

#### U.S. ENVIRONMENTAL PROTECTION AGENCY

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

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X Registration Reregistration

(under FIFRA, as amended)

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EPA	Reo.	Num	her:

Date of Issuance:

92413-10

8/30/17

Term of Issuance:

Conditional, Time-Limited Expires: 08/30/2019

Name of Pesticide Product:

Tevra Imidacloprid + Pyriproxyfen Spot On for Cats

Name and Address of Registrant (include ZIP Code):

Dr. Olaf Hansen Tevra Brands, LLC 401 North 1<sup>st</sup> St La Salle, CO, 80645

**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)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:	Date:	
VE	8/30/17	
Venus Eagle, Product Manager 01		
Invertebrate-Vertebrate Branch 3, Registration Division (7505P)		

- 2. This registration is time-limited and expires 08/30/2019.
- 3. At least three months before your intended sale/distribution date submit a mock up copy of the label. You may not sell/distribute this product until the Agency reviews and approves the mock up copy of the label. Once the mock-up label is approved, you must inform the Agency when the product is first released for shipment.
- 4. 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
- 5. 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 cats 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 dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for cats 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 cat incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range, as applicable.
- Table showing number of incidents for each cat breed, where provided.
- Table showing number of incidents in cats for each clinical sign.
- Table showing number of incidents in cats 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.

- 6. You are required to comply with the data requirements described in the DCI or EDSP Order identified below:
  - a. Imidacloprid GDCI-129099
  - b. Imidacloprid EDSP-129099
  - c. Pyriproxyfen GDCI-129032
  - d. Pyriproxyfen EDSP-129032

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1

7. 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.

- 8. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 92413-10."
- 9. Submit a 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 11/28/2016

If you have any questions, please contact Jacquelyn Herrick by phone at 703-347-0559, or via email at herrick.jacquelyn@epa.gov.

Enclosure



08/30/2017

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

92413-10

#### **TEVRA Master Label**

Cats Spot On Imidacloprid + Pyriproxyfen

# **{FRONT PANEL OF CARTON}**

[Optional text appears in brackets/parenthesis – the final label may include some or all of the optional text]

{ } Braces indicate location of text on container or note to the EPA reviewer.

# **TEVRA Imidacloprid + Pyriproxyfen Spot On for Cats**

{Market Label-the word Cat will be at least 75% in height of the largest letter in the primary brand name.}

{Market Label-a large clear picture of a cat in the respective weight range will be on the front panel of the label.}

{One of the following statements will appear on appropriate weight band market label prominently on front panel, enclosed in a box, as required per Agency's pet spot-on mitigation measures}

For use ONLY on cats [&][and] kittens [weighing] 2 [-][to] 5 lbs. and over 8 weeks [old][of age][or older] {0.23 ml size package}

For use ONLY on cats [&][and] kittens [weighing] 5 [-][to] 9 lbs. and over 8 weeks [old][of age][or older] {0.40 ml size package}

For use ONLY on cats [&][and] kittens [weighing] [more than][over][>] 9 lbs. and over 8 weeks [old][of age][or older] {0.80 ml size package}

{following text will be in addition to the above required language}

Small Cats {only for use on label for 2-5 lbs and 8 weeks or older product}

Medium Cats {only for use on label for 5-9 lbs and 8 weeks or older product}

Large Cats {only for use on label for >9 lbs and 8 weeks or older product}

# **ACTIVE INGREDIENTS:**

Imidacloprid	9.10%
Pyriproxyfen	0.46%
OTHER INGREDIENTS.	90.44%
TOTAL:	100.00%

# KEEP OUT OF REACH OF CHILDREN WARNING

See [[back] or [side]] [[label] or [panel]] and insert within carton for FIRST AID and PRECAUTIONARY STATEMENTS and insert for complete Directions for Use

**NET CONTENT: Z fl oz Y – X fl oz applicators** 

[0.0078 fl oz (0.23 mL) applicators] [0.014 fl oz (0.4 mL) applicators] [0.027 fl oz (0.8 mL) [applicators]

{Note to reviewer: X is the liquid amount of one applicator; Y is the number of applicators that are in the carton; Z is the sum of the liquid amounts}

