

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

October 7, 2021

TEVRA Brands, LLC c/o Brien O'Loughlin, Agent Pyxis Regulatory Consulting Inc. 4110 136<sup>th</sup> St. Gig Harbor, WA 98332

Subject: Label Amendment – Response to agency-initiated letter requesting removal of

compare to claims.

Product Name: TEVRA Deltamethrin + Pyriproxyfen Collar for Dogs

EPA Registration Number: 92413-14 Application Date: August 2, 2021

Decision Number: 577962

Dear Mr. O'Loughlin:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, 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.

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 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 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.

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

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with FIFRA section 6. If you have any questions, please contact Elizabeth Andrews by phone at 703-347-8770, or via email at Andrews. Elizabeth@epa.gov.

Id Herrick

Sincerely,

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

Enclosure

{Note to reviewer: [Text] in brackets denotes optional text. The final label may include some or all of the optional text. {Text} in braces denotes where in the final label text will appear and notes to reviewer.}

{Front label}

{Picture of the appropriate size dog will be included on front panel}

## Tevra Deltamethrin + Pyriproxyfen Collar for Dogs

#### **ACTIVE INGREDIENTS:**

| Deltamethrin      | 4.00%         |
|-------------------|---------------|
| Pyriproxyfen      | 0.50%         |
| OTHER INGREDIENTS | <u>95.50%</u> |
| Total             | 100.00%       |

## ACCEPTED

10/07/2021

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

92413-14

#### DO NOT ALLOW CHILDREN TO PLAY WITH COLLAR

## **CAUTION**

See Back[Label][Panel] for First Aid and Additional Precautionary Statements

Net Weight:

{Single Packs contain 1 or 2 collars (1-count, 2-count); Multi Pack(s): each labeled package contains 1 or 2 collars; a Multi Pack is a clam shell that contains 1, 2 or 3 labeled packages containing the same number of collars with no over-wrap labeling. Text on all packages will be legible through clam shell outer packaging.; multi-pack claims will be either on clam shell or front label. Multi Packs will have a statement of net weight that will include individual collar weight as well as appropriate total weight.}

## {Single pack, one collar}

#### **One Collar**

[One Size Fits All: 0.97 oz. (27.5 g) [Collar] [[Adjustable—]One Size Fits All]

{Small}[0.65 oz. (18.4 g) [Collar] [Fits neck up to 15["][inches]]

{Medium}[0.85 oz. (24.1 g) [Collar] [Fits neck up to 20["][inches]]

{Large}[0.97 oz. (27.5 g) [Collar] [Fits neck up to 23["][inches]]

#### {Single pack, two collars}

## **Two Collars**

[One Size Fits All: 1.94 oz. (55 g) [Collar] [[Adjustable—]One Size Fits All]

{Small}[1.3 oz. (36.8 g) [Collar] [Fits neck up to 15["][inches]]

{Medium}[1.70 oz. (48.2 g) [Collar] [Fits neck up to 20["][inches]]

{Large}[1.94 oz. (55 g) [Collar] [Fits neck up to 23["][inches]]

#### {3 x 1-count; 3 collars total}

#### 3 Collars

[One Size Fits All: 2.91 oz. (82.5 g) [Collar] [[Adjustable—]One Size Fits All]

{Small}[1.95 oz. (55.2 g) [Collar] [Fits neck up to 15["][inches]]

{Medium}[2.55 oz. (72.3 g) [Collar] [Fits neck up to 20["][inches]]

{Large}[2.91 oz. (82.5 g) [Collar] [Fits neck up to 23["][inches]]

## {2 x 2-count. 4 collars total}

#### **4 Collars**

[One Size Fits All: 3.88 oz. (110 g) [Collar] [[Adjustable—]One Size Fits All]

{Small}[2.6 oz. (36.8 g) [Collar] [Fits neck up to 15["][inches]]

