
- [Stay in Place design]
- [Won't slide and stretch]
- [Won't be too loose or too tight [...fits just right [!]]]
- [Grreat Fit]
- [Grr.eat [Fit]]
- [GRR...eat FIT]
- [Cut to size]
- [Size to fit]
- [Fit to size]
- [Adjustable]
- [Fits all size dogs]
- [Right Size Collar [Design]]
- [Fits securely on any size dog]
- [Notched to fit securely on any size dog]
- [Fits Neck to [specific inch size]]
- [Fits neck up to [15"] [20"] [23"][26"]
- [Fits right over existing collar]

All Other

- [Time Release formula]
- [Continuous protection]
- [[Features] insecticide-release technology]
- [Long[-]Lasting for 6[six] months]
- [6[six] months protection]
- [Long Lasting Protection for 180 days]
- [Long Lasting Protection for 6[six] months]
- [Apply new collar every 180 days]
- [Apply new collar every 6[six] months]
- [All Weather Collar]
- [Not affected by water] [Water resistant]
- [Rugged][and][weatherproof]
- [Wetting will not impair the collar's effectiveness or the dog's protection]
- [Convenient]
- [Easy to (use)(apply)(attach)]
- [Cut off excess length]
- [Tevra collar technology]
- [For dog(s) (and puppies) 12 weeks of age and older]
- [For [Dogs], [Large Dogs], [Medium Dogs] [Small Dogs & Puppies] [Small Breeds]]
- [[Fresh][Powdery][Clean] Scent]
- [Specific fragrance noted here][Scent][Fragrance]]

- [Specific printed design described here (i.e., animal paw print, paw print, etc.][print][design][collar]
- [Glow-in-the Dark][Collar Cover][Protector Band]
- [Save Now!]
- [Great Value]
- [Better Value]
- [Bonus Pack]
- [Club Pack]
- [Club Size]
- [Value Size]
- [Value Pack]
- [Multi[[-][Pack]
- [[X] % Free]
- [Buy [X] and Save]
- [Buy More and Save]
- [Buy [X] Get [X] Free]
- [(X) Month(s) Free!]
- [X+X=X Bonus Pack!]
- [Coupon Inside!]
- [Product Coupons on inside or outside of package]
- [Available without a visit to a veterinarian]