,7505-3



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

01/11/2012

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Mr. Edward Lawrence Ecto Development Corporation 850 NW Pink Hill Road Blue Springs, MO 64015

JAN 1 1 2012

Dear Mr. Lawrence:

Subject: Amendment: Comply with Agency letter dated September 30, 2011, Change Product Name:
OLD NAME : Ecto Flea & Tick Insecticide with IGR
NEW NAME: Ecto Dog Flea & Tick Insecticide with IGR
EPA Reg. No. 67505-3
Your submissions dated November 14 and November 17, 2011 and
Your e-mail submission of January 11, 2012

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 3(c)(7)(a), is acceptable and a stamped copy of the label is enclosed for your records. The Agency's records will be updated to reflect the change in product name:

OLD NAME : Ecto Flea & Tick Insecticide with IGR NEW NAME: Ecto Dog Flea & Tick Insecticide with IGR

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on <u>nonrefillable</u> containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions regarding this letter, please contact Dana Pilitt, Ph.D. of my staff at (703) 305-7071 or via e-mail at <u>pilitt.dana@epa.gov</u>.

Sincerely,

1 Ceebk

Richard Gebken Product Manager 10 Insecticide Branch Registration Division (7505P)

# [FRONT PANEL] ECTO DOG FLEA AND TICK INSECTICIDE WITH IGR

# PLEASANT CITRUS SCENT FLEA AND TICK CONTROL FOR DOGS AND PUPPIES OVER 12 WEEKS OF AGE

### [Picture of dog in weight range]

[Use Only For Dogs between 5 to 15 lbs] [Use Only for Dogs between 15 & 33 lbs] [Use Only for Dogs between 33 & 66 lbs] [Use Only for Dogs over 66 lbs]

[Only 1 of above descriptions per package label]

### DO NOT USE ON CATS

BREAKS FLEA LIFE CYCLE!

KILLS AND REPELS FLEAS UP TO 3 TO 4 WEEKS!

- KILLS FLEA EGGS AND LARVAE FOR UP TO 123 DAYS!
- PREVENTS FLEA EGGS FROM DEVELOPING INTO BITING ADULTS FOR UP TO 123 DAYS!
- KILLS AND REPELS MOSQUITOES!
- PROTECTS AGAINST BLOOD FEEDING BY MOSQUITOES (vector of Heart Worm) UP TO 4 WEEKS!
- KILLS AND REPELS TICKS FOR UP TO 4 WEEKS!
- KILLS AND REPELS DEER TICKS (which may carry Lyme disease) FOR UP TO 4 WEEKS!
- KILLS AND REPELS BROWN DOG TICKS (Rhipicephalus sanquineus) FOR UP TO 3 TO 4 WEEKS!
- KILLS AND REPELS AMERICAN DOG TICKS (Dermacentor variabilis) FOR UP TO 3 TO 4 WEEKS!
- MONTHLY APPLICATION!
- MONTHLY FLEA, TICK AND MOSQUITO TREATMENT!
- KILLS AND REPELS FLEAS AND TICKS FOR UP TO A MONTH!
- KILLS AND REPELS ADULT FLEAS FOR UP TO 3 TO 4 WEEKS!
- KILLS FLEA EGGS AND LARVAE [FOR UP TO 4 MONTHS] [FOR 123 DAYS]
- KILLS AND REPELS TICKS FOR UP TO [4 WEEKS] [3 TO 4 WEEKS] INCLUDING DEER TICKS! (which may carry Lyme disease), BROWN DOG TICKS & AMERICAN DOG TICKS!
- KILLS AND REPELS [ADULT FLEAS] FOR UP TO 3 TO 4 WEEKS!

## ACTIVE INGREDIENTS

* Permethrin: (CAS #52645-53-1)	. 45.0 %
Pyriproxyfen: (CAS #95737-68-1) (Nylar**)	. 5.0 %
OTHER INGREDIENTS	. 50.0 %
TOTAL	100.0 %

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

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)] OR [0.05 fl. oz. (1.5mL)] OR [0.10 fl. oz. (3 mL)] OR [0.15 fl. oz. (4.5 mL)]

EPA Reg. No.: 67505-3

EPA: Est. No .:

Manufactured For: Ecto Development Corporation Blue Springs, MO 64015

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January 11, 2012]

No Cat Icon

(Cat with circle & bar across)

Minimum Size 1.5 x 1.5 cm

DO NOT USE ON CATS - MAY BE FATAL

["No Cat" Icon on front panel - lower right corner]



ACCEPTED

JAN 1 1 2012

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pertoide

Reg. No. 67505-3

# SIDE/BACK PANEL ECTO DOG FLEA AND 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. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately. 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		
If Swallowed	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>		
lf 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 advise.</li> </ul>	SIDE EFFECTS Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as	
	HOT LINE NUMBER	vomiting or diarrhea have	

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-XXX-XXXX for emergency medical treatment information.

