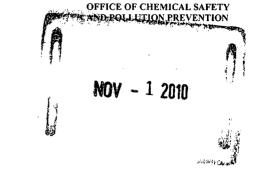
67505-3



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



ECTO Development Corporation 1229 Jesse James Road Excelsior Springs, MO 64024-1186

Dear Mr. Dyer:

Mr. Joseph E. Dyer

Subject: Amendment- me-too based on EPA Reg. Number 75844-8 Ecto Flea & Tick Insecticide with IGR EPA Registration Number 67505-3 Your submission dated September 27, 2010

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable with the following comments:

1. Wherever "Vector of LYME DISEASE" appears on the label change to ""which may carry Lyme disease'.

2. Update your label in accordance with PR Notice 2007-4 for Storage and Disposal.

A copy of a stamped label is enclosed for your records.

If you have any questions regarding this action, please contact Linda A. DeLuise of my team at (703) 305-5428.

Sincerely yours,

Juda A.D. L ...

Richard Gebken Product Manager (13) Insecticide Branch Registration Division (7504P)

Enclosure

ECTO FLEA & TICK INSECTICIDE WITH IGR [CAT ICON IN CIRCLE WITH SLASH THROUGH IT]
PLEASANT CITRUS SCENT FLEA & TICK CONTROL FOR DOGS AND PUPPIES OVER 12 WEEKS OF AGE BIO SPOT FLEA & TICK CONTROL FOR DOGS [15 lbs and Under] [Between 15 & 33 lbs] [Between 33 & 66 lbs] [66lbs & Over] DO NOT USE ON CATS ACCEPTED with COMMENTS
<ul> <li>BREAKS FLEA LIFE CYCLE!</li> <li>KILLS &amp; REPELS FLEAS UP TO 3 TO 4 WEEKS!</li> <li>KILLS &amp; REPELS FLEAS UP TO 3 TO 4 WEEKS!</li> <li>PREVENTS FLEA EGGS FROM DEVELOPING INTO BITING ADULTS FOR Underteice 123 DAVasecticide, semended, for the pesticide</li> <li>PROTECTS AGAINST BLOOD FEEDING BY MOSQUITOES (vector of History Moderney Revealed and the semended, for the pesticide</li> <li>KILLS &amp; REPELS TICKS FOR UP TO 4 WEEKS!</li> <li>KILLS &amp; REPELS DEER TICKS (vector of LYME DISEASE) FOR UP TO 4 WEEKS!</li> <li>KILLS &amp; REPELS BROWN DOG TICKS (Rhipicephalus sanguineus) FOR UP TO 3 TO 4 WEEKS!</li> <li>KILLS &amp; REPELS AMERICAN DOG TICKS (Dermacentor variabilis) FOR UP TO 3 TO 4</li> </ul>
<ul> <li>WEEKS!</li> <li>MONTHLY APPLICATION!</li> <li>MONTHLY FLEA, TICK AND MOSQUITO TREATMENT!</li> <li>KILLS AND REPELS FLEAS AND TICKS FOR UP TO A MONTH!</li> <li>KILLS AND REPELS ADULT FLEAS FOR UP TO 3 TO 4 WEEKS!</li> <li>KILLS FLEA EGGS AND LARVAE [FOR UP TO 4 MONTHS] [FOR 123 DAYS]</li> <li>KILLS AND REPELS TICKS FOR UP TO [4 WEEKS] [3 TO 4 WEEKS] INCLUDING DEER TICKS (vector of LYME DISEASE), BROWN DOG TICKS &amp; AMERICAN DOG TICKS!</li> <li>KILLS AND REPELS [ADULT FLEAS] FOR UP TO 3 TO 4 WEEKS!</li> </ul>
ACTIVE INCREDIENTS *Permethrin: (CAS #52645-53-1)
U.S. Patent No. 5,942,525 (Nylar**) is a Registered Trademark of McLaughlin Gormley King and Company KEEP OUT OF THE REACH OF CHILDREN DO NOT USE ON CATS CAUTION
SEE SIDE/BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
Net Contents: [0.03 fl. oz. (1 mL)][0.05 fl. oz.(1.5mL)][1 fl.oz (3.0 mL)] [4.5 mL] Applicator
EPA Reg. No.: 67505-3 EPA Est. No.:
Manufactured For: Ecto Development Corporation
Excelsior Springs, MO 64024Excelsion of the second sec