{Note to reviewer: Y does not equal 1 for the 0.027 fl oz (0.8 mL) applicator size; Y can be 3, 4, 6, and 8 for the 0.027 fl oz (0.8 mL) applicator size; Y can be 1, 3, 4, 6, and 8 for the 0.078 fl oz (0.23 mL) and 0.014 fl oz (0.4mL) applicator size}

# [Begin Optional Active Ingredient Reference Statements]

Contains the active ingredients in Advantage II\* (or)
Contains the same active ingredients as Advantage® II\* (or)
Contains imidacloprid and pyriproxyfen, the active ingredients used in Advantage® II\*
\*[This product is not manufactured by Bayer Healthcare LLC, the makers of Advantage® II] [OR]
[Advantage® II is a registered trademark of Bayer Healthcare LLC]}

{Note to reviewer: At least one of the Bayer disclaimers below will appear on the product label}

[\*[Brand Name] [This product] contains [imidacloprid and pyriproxyfen], the active ingredients used in [Advantage®II] [Advantage®II Kitten] [Advantage®II Small Cat] [Advantage®II Large Cat]\*

{AND / OR}

{Note to reviewer: Text for footnote statement one}

[\*[Brand Name] [This product] is not manufactured [or distributed] by Bayer Healthcare LLC, the makers of

[Advantage® II] [Advantage® II Kitten] [Advantage® II Small Cat] [Advantage® II Large Cat]

{AND}

{Note to reviewer: Text for footnote statement two. Note that Text for footnote statement two will only be used if Text for footnote statement one is used. The following statement will not appear on the label without statement one.}

[Advantage® II] [Advantage® II Kitten] [Advantage® II Small Cat] [Advantage® II Large Cat] is a registered trademark of Bayer Healthcare LLC.]

[End Optional Active Ingredient Reference Statements]

**{END - FRONT PANEL OF CARTON}** 

## **{BACK PANEL OF CARTON/SIDE PANEL OF CARTON}**

[The active ingredients in [Brand Name][this product] are imidacloprid and pyriproxyfen. This product is formulated to control fleas on cats. [[Brand Name][This product] kills fleas within 12 hours and prevents further flea infestations for [up to] [[4][four]weeks][1][one] month][30 days].]

# READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON CATS AND KITTENS 8 WEEKS OF AGE OR OLDER.

#### **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 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.

## 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.

# Note to Physician

Treat the patient symptomatically.

# **HOT LINE NUMBER**

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

### **PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS. WARNING.** Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes or on clothing. Wash hands thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on cats only. Individual sensitivities may occur after using ANY pesticide product for cats. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Do not treat your cat with more than one pesticide product at a time. Over dosing your cat can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing cats.

**Side Effects**: Monitor your cat after application. [Some cats may experience temporary startle effects when any product is applied.] Cats 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 cat 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 cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your cat and continue to monitor your cat for the next 24 hours.

# **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 CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

#### **Restrictions:**

- DO NOT ALLOW CHILDREN TO APPLY PRODUCT.
- Do not use on animals other than cats.
- Do not allow your cat to ingest this product.
- Do not reapply for [[four] [4] weeks] [30days].
- Do not use on kittens under 8 weeks of age. Do not apply to cats weighing less than [2] [5] [9] lhs
- Weigh your cat to be sure you are applying the right dose formulated for the weight of your cat.
- Use entire contents of applicator on each cat. Do not split one applicator between two cats. Do not use multiple applicators on one cat.
- Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.
- Do not have contact or allow children to have contact with the treated area until completely dry.
- Do not apply more than one applicator per treatment for one cat regardless of the cat's weight.

{Note to reviewer: A box labeled "Side effects" will be at the lower right hand corner of the back panel.}

#### How to Apply:

[Apply entire content between shoulder blades]



- 1. Hold cat with one hand and use the other hand to apply the solution.
- 2. Hold applicator facing away from you and your cat's eyes, invert the applicator and use the narrow end to part the cat's hair.
- 3. Squeeze applicator firmly to apply all of the solution [on] [to] the cat's skin as a spot between the shoulder blades.

{For cartons containing 0.23 mL (0.0078 fl oz) applicator}

Only For Cats Weighing 2 [-][to] 5 lbs. Do not apply to Cats weighing less than 2 lbs, 8 weeks or older.