Adverse Reactions: Some animals may be sensitive to ingredients in this product. Reactions in dogs may include skin sensitivity. Dogs may show lethargy, increased pruritus (itchiness), erythema (redness), rash and hair discoloration or hair loss at the application site. Observe the dog following treatment. Sensitivity may occur after using ANY pesticide product on pets. If signs of sensitivity occur bathe your dog with a mild, non-insecticidal shampoo and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately.

No Cat Icon (Cat with circle &

also been reported. If these or other side effects occur,

consult your veterinarian or

1-800- XXX-XXX

(Cat with circle & bar across) Minimum Size 1.5 x 1.5 cm

DO NOT USE ON CATS - MAY BE FATAL ["No Cat" Icon on back panel - lower right corner]

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## SIDE / BACK PANEL ECTO DOG FLEA AND 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 other 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 and do not allow the dog to ingest this product. 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.

[Use Only For Dogs Between 5 - 15 lbs: (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. Do not use on dogs less than 5 pounds.

[Use Only for Dogs Between 15 & 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.]

[Use Only for Dogs Between 33 & 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 (1.5mL) as a spot or stripe 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 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 stripe 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.]

[Use Only for Dogs Over 66 lbs: (1.5 mL 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 (1.5mL) continuing the stripe down the center of the dog's back and apply a third tube (1.5mL) to the dog's back directly in front of the base of the tail. DO NOT USE MORE THAT 3 TUBES REGUARDLESS OF DOG SIZE.] OR

[(4.5 mL applicator tubes) Apply approximately half of the tube (2.25 mL) of product solution as spot or stripe to the dog's back between the shoulder blades <u>and</u> apply the rest of the tube's contents (2.25 mL) as a spot or stripe to the dog's back directly in front of the base of the tail. DO NOT USE MORE THAN A 4.5 mL DOSE REGUARDLESS OF DOG SIZE.] **OR** 

[(4.5 mL applicator tubes) Apply the entire tube (4.5 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. DO NOT USE MORE THAN A 4.5 mL DOSE REGUARDLESS OF DOG SIZE.]

#### "No Cat Icon"

(Cat with circle & bar across) Minimum Size 1.5 x 1.5 cm

DO NOT USE ON CATS - MAY BE FATAL ["No Cat" Icon on back panel

lower right corner]

# SIDE / BACK PANEL ECTO DOG FLEA AND TICK INSECTICIDE WITH IGR

#### DIRECTIONS FOR USE (Continued)

### **HOW TO APPLY:**

**FOR TUBES IN BLISTER CARD:** Remove product tube from package. Holding tube with the 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 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 tube and put in trash.

**FOR FLAT CARD UNIT DOSE PACKAGING:** [For push pin type applicator] Remove one product tube from the 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, with tube close to dog's 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 the 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 1.0mL (1.5mL) (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 BOTTLE MULTI-DOSE PACKAGING:** Insert dropper tube into insecticide solution, squeeze bulb and then release to fill tube barrel to 1.0 mL (1.5mL) (3.0 mL) (4.5 mL) line. Position dropper tube end in the 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

"No Cat Icon"

(Cat with circle & bar across) Minimum Size 1.5 x 1.5 cm

DO NOT USE ON CATS - MAY BE FATAL ["No Cat" Icon on back panel - lower right corner]

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# SIDE / BACK PANEL ECTO DOG FLEA AND TICK INSECTICIDE WITH IGR

**ECTO DOG FLEA AND 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:** 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.

# NOTICE OF WARRANTY

**ECTO DEVELOPMENT CORPORATION** MAKES NO WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR OTHERWISE, EXPRESSED OR IMPLIED CONCERNING THIS PRODUCT OR ITS USES WHICH EXTEND BEYOND THE USE OF THIS 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 UPON ME-TOO APPLICATIONS

For use on Dogs and puppies over 12 weeks of age [Kills, repels, and prevents re-infestation of fleas for up to 5 weeks] [Kills, repels, and prevents re-infestation of fleas for up to 4 weeks] [Kills flea eggs and larvae for up to 8 weeks] [Kills flea eggs 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 5 different kinds of pests on dogs] [Kills five different kinds of pests on dogs] [Kills 5 different canine pests] [Kills five different canine pests] [Kills canine pests belonging to Five different orders] [Kills canine pests belonging to 5 different orders] [Seven in one Protection] [7 in 1 Protection] [Six in One Protection] [6 in 1 Protection] [Five in One Protection] [5 in 1 Protection]