# SIDE/BACK PANEL FLEA & TICK INSECTICIDE WITH IGR

# READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS OVER 12 WEEKS OF AGE DO NOT USE ON CATS

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Hazards to Humans: Harmful if swallowed. Avoid contact with eyes or clothing. Causes moderate eye irritation. Wash thoroughly with soap and water after handling.

Hazards to Domestic Animals: FOR EXTERNAL USE ON DOGS ONLY. Do not use on puppies under 12 weeks of age. 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. DO NOT USE ON CATS or animals other than dogs. Cats which actively groom or engage in close physical contact with treated dogs may be at risk of serious harmful effect. Certain medications can interact with pesticides. It is advisable to consult a veterinarian before using this product with any other pesticide or drug.

FIRST AID									
<ul> <li>If Swallowed ° Call a poison control center or doctor immediately for treatment advice.</li> <li>Provide the system of the system of</li></ul>									
If In Eyes	<ul> <li>Hold eyes open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>								
HOT LINE NUMBER									
or doctor, or medical treat	Auct container or label with you when calling a poison control center c going for treatment. You may also contact 1-800-858-7378 for emergency ment information.								
Reactions in pruritis (itc at the applic after using A dog with a m	tions: Some animals may be sensitive to ingredients in this product. dogs may include skin sensitivity. Dogs may show, lethargy, increased hiness), erythema (redness), rash and hair discoloration or hair loss bation site. Observe the dog following treatment. Sensitivity from occur NY pesticide product on pets. If signs of sensitivity occur bathe your ild, non-insecticidal shampoo and rinse with large amounts of water. If e, consult a veterinarian immediately.								

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# SIDE/BACK PANEL ECIO FLEA & TICK INSECTICIDE WITH IGR

#### ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not add directly to water. Do not contaminate water when disposing of product or packaging.

### DIRECTIONS FOR USE

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

DO NOT USE ON CATS or animals other than dogs. May be toxic and potentially fatal if applied to or ingested by cats. Do not get this product in your dog's eyes or mouth. Repeat applications may be made if necessary, but do not apply more often than once every 3 weeks, except to reapply after shampooing the dog.

[For Dogs Weighing 15 lbs and Under: (1.0 mL applicator tubes) Apply one tube (1.0 mL) of product solution as a spot or stripe to the dog's back between the shoulder blades.]

[For Dogs Weighing Between 15 and 33 lbs: (1.5 mL applicator tubes) Apply one tube (1.5 mL) of product solution as a spot or stripe to the dog's back between the shoulder blades.]

[For Dogs Weighing Between 33 to 66 lbs: (1.5 mL applicator tubes) Apply one tube (1.5 mL) of product solution as a spot or stripe to the dog's back between the shoulder blades <u>and</u> apply a second tube (1.5 mL) as a spot or strip to the dog's back directly in front of the base of the tail.] OR

[(3 mL applicator tubes) Apply approximately half of the tube (1.5 mL) of product solution as a spot or stripe to the dog's back between the shoulder blades <u>and</u> apply the rest of the tube's contents (1.5 mL) as a spot or strip to the dog's back directly in front of the base of the tail.] OR

[(3 mL applicator tube) Apply the entire tube (3.0 mL) as a continuous stripe on the dog's back starting between the shoulder blades and ending directly in front of the base of the tail.]