[including small cats or kittens, only 8 weeks or older] Apply one applicator 0.23 mL (0.0078 fl oz) directly to skin as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

{For cartons containing 0.4 mL (0.014 fl oz) applicator}

Only For Cats Weighing 5 [-][to] 9 lbs. Do not apply to Cats weighing less than 5 lbs, 8 weeks or older.

[including small cats or kittens, only 8 weeks or older] Apply one applicator 0.4 mL (0.014 fl oz) directly to skin as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

# {For cartons containing 0.8 mL (0.027 fl oz) applicator}

Only For Cats Weighing Over 9 lbs. Do not apply to cats weighing less than 9 lbs. Do not use more than one applicator on cats greater than 9 lbs. Apply one applicator 0.8 mL (0.027 fl oz) directly to skin as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

## **FREQUENCY OF APPLICATION**

[Use [Brand Name {or} this product] monthly for control of flea[s] [infestations].]

[[Studies show that] [Brand Name {or} This product] kills fleas within 12 hours of application and [lasts {or} protects] for [up to] [[four][4] weeks][30 days][one month].]

[[Brand Name {or} This product] kills reinfesting fleas within [2][two] hours and prevents further infestations of fleas [for [up to] [[four][4] weeks][30 days][one month]].]

[[Brand Name {or} This product] [targets multiple flea life stages] [and] [kills flea eggs and larvae before they develop into biting adults].]

[[Brand Name][This product] breaks the flea life cycle by killing flea eggs, flea larvae, and adult fleas.] [Apply monthly for effective flea control.]

[[Brand Name {or} This product] is waterproof and remains effective, even after water immersion or exposure to sunlight [and][or] [rain]. Allow treated area to dry thoroughly before getting wet.] [Allow treated area to dry thoroughly.]

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**STORAGE:** Do not remove applicator from pack until ready to use. Store in a cool (below 77°F[/][25°C]), dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

**PESTICIDE DISPOSAL AND CONTAINER HANDLING: Non-refillable container. If empty:** Do not reuse or refill this container. 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.

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

{Note to reviewer: If the coupon appears on the outside of the package, it will not obscure

mandatory language}

[Coupon(s) inside or on outside of box]

Lot No.

[Distributed by:] [Manufactured by:] EPA Reg. No. 92413 - xxx

Tevra Brands, LLC Omaha, Nebraska, 68127 EPA Est. No. [BAR CODE AREA]

{END - BACK/SIDE PANEL OF CARTON}

Cats Spot On Imidacloprid + Pyriproxyfen

# **{LABEL ON INDIVIDUAL APPLICATOR}**

Brand Name for Cats

[2-5] [5-9] [>9 lbs] lbs. ≥ 8 wks

Imidacloprid 9.10%, Pyriproxyfen 0.46%
0.0078 fl oz {or} 0.014 fl oz {or} 0.027 fl oz

Keep Out of Reach of Children

Warning

Read Entire Label Before Use

EPA Reg. No. 92413 – x

Lot #

For external use on cats only

**{END - LABEL ON INDIVIDUAL APPLICATOR}** 

[BRAND NAME]

# READ ENTIRE LABEL BEFORE EACH USE.

USE ONLY ON CATS AND KITTENS 8 WEEKS OF AGE OR OLDER weighing [2-5], [5-9], or [>9] lbs.

# {One of the following statements will appear prominently on appropriate weight band market label enclosed in a box, as required per Agency's pet spot-on mitigation measures:}

For use ONLY on cats [&][and] kittens [weighing] 2 [-][to] 5 lbs. and over 8 weeks [old][of age] [or older] {0.23 ml size package}

{OR}

For use ONLY on cats [&][and] kittens [weighing] 5 [-][to] 9 lbs. and over 8 weeks [old][of age] [or older]{0.40 ml size package}

(OR)

ONLY for cats [&][and] kittens over 8 weeks [old][of age][or older] and [weighing] 2 [-][to] 5 lbs {0.23 ml size package}.

{OR}

ONLY for cats [&][and] kittens over 8 weeks [old][of age] ][or older] and [weighing] 5 [-][to] 9 lbs {0.40 ml size package}.