"No Cat Icon"

(Cat with circle & bar across) Minimum Size 1.5 x 1.5 cm

DO NOT USE ON CATS - MAY BE FATAL ["No Cat" Icon on back panel - lower right corner] **TUBE LABEL** (folding card and flat card packaging designs)

# ECTO DOG FLEA AND TICK INSECTICIDE WITH IGR

## PERMETHRIN 45% W/W PYRIPROXYFENN 5% W/W

## KEEP OUT OF REACH OF CHILDREN

# [CAT ICON IN CIRCLE WITH SLASH THROUGH IT LOCATED ON TUBE ]

"No Cat Icon"

(Cat with circle & bar across) Minimum Size 1.5 x 1.5 cm

### DO NOT USE ON CATS - MAY BE FATAL

READ DIRECTIONS AND PRECAUTIONS BEFORE USING

[ONE OF THE FOLLOWING TEXTS PER TUBE OR VIAL - SEE ATTACHMENT A]

Only For Dogs 5 to 15 lbs. and over 12 weeks of age.

Only for Dogs 15 to 33 lbs, and over 12 weeks of age.

Only for Dogs 33 to 66 lbs. and over 12 weeks of age

Only for Dogs over 66 lbs. and over 12 weeks of age

> EPA Reg No. 67505-3 Lot No. 0000000

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# TAB LABEL (folding card and tabbed card packaging designs)

## ECTO DOG FLEA AND TICK INSECTICIDE WITH IGR

## ACTIVE INGREDIENTS

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

### KEEP OUT OF REACH OF CHILDREN

## [CAT ICON IN CIRCLE WITH SLASH THROUGH IT LOCATED ON TAB LABEL]

"No Cat Icon"

(Cat with circle & bar across) Minimum Size 1.5 x 1.5 cm

### DO NOT USE ON CATS - MAY BE FATAL

## SEE MAIN LABEL FOR ADDITIONAL PRECAUTIONS AND INSTRUCTIONS FOR USE.

#### [ONE OF THE FOLLOWING TEXTS PER TAB – SEE ATTACHMENT A]

Only For Dogs 5 to 15 lbs and over 12 weeks of age.

Only for Dogs 15 to 33 lbs and over 12 weeks of age.

Only for Dogs 33 to 66 lbs and over 12 weeks of age.

Only for Dogs over 66 lbs and over 12 weeks of age.

EPA Reg No. 67505-3 Lot No. 0000000

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OUTER BOX LABEL (Contains the following labeling plus full product label)

### ECTO DOG FLEA & TICK INSECTICIDE WITH IGR

NYLAR<sup>™</sup> inhibits development of the mature stages of the flea for up to 4 months preventing them from reaching the biting adult stage.

(Nylar) Registered Trademark of McLaughlin Gormley King and Company

## PICTURE OF THE FLEA LIFE CYCLE HERE

As part of a complete flea control program, use a suitable outdoor yard spray. Indoors use, a suitable carpet spray / powder and clean dog bedding and premises

## 4 STEPS FOR COMPLETE FLEA CONTROL

Step 1 – Shampoo or dip your dog.

- Step 2 Treat indoor and outdoor premises with indoor and outdoor sprays, foggers and powders.
- Step 3 Apply Ecto Dog Flea and Tick Insecticide with IGR for up to four weeks adult flea and tick control.

Step 4 – Maintenance treatments with on-animal sprays and powders.

# DO NOT USE ON CATS

"No Cat Icon"

(Cat with circle & bar across) Minimum Size 1.5 x 1.5 cm

DO NOT USE ON CATS - MAY BE FATAL

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# ATTACHMENT A

VIEW OF APPLICATOR VIAL / TUBE LABELING [OR IMMEDIATE CONTAINER LABELING]

Keep out of reach of Children

READ DIRECTIONS AND PRECAUTIONS BEFORE USING

Only For Dogs 5 to 15 lbs. and over 12 weeks of age.

> DO NOT USE ON CATS - MAY BE FATAL

"No Cat Icon"

(Cat with circle & bar across) Minimum Size

1.5 x1.5 cm

EPA Reg. No. 67505-3

[ONE OF THE FOLLOWING TEXTS PER VIAL / TUBE OR IMMEDIATE CONTAINER LABELING]

Only For Dogs 5 to 15 lbs. and over 12 weeks of age.

Only for Dogs 15 to 33 lbs. and over 12 weeks of age.

Only for Dogs 33 to 66 lbs. and over 12 weeks of age

Only for Dogs Over 66 lbs. and over 12 weeks of age

[67505-3

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