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{Medium}[3.4 oz. (96.4 g) [Collar] [Fits neck up to 20["][inches]] {Large}[3.88 oz. (110 g) [Collar] [Fits neck up to 23["][inches]]

## {3 x 2-count; 6 collars total; X=6} [5.82 oz. (165 g)]

{Small}[3.9 oz. (110.4 g) [Collar] [Fits neck up to 15["][inches]] {Medium}[5.1 oz. (144.6 g) [Collar] [Fits neck up to 20["][inches]] {Large}[5.82 oz. (165 g) [Collar] [Fits neck up to 23["][inches]]

#### **6 Collars**

[One Size Fits All: 5.82 oz. (165 g) [Collar] [[Adjustable—]One Size Fits All] {Small}[3.9 oz. (110.4 g) [Collar] [Fits neck up to 15["][inches]] {Medium}[5.1 oz. (144.6 g) [Collar] [Fits neck up to 20["][inches]] {Large}[5.82 oz. (165 g) [Collar] [Fits neck up to 23["][inches]]

{End Front Label}

{Back label}

#### [Product Name]

## READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS AND PUPPIES 12[TWELVE] WEEKS OF AGE AND OLDER DO NOT USE ON CATS

#### [PRODUCT INFORMATION]

[[Product Name][This collar] kills fleas and ticks for [6[six] months][180 days]. Use [Product Name] year-round for most effective control. [Replace every [6[six] months] [180 days].]

[[Product Name], containing deltamethrin insecticide and [the Insect Growth Regulator] pyriproxyfen, has been formulated using insecticide release technology.]

Maximum effectiveness may not occur for 2-3 weeks after collar placement.

[The collar will kill fleas (Ctenocephalides sp.) on the dog and will continue to kill fleas for [6[six] months][180 days], thus working to kill fleas from the environment that may appear later on the dog. Collar will also kill ticks for [6[six] months][180 days]. 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. The collar will sterilize adult fleas and will sterilize [and kill] flea eggs\*. This collar should be worn continuously.] [Reapply a new collar every [6[six] months][180 days].]

\*excluding California

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Do not open protective [pouch][package] until ready to use. Do not let children play with this collar. 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.

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.

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

#### 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 AND PUPPIES 12[TWELVE] WEEKS AND OLDER For indoor use only.

#### **RESTRICTIONS**

- Do not use on puppies under 12[twelve] weeks.
- Do not use on cats.
- Do not open [wrapper][pouch][package]until ready to use.
- Do not let children play with collar.
- {For multi-packs only} [Use only one collar per dog at a time.]
- Dust forms on collar during storage. Do not get dust in mouth or eyes.
- Application of product on pets must only be done indoors.

## { EXTRUDED COLLARS}

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. Two fingers should fit between the collar and neck. Leave 2 or 3 inches for extra adjustment. Cut off excess length, wrap in newspaper and dispose of in trash. Wash hands after [installing] [placing] collar on dog. Replace collar every [6[six] months.][180 days.]

#### { INJECTION MOLDED COLLARS}

- [[1.] 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. Discard tabs in the trash.]
- [[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, wrap in newspaper and dispose of in the trash.]



[ ]

[4.] Wash hands after [installing] [placing] collar on dog. Replace collar every [6[six] months][180 days].]

#### 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 animals. **Pesticide Disposal and Container Handling:** Do not reuse container or used collar. Dispose of in trash.

#### [WARRANTY

Read the entire Directions for Use and Warranty before using this Product. To the extent consistent with applicable law 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

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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 [Manufactured for the USA] Non-Emergency, call 1-844-276-3290 [lot, date & label code]

[Distributed by:][Manufactured for:]

Tevra Brands, LLC. [BAR CODE AREA]

9100 F Street, Suite 200

Omaha, Nebraska, 68127 EPA Reg. No. 92413-14 EPA Est. No. XXXXX-XXX

{End Back label}

[ABNs:]