For use ONLY on cats [&][and] kittens [weighing] [more than][over][>] 9 lbs. and over 8 weeks [old][of age][or older] {0.80 ml size package}

{OR}

ONLY for cats [&][and] kittens over 8 weeks [old][of age][and older] and [weighing] [more than] [over][>] 9 lbs {0.80 ml size package}.

{following text will be in addition to the above required language}

Small Cats {only for use on label for 2-5 lbs and 8 weeks or older product}

Medium Cats {only for use on label for 5-9 lbs and 8 weeks or older product}

Large Cats {only for use on label for >9 lbs and 8 weeks or older product}

#### **ACTIVE INGREDIENTS:**

Imidacloprid	9.10%
Pyriproxyfen	0.46%
OTHER INGREDIENTS	
TOTAL:	100.00%

{Note to reviewer: Font size of the KOOROC statement and Signal word will be in compliance with Label Review Manual Ch. 3.}

# KEEP OUT OF REACH OF CHILDREN WARNING

#### **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 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.

# 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.

#### **HOT LINE NUMBER**

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

#### **NOTE TO PHYSICIAN**

Treat the patient symptomatically.

#### **PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS. WARNING.** Causes substantial but temporary eye injury. Harmful if swallowed. Do not get in eyes or on clothing. Wash hands thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS. For external use on cats only. Individual sensitivities may occur after using ANY pesticide product for cats. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Do not treat your cat with more than one pesticide product at a time. Over dosing your cat can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing cats.

**Side Effects**: Monitor your cat after application. [Some cats may experience temporary startle effects when any product is applied.] Cats 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 cat 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 cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your cat and continue to monitor your cat for the next 24 hours.

# **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 CAT, READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

#### **Restrictions:**

- DO NOT ALLOW CHILDREN TO APPLY PRODUCT.
- Do not use on animals other than cats.
- Do not allow your cat to ingest this product.
- Do not reapply for [[four] [4] weeks][30days].
- Do not use on kittens under 8 weeks of age. Do not apply to cats weighing less than [2] [5] [9] lbs.
- Weigh your cat to be sure you are applying the right dose formulated for the weight of your cat.
- Use entire contents of applicator on each cat. Do not split one applicator between two cats. Do not use multiple applicators on one cat.
- Separate the treated cat from all other cats and dogs for 24 hours after treatment has been applied.
- Do not have contact or allow children to have contact with the treated area until completely dry.
- Do not apply more than one applicator per treatment for one cat regardless of the cat's weight.

[The active ingredients in [Brand Name][this product] are imidacloprid and pyriproxyfen. This product is formulated to control fleas on cats. [[Brand Name][This product] kills fleas within 12 hours and prevents further flea infestations for [up to] [[4][four]weeks][1][one] month][30 days].]

# **How to Open:**

# [Clip. Part. Squeeze.]

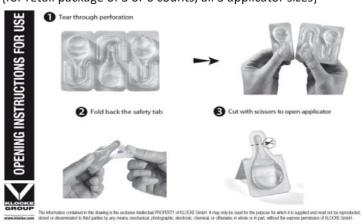
[Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting [Brand Name] where it needs to be.]

## [Application Instructions]

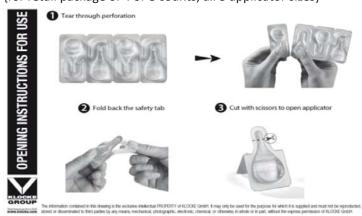
# for retail package of 1 count: for young for 0.078 fl oz (0.23 mL) and 0.014 fl oz (0.4mL) applicator size



# {for retail package of 3 or 6 counts, all 3 applicator sizes}



# {for retail package of 4 or 8 counts, all 3 applicator sizes}



[Apply entire content between shoulder blades]



#### How to Apply:

- 1. Hold cat with one hand and use the other hand to apply the solution.
- 2. Hold applicator facing away from you and your cat's eyes, invert the applicator and use the narrow end to part the cat's hair.
- 3. Squeeze applicator firmly to apply all of the solution [on] [to] the cat's skin as a spot between the shoulder blades.

