



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

November 9, 2010

Ms. Michelle Foster, Regulatory Affairs Specialist Virbac AH, Inc. 3200 Meacham Boulevard Fort Worth, TX 76137-4611

Subject:

Label Notification(s); Pesticide Registration Notification (PRN) 98-10

ZEMA IGR PREMISE SPRAY, EPA Reg. No. 2382-183

Your Submission Dated September 23, 2010

Dear Ms. Foster:

The Agency is in receipt of your application for Pesticide Notification under Pesticide Registration Notification (PRN) 98-10, dated September 23, 2010, for the referenced product. The Registration Division has conducted a review of this request for its applicability under PRN 98-10, and finds that the action(s) requested fall within the scope of PRN 98-10.

Please be reminded that 40 CFR §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 non-refillable containers. The code may appear either on the label (and can be added by non-Notification/PRN 98-10) or durably marked on the container itself.

The label submitted with this application has been time-stamped "Notification," and will be placed within the administrative file for this product. If you have any questions, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at <u>Rodia.Carmen@epa.gov</u>.

Sincerely yours

Richard J. Gebken Product Manager (10)

Insecticide Branch

Registration Division (7504P)

002382-00183 D441124

Plaase read instructions on	reverse before comple	ting form.	Form Appr	roved, OMB No. 2	070-0060	Print Form			
<b>\$EPA</b>	Environmenta	Inited States I Protection Agington, DC 20460	ency		Amendment		OPP Identifier Number		
Application for Pesticide - Section I									
1. Company/Product Number 2382-183			2. EPA Product Manager 3. I			Proposed Classification			
4. Company/Product (Name) Zema IGR Premise Spray			PMI			None Rest	ricted		
5. Name and Address of Ap Virbac AH, Inc. PO Box 162059 Fort Worth, TX 76161	oplicant <i>(Include ZIP Co</i> s is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No.  Product Name						
Section - II									
Amendment - Expla	n below. ponse to Agency letter	r deted	Final printed labels in response to Agency letter dated "Me Too" Application.			· · · · · · · · · · · · · · · · · · ·			
X Notification - Explain below.			Other - Exp	Other - Explain below.			DTIFICATION		
Explanation: Use additional page(s) if necessary. (For section I and Section II.) - NOV - 9 2010  For the purposes, content and attachments to this Notification refer to the Cover Letter dated September 23, 2010.									
Section - III									
1. Material This Product W	ill Be Packaged In:		`						
Child-Resistant Packaging  Yes  No  * Cartification must be submitted  Unit