Tevrapet ProAct Plus for Dogs Vetality Protect Plus for Dogs

Tevrapet ProAct Plus Flea & Tick Collar for Dogs

ProAct Plus Flea & Tick Collar for Dogs

Vetality Protect Plus flea & tick collar for Dogs

Protect Plus flea & tick collar for Dogs

Avantect 2 Flea & Tick Collar For Dogs

Firstact Plus Flea & Tick Collar for Dogs

Firstect Plus Flea & Tick Collar for Dogs

Avantect 2 for Dogs

Vetality Avantect 2 for Dog

Vetality Avantect 2 Flea & Tick Collar for Dogs

ProAct Plus Collar for Dogs

Tevrapet ProAct flea and tick collar for Dogs

Vetality Protect flea and tick Collar for Dogs

**Protect Plus for Dogs** 

ProLONG Plus Flea & Tick collar for dogs

Tevrapet ProLONG Plus Flea & Tick collar for Dogs

Vetality ProLONG Plus Flea & Tick collar for Dogs

Vetality Avantect II Collar for Dogs

Avantect II Collar for Dogs

Activate II Collar for Dogs

Tevrapet Activate II Collar for Dogs

Vetality Avantect II Flea & Tick Collar for Dogs

Avantect II Flea & Tick Collar for Dogs

Activate II Flea & Tick Collar for Dogs

Tevrapet Activate II Flea & Tick Collar for Dogs

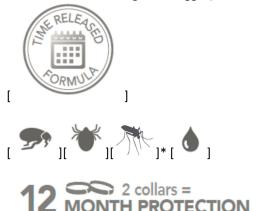
**Vetality Avantect II for Dogs** 

Avantect II for Dogs

Activate II for Dogs **Tevrapet Activate II for Dogs** 

{Note to reviewer: Each optional graphic below may or may not appear anywhere on the finished label}

[Fleas, Flea Eggs\*, Ticks, Waterproof-drop, hourglass, breaks-flea-life-cycle\*, kills-flea-eggs for [6[six] months][180 days]\*, kills flea eggs\*, {only when 2 collars are offered}, lock-and-stay-design, moldedcollar, comfort-fit-design, flea-eggs\*]



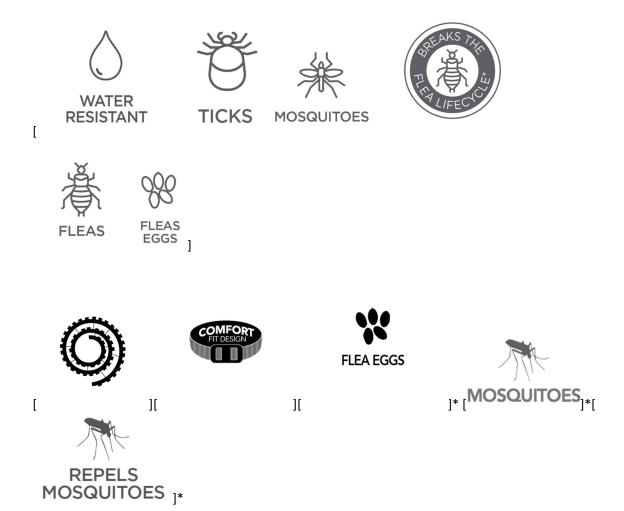












<sup>\*</sup>excluding California

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

## Fleas and Flea Eggs\*

- Flea [control] [prevention] for dogs & puppies 12[twelve] weeks or older
- Kills [Adult] Fleas for [6[six] months] [180 days[!]
- Provides [6[six] months] [180 days] 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 transmit 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]
- Sterilizes adult fleas for [6[six] months][180 days]\*
- Sterilizes [and kills] flea eggs for [6[six] months][180 days]\*
- Kills flea eggs for [6[six] months][180 days]\*

- Kills Fleas and Flea Eggs for [6[six] months][180 days]\*
- Plus Pyriproxyfen
- Pyriproxyfen added
- Includes an IGR