## {For cartons containing 0.23 mL (0.0078 fl oz) applicators}

Only For Cats Weighing 2 [-][to] 5 lbs. Do not apply to Cats weighing less than 2 lbs, 8 weeks or older.

[including small cats or kittens, only 8 weeks or older] Apply one applicator 0.23 mL (0.0078 fl oz) directly to skin as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

## {For cartons containing 0.4 mL (0.014 fl oz) applicators}

Only For Cats Weighing 5 [-][to] 9 lbs. Do not apply to Cats weighing less than 5 lbs, 8 weeks or older.

[including small cats or kittens, only 8 weeks or older] Apply one applicator 0.4 mL (0.014 fl oz) directly to skin as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

# {For cartons containing 0.8 mL (0.027 fl oz) applicators}

Only For Cats Weighing Over 9 lbs. Do not apply to cats weighing less than 9 lbs. Do not use more than one applicator on cats greater than 9 lbs. Apply one applicator 0.8 mL (0.027 fl oz) directly to skin as a spot between the shoulder blades. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

## **FREQUENCY OF APPLICATION**

[Use [Brand Name {or} this product] monthly for control of flea[s] [infestations].]

[[Studies show that] [Brand Name {or} This product] kills fleas within 12 hours of application and [lasts {or} protects] for [up to] [[four][4] weeks][30 days][one month].]

[[Brand Name {or} This product] kills reinfesting fleas within [2][two] hours and prevents further infestations of fleas [for [up to] [[four][4] weeks][30 days][one month]].]

[[Brand Name {or} This product] [targets multiple flea life stages] [and] [kills flea eggs and larvae before they develop into biting adults].]

[[Brand Name][This product] breaks the flea life cycle by killing flea eggs, flea larvae, and adult fleas.] [Apply monthly for effective flea control.]

[[Brand Name {or} This product] is waterproof and remains effective, even after water immersion or exposure to sunlight [and][or] [rain]. Allow treated area to dry thoroughly before getting wet.] [Allow treated area to dry thoroughly.]

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. **STORAGE:** Do not remove applicator from pack until ready to use. Store in a cool (below 77°F[/][25°C]), dry place inaccessible to children and pets. Do not refrigerate. Protect from direct sunlight.

**PESTICIDE DISPOSAL AND CONTAINER HANDLING: Non-refillable container. If empty:** Do not reuse or refill this container. 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**

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. All such risks shall be assumed by the user or buyer. Tevra is committed to providing high quality products. To the extent consistent with applicable law, Tevra 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, 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.]

[If you have questions or comments about this product, please write: Tevra Brands Pet Owner Response, 9100 F St., Suite 200, Omaha, NE 68127 [Satisfaction Guaranteed.] [If you are not satisfied, we will make it right with a replacement or refund.]

In Case of Emergency, call: 1-800-775-9416 Non-Emergency, call: 1-844-276-3290 [Distributed by:] [Manufactured by:] Tevra Brands, LLC Omaha, Nebraska, 68127

# {END OF PACKAGE INSERT LABEL}

{Note to Reviewer: the icons below may appear on the label where the word "[icon]" appears}
Optional graphics that may appear anywhere on the label:









**{START – PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE OR INSERT OR REMINDER CARD OR CALENDAR STICKERS OR MAGNET}** 

[Clip. Part. Squeeze.]

[Easier-than-ever applicator lets you *clip* the tip, *part* the fur and *apply* directly to the skin – putting [Brand Name] where it needs to be.]

# [Application Instructions]

#### **How to Open:**

- 1. Remove product applicator[s] from the package.
- 2. Separate one applicator from the others. Hold the applicator with notched end pointing up and away from the face and body. Use scissors to cut off the narrow end at the notches along the line.

# How to Apply:

- 1. Hold cat with one hand and use the other hand to apply the solution.
- 2. Hold applicator facing away from you and your cat's eyes, invert the applicator and use the narrow end to part the cat's hair.
- 3. Squeeze applicator firmly to apply all of the solution [on] [to] the cat's skin as a spot between the shoulder blades.