[For Dogs Weighing 66 lbs and Over: (1.5mL applicator tubes) Apply one tube (1.5 mL) of product solution as a stripe to the dog's back between the shoulder blades and apply a second tube (1.5 mL) continuing the stripe down the center of the dog's back and apply a third tube (1.5 mL) to the dog's back directly in front of the base of the tail.] OR

[(4.5 mL applicator tubes) Apply approximately half of the tube (2.25 mL);  $\partial_{c} \partial_{c} \partial_{c}$  product solution as a spot or stripe to the dog's back between the shoulder blades and apply the rest of the tube's contents (2.25 mL) as a spot or strip to the dog's back directly in front of the base of the tail.] OR

[(4.5 mL applicator tube) Apply the entire tube (4.5 mL) as a gootinuous stripe on the dog's back starting between the shoulder blades and ending directly in front of the base of the tail.]

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### ECTO FLEA & TICK INSECTICIDE WITH IGR

### DIRECTIONS FOR USE (Continued)

### HOW TO APPLY:

FOR SARAN TUBES IN BLISTER CARD: Remove product tube from package. Holding tube with notched end pointing up and away from face and body, snap or cut off narrow end at notches. Invert tube over dog and use open end to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin. Wrap tube and put in trash.

FOR FLAT CARD (doubled) UNIT-DOSE PACKAGING: Separate cards along the perforated line. Holding separated card by its wide end with narrow end pointed up and away from face and body, cut along dotted line. Invert card over dog and use narrow end of the card to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin. Wrap card and put in trash.

FOR FLAT CARD UNIT DOSE PACKAGING: [For push pin type applicator] Remove one product tube from card. With cap end pointed up and away from face and body, depress cap to pierce tube end. Carefully remove cap, invert tube over dog, and with tube in close to dogs skin, squeeze tube to apply product. Wrap empty tube and put in trash.

FOR FOLDING CARD OR TABBED CARD UNIT-DOSE PACKAGING: Remove product tab by tearing along perforation. Holding tab with tube end pointed up and away from face and body, cut along dotted line. Invert tab over dog and use narrow end of card to part dog,s hair. Squeeze tube firmly to apply all of the solution to the dog's skin. Wrap tab and put in trash.

BLISTER CARD WITH TRI-LAYER TUBES: Remove product tube(s) from package. Fold along perforation between tubes and tear off one tube. {Return unused tubes to package.} Holding tube with notched end pointing up and away from face and body, snap off narrow end at notches. Invert tube over dog and use open end to part dog's hair. Squeeze tube firmly to apply all of the solution to the dog's skin. Wrap tube and put in trash.

FOR MULTI-DOSE PACKAGING: Withdraw 1.0 mL (1.5 mL) (3.0 mL) (4.5 mL) of solution at a time. Apply entire given dose directly to the skin at the indicated locations.

FOR DROPPER BOITLE MULTI-DOSE PACKAGING: Insert dropper tube into insecticide solution, squeeze bulb and then release to fill tube barrel to 1.0 mL (1.5 mL) (3.0 mL) (4.5 mL) line. Position dropper tube end in dog's hair next to skin and squeeze bulb to apply all of the solution to the dog's skin as indicated for dog's size.

FOR SALE TO VETERINARIANS ONLY

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### SIDE/BACK PANEL ECIO FLEA & TICK INSECTICIDE WITH IGR

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ECIO FLEA & TICK INSECTICIDE WITH IGR is an effective and easy to use product. This product has demonstrated greater than 92% control of fleas within one day of application. This product prevents eggs from fleas on treated dogs from developing into biting adults for up to [4 months] 123 days. As with all flea and tick control products, This product should be used as part of a program aimed at reducing flea populations in the dog's environment (bedding, carpets, kennel, yard). Consult your veterinarian, entomologist, or retailer for program recommendations.

# STORAGE AND DISPOSAL

**Storage:** Store in a cool dry place away from heat and open flame. Protect from freezing.

Disposal: Do Not Puncture or Incinerate! If empty: Place in Trash or offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions:

# NOTICE OF WARRANTY

ECTO DEVELOPMENT CORPORATION MAKES NO WARRANTY OF MERCHANIABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR OTHERWISE, EXPRESSED OR IMPLIED CONCERNING THIS PRODUCT OR ITS USES WHICH EXTEND BEYOND THE USE OF THE PRODUCT UNDER NORMAL CONDITIONS IN ACCORDANCE WITH THE STATEMENTS MADE ON THIS LABEL.