#### Ticks

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

## Mosquitoes\*

- Repels mosquitoes for [6[six] months][180 days]\*
- Reduces mosquito bites for [6[six] months][180 days]\*
- Reduces blood feeding by mosquitoes for [6[six] months][180 days]\*
- Protects against mosquito bites for [6[six] months][180 days]\*

#### **Multiple Pests**

- Provides [6[six] months][180 days] control [of fleas [and] [&] ticks][and][repels mosquitoes]
- Kills Fleas [and][&] Ticks
- Kills Fleas and Ticks for [6[six] months][180 days]
- Provides full season, [6[six] months][180 days] protection against fleas [and] ticks [and] [repels mosquitoes\*]
- Kills fleas[, ][flea eggs\*][, ][ticks][, ][and][repels mosquitoes\*] for 6 [six]months[180 days] \*excluding California

#### Multiple Package Claims {Claims for packages with 2 collars}

- Each Collar = [6[Six] months][180 days] protection [against fleas & ticks][fleas, flea eggs\*, ticks & repels mosquitoes\*]
- Two [2] Collars, worn [one at a time][consecutively] [provide][=] 12[twelve] months protection
  [against fleas & ticks] fleas [and] ticks [and] [repels mosquitoes\*]
   \*excluding California

### **Collar Fit Claims**

- For Dogs [and Puppies] over 12[twelve] weeks old
- Lock and Stay Design
- Click and Stay Design
- Pull and Click
- Clicks into place
- Click to Fit Design

<sup>\*</sup>excluding California

<sup>\*</sup>excluding California

- Modern Click to Fit Design
- [New] Lock and Fit Design {Note to reviewer: the claim "New" will be removed after 6 months}
- 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
- {Only for adjustable size collar} Adjustable One Size Fits [Large][Medium][Small][Small Breed]
   Dogs
- {Only for adjustable size collar} Fits all size dogs over 12[twelve] weeks old [Cut off excess collar]
- Right Size Collar [Design]
- {Only for adjustable size collar} Fits securely on any size dog [Cut of excess collar]
- Fits Neck to [specific inch size]
- Fits right over existing collar

#### **All Other**

- Time Release formula
- Continuous protection for [6[six] months][180 days]
- ICON 6-Months of Continuous protection:



**CONTINOUS PROTECTION** 

- [Features] insecticide-release technology
- [6[six] months][180 days] protection
- Long Lasting Protection for [6[six] months][180 days]
- Apply new collar every [6[six] months][180 days]
- All Weather Collar
- Not affected by water [Water resistant]
- Rugged [and][weatherproof]
- Wetting will not impair the collar's effectiveness or the pet's protection

- Convenient
- Easy to use[apply][attach]
- Cut off excess length
- Tevra collar technology
- For dog(s) (and puppies) 12 [twelve]weeks of age and older
- [Fresh][Powdery][Clean] Scent
- Specific fragrance noted here[Scent][Fragrance]]
- Collar Cover[Protector Band]
- Save Now!
- Great Value
- Better Value
- Bonus Pack [Club Pack][Club Size][Value Size][Value Pack][[Multi-Pack] {Note to reviewer: Each labeled package contains 1 or 2 collars. Bonus Pack (or Club Pack, Club Size, Value Size, Value Pack, or Multi Pack) will contain more than 1 labeled package containing the same number of collars in a clamshell outer package. There is no over-wrap labeling. Text on all packages will be legible through clam shell outer packaging.}
- Buy [X] and Save {X= 2 or 3; one or two collars are packaged in one container; if you buy more than one package, X is >1}}
- Buy More and Save
- [BOGO] Buy One Get One FREE
- [BOGO] Buy One Get one 50% Off
- 1+1=2 Bonus Pack!
- 2+1=3 Bonus Pack!
- Coupon Inside!
- Product Coupons on inside or outside of package {Note to reviewer: if product coupon is on outside of package, none of the text on the label will be obscured}