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

- [1] Read the label completely and follow directions
- [2] Weigh your cat
- [3] Do NOT use this product on dogs
- [4] Do NOT treat with more than one pesticide product at a time
- [5] Separate the treated cat from all other animals after [treatment {or} application] to avoid chance of ingestion until product has dried
- [6] Do NOT split applicator between cats [and use the ENTIRE applicator contents]

## [Monthly reminder card]

[Brand Name][This product]

[Monthly reminder card]

[2][3][4][5][6][12][24][Month [Treatment] [Application] Tracker][Carecard]

[For year round protection apply [Brand Name][this product] monthly.]

[Cat's Name (Empty blank for owner to fill in name)]

[Cat's Weight (Empty blank for owner to fill in name)]

[First][1st] [Second][2nd] [Third][3rd] [Fourth][4<sup>th</sup>] [Fifth][5<sup>th</sup>] [Sixth][6<sup>th</sup>] [Seventh][7<sup>th</sup>]

[Eighth][8<sup>th</sup>] [Ninth][9<sup>th</sup>] [Tenth][10<sup>th</sup>] [Eleventh][11<sup>th</sup>] [Twelfth][12<sup>th</sup>]

[Dose] [Treatment] [Application](Empty blank for owner to fill in date)(Date: MM/DD/YY)]

[Application Date] [Date of Application]

# [Calendar stickers with Brand Name]

[Place stickers on your calendar as a reminder to reapply [Brand Name][this product] in 30 days.] [Monthly Application Reminder Magnet (image of reminder magnet)]

[Place sticker on your calendar [or refrigerator] to remind yourself to apply [Brand Name][this product] to your cat]

# [Magnet]

[Enclosed for your convenience is an application reminder magnet. Push the (reset) button, and the reminder light will blink twice. The reminder tag is now set for 30 days. At the end of 30 days, the reminder light will blink, reminding you to reapply [Brand Name][this product]. Press the button once and the blinking light will stop. Press the button again and this will reset the timer for another 30 days.]

# {END – PACKAGE COPY OR FOLDED PANEL/FLAP OF FRONT OF PACKAGE OR INSERT OR REMINDER CARD OR CALENDAR STICKERS OR MAGNET}

# [Flea Marketing Claims]

[Prevents further flea infestation for up to [[four][4] weeks][1 month] with [just] one treatment] [Prevents further flea infestation for up to [[four][4] weeks][1 month] with [just] one application]

[One treatment prevents further flea infestation for a month]

[Prevents flea re-infestations for 30 days [1 month]]

[For the prevention and treatment of Flea Infestations]

[[Brand Name] Prevents further flea infestation for [[four][4] weeks][1 month]]

[Kills fleas within 12 hours on cats [and prevents further infestations for up to [[4][four] weeks][[1][one][a] month]]

[Kills fleas within 12 hours [of application][on cats]]

[Kills reinfesting fleas within 2 hours]

[Kills [adult] fleas before they lay eggs]

[[Brand Name][This product] kills fleas and may reduce the incidence of a hypersensitivity skin disorder called flea allergy dermatitis (FAD), which may be caused by the feeding activity of fleas on cats]

[Apply monthly [for effective flea control]]

[Apply monthly [to control and prevent fleas]]

[Apply monthly treatments for optimal control and prevention of fleas]

[Kills fleas]

[Kill fleas within 12 hours, continues to kill for up to 4 weeks]

[Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation]

[Kills fleas, which may be a source of flea allergy dermatitis, within 12 hours]]

[Controls existing flea infestation by killing adult fleas]

[Active against fleas]

[Kills fleas on cats and kittens over 8 weeks [old][of age] and [2-5][ 5-9] [over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Kills fleas on cats weighing [2 to 5] [5 to 9] [over 9] lbs and over 8 weeks old {weight range dependent upon appropriate ml/fl oz package size}]

[(Begins/Starts) working through contact]

[[Brand Name] Offers protection against fleas]

[Flea control for cats [and kittens] over 8 weeks [old][of age] and [2-5][5-9][over 9] lbs[pounds]]

{weight range depends upon appropriate ml/fl oz package size}

[Once per month topical flea treatment for cats]

[Monthly topical flea treatment for cats]

[Once-a-month topical treatment for cats]

[Flea control for cats and kittens over 8 weeks [old][of age] and [2-5][5-9][over 9] lbs[pounds]]