OR

Buyer assumes all responsibility for safety and use not in accordance with directions.

The use of any notice of warranty statement is optional.

ALTERNATE MARKETING CLAIMS BASED ON ME-TOO APPLICATION:

For use on Dogs and puppies over 12 weeks of age [Kills, repells and prevents re-infestation of fleas for up to 5 weeks] [Kills, repells and prevents re-infestation for fleas for up to 4 weeks] [Kills flea eggs and larvae for up to 8 weeks] [Kills flea eqqs and larvae for up to 6 weeks] [Kills flea eggs and larvae for up to 4 weeks] [Breaks the flea life cycle] [Kills, repels and prevents re-infestation of ticks for up to 6 weeks] [Kills, repels and prevents re-infestation of ticks for up to 4 weeks] [Kills, repels mosquitoes, lice and mites on dogs for up to 4 weeks] [Kills five different kinds of pests on dogs] [Kills 5 different kinds of pests on dogs] [Kills five different canine pests] 66.66 C C [Kills 5 different canine pests] ceee ι ιι ι ι ιίιι [Kills canine pests belonging to Five different orders] [Kills canine pests belonging to 5 different orders] ć [Seven in one Protection] [7 in 1 Protection] [Six in 1 Protection] ر د [6 in 1 Protection] cccc [Five in 1 Protection] ιιιι [5 in 1 Protection] . . . . . . . . . 67505-3 *ccc* cui Page 5 of 8

September 14, 2010 E03DL01C.DOC-5 ECIO FLEA & TICK INSECTICIDE WITH IGR

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PERMETHRIN 45% W/W PYRIPROXYFEN 5% W/W

# KEEP OUT OF THE REACH OF CHILDREN

DO NOT USE ON CATS OR [CAT ICON IN CIRCLE WITH SLASH THROUGH IT]

READ DIRECTIONS AND PRECAUTIONS BEFORE USING

EPA Reg. No. 67505-3

67505-3 Page 6 of 8 September 14, 2010 E03DL01C.DOC-6 TAB LABEL (folding card and tabbed card packaging designs)

# ECTO FLEA & TICK INSECTICIDE WITH IGR

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# ACTIVE INGREDIENTS

Permethrin:								
Pyriproxyfen	: (CAS	5 #95737-	68-1)	 	• • • • •	 • • • •	 	5.0%

\* cis/trans ratio: Max 55% (+) cis and min 45% (+) trans

KEEP OUT OF THE REACH OF CHILDREN

DO NOT USE ON CATS OR [CAT ICON IN CIRCLE WITH SLASH THROUGH IT]

# SEE MAIN LABEL FOR ADDITIONAL PRECAUTIONS AND INSTRUCTIONS FOR USE

EPA Reg. No. 67505-3

67505-3 Page 7 of 8 September 14, 2010 E03DL01C.DOC-7 OUTER BOX LABEL (Contains the following labeling plus full product label)

# ECTO FLEA & TICK INSECTICIDE WITH IGR

BIOLAR (NYLAR) inhibits development of the immature stages of the flea for up to 4 months preventing them from reaching the biting adult stage.

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(Nylar) Registered Trademark of McLaughlin Gormley King and Company

### PICTURE OF FLEA LIFE CYCLE HERE

As Part of a complete flea control program USE Bio Flea Halt! Outdoor Yard Spray Concentrate, and Bio Flea Halt! Carpet Powder or Carpet Spray with Biolar Insect Growth Regulator, along with on-animal flea & tick products.

### 4 STEPS FOR COMPLETE FLEA CONTROL

Step 1 - Shampoo or dip your dog

- Step 2 Treat indoor and outdoor premise with Bio Flea Halt! indoor and outdoor sprays, foggers and powders
- Step 3 Apply Bio Spot-On for up tp four weeks adult flea and tick control
- Step 4 Maintenance treatments with on-animal sprays and powders

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