{weight range depends upon appropriate ml/fl oz package size}

[Flea control for cats and kittens 8 weeks [of age] or older and [2-5][5-9] [over 9] lbs[pounds]]

{weight range depends upon appropriate ml/fl oz package size}

[[Once per month][Monthly] topical flea treatment for cats over 8 weeks [old][of age] and [2-5][5-

9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[[Once per month][Monthly] topical flea treatment for cats 8 weeks [of age] or older and [2-5] [5-

9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Once-a-month topical [treatment] [for] flea prevention and treatment for cats 8 weeks [of age] or older and [2-5][5-9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[[Brand Name][This product] is for the treatment and prevention of fleas on cats over 8 weeks [old][of age] and [2-5][5-9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[[Brand Name][This product] is for the treatment and prevention of fleas on cats 8 weeks [of age] or older and [2-5][5-9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Prevents and treats flea[s] [infestations]]

[Kills reinfesting fleas on cats within 2 hours]

[For the prevention and treatment of Flea Infestations]

[[Brand Name] Prevents further flea infestation for up to [[four][4] weeks]][[1][one][a] month]]

[Controls existing infestations by killing adult fleas for 30 days]

[Controls existing flea infestations on cats and protects against further infestations]

[Use [of Brand Name][of this product]] kills fleas which may cause flea bite hypersensitivity [and][or] [flea allergy dermatitis] [FAD]]

[Use [of Brand Name][of this product] kills fleas which may cause [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[Monthly treatment [with Brand Name][with this product] kills fleas which may cause [flea bite hypersensitivity] [and][or] flea allergy dermatitis [FAD]]

[May be used year-round for control of fleas]

# [IGR Marketing Claims]

[Prevents flea eggs from hatching]

[Prevents flea eggs from developing into [biting] adult fleas]

[Prevents the development of flea eggs into [biting] adult fleas]

[Prevents the development of flea larvae into [biting] adult fleas]

[Controls existing flea eggs]

[Kills flea eggs]

[[Brand Name][This product] contains Pyriproxyfen [PPF] [an insect growth regulator (IGR)] to kill flea eggs [and protect against reinfestation]]

[Targets multi-stages of the flea lifecycle]

[Controls multi-stages of flea lifecycle]

[[Brand Name][This product] is a flea ovicide, larvicide, and adulticide]

[Provides multi-stage flea control]

[Kills [flea eggs and] flea larvae]

[Breaks the flea life cycle]

[Prevents multi-stages of the flea life cycle from developing]

[Provides comprehensive flea prevention]

[Provides comprehensive flea control]

[[Brand Name][This product] inhibits the immature flea life stages (except pupae) from developing, preventing them from becoming [biting] adult[s] [fleas]]

[Controls existing flea eggs and fleas and prevents future infestations for 4 weeks [1 month] [30 days]]

[Monthly treatment controls existing flea eggs and fleas and prevents future infestations for 4 weeks [1 month] [30 days]]

## [COMBO Marketing Claims]

[2-way protection kills adult fleas and flea eggs]

[[2 –Way] Protection against adult fleas and flea eggs for up to 1 Month]

[3-way protection kills adult fleas, larvae and eggs][Kills flea eggs, larvae, and [adult] fleas]

[Kills [adult] fleas, [and] flea eggs, [and flea larvae]]

[Kills [adult] fleas, flea eggs and flea larvae for up to four [4] weeks][1 month]]

[Kills [adult] fleas, larvae, and eggs [, providing three-way protection]]

# All Other Marketing Claims]

[Apply to [cats and] kittens over 8 weeks old and [2-5][5-9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Apply to [cats and] kittens 8 weeks or older and [2-5][5-9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[[Formulated for] Cats and Kittens Over 8 Weeks [Old][of Age] and [2-5][5-9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[[Formulated for] Cats and Kittens 8 Weeks [of Age] or Older and [2-5][5-9][over 9] lbs[pounds]] {weight range depends upon appropriate ml/fl oz package size}

[Can be used on kittens over 8 weeks [old][of age] [or] 8 weeks [of age] or older and [2-5][5-9][over 9] lbs[pounds] {weight range depends upon appropriate ml/fl oz package size}

[Convenient] [Convenient, easy to apply topical solution]

[Easy application] [Easy to apply product]

[Easy to Use [Application]]

[One Step Hassle Free Protection!]

[Waterproof]

[Kills fleas even if your cat gets wet]

[Remains effective, even after [bathing,][shampooing,] water immersion, or exposure to [sunlight]

[and][or] rain]

[Fragrance[-]free]

[Once a month treatment]

[Apply once every [4 weeks] [month] [30 days]!] [4 Week Dose!] [1 Month Dose!] [30 Day Dose!]

[For year-round protection, apply [Brand Name][this product] monthly]

[One applicator][1 Month Supply][Three applicators][3 Month Supply][Four applicators][4 Month Supply][Six applicators][6 Month Supply][Eight applicators][8 Month Supply]

[Direct to skin applicators]
[Easy to Use applicators]
[No-mess [open] [applicators]]
[Clip-tip design applicators][!]]

# [Consumer Value Marketing Claims]

{Note to reviewer: If the coupon appears on the outside of the package, it will not obscure mandatory language}

[Coupon Inside]

[Save Now!]

[Club Pack - [8][6] Month Supply]

[Value Size]

[Club Size]

[Bonus Size]

[Club Pack]

[Great Value]

[Better Value]

[Bonus Pack]

[Bonus Buy]

[[1][4][6][8] pack]

[Twin Pack]

# [Try Now, Save Later!]

{Note to reviewer: Combinations will correspond to net contents. All applicators must be included inside the box/carton. Buying a larger pack reduces the price of the applicators therein due to economy of scale. No additional applicators are provided.}

[(x) + (x) bonus pack!]

[Buy more and save!]

[Buy X Get Y Free]

[Buy 3 get 1 free]

[(x)% (More) (Free)!]

[33% more free]

[(x) Dose(s) Free!]

[(x) Day(s) (Free)!]

[(x) Month(s) Free!]

[(x) Day(s) of treatment- Free!]

[(x) Tube(s) Free!]

[(x) Applicator(s) Free!]

[(x) Application(s) Free!]

[[New!] {only for use for 6 months from date of registration}

# [ABNs]

TevraPet Activate [Topicals] for Cats Vetality Activate Plus [Topicals] for Cats Tevrapet Activate II [Topicals] for Cats Vetality Avantect Plus [Topicals] for Cats Vetality Avantect II [Topicals] for Cats Vetality Avantect [Topicals] for Cats Vetality Advanced [Topicals] for Cats Evergreen II Spot on for Cats Avantect II for Cats **Activate Plus for Cats** Truveta for Cats ActiGuard for Cats ActiGuard II for Cats Tevrapet ActiGuard II for Cats Vetality ActiGuard II for Cats TevraPet Activate II [Topicals] for Cats Vetality Activate II [Topicals] for Cats Vetality Advanced II [Topicals] for Cats Vetality Avantect II [Topicals] for Cats Vetality Avantect Plus for Cats **Evergreen II Topicals for Cats** Activate II [Topicals] for Cats Activate Plus [Topicals] for Cats Tevrapet Avanta II [Topicals] for Cats Tevrapet Avenger II [Topicals] for Cats Tevrapet Advanced II [Topicals] for Cats Tevrapet Avante II [Topicals] for Cats Vetality Avanta II [Topicals] for Cats Vetality Avenger II [Topicals] for Cats Vetality Advanced II [Topicals] for Cats Vetality Avante II [Topicals] for Cats Vetality Avant II [Topicals] for Cats Vetality Aventect II [Topicals] For Cats Vetality Advocate II [Topicals] for Cats Avante II [Topicals] for Cats Avanta II [Topicals] for Cats Avenger II [Topicals] for Cats Avant II [Topicals] for Cats Aventect II [Topicals] for Cats Advocate II [Topicals] for Cats Tevrapet Advocate II [Topicals] for Cats Vetality Advocate II [Topicals] for Cats AventSpot II [Topicals] for Cats ActiSpot II [Topicals] for Cats Tevrapet ActiSpot II [Topicals] for Cats Tevrapet ACTISPOT II [Topicals] for Cats Advotect II [Topicals] for Cats Vetality Advotect II [Topicals] for Cats Tevrapet Advotect II [Topicals] for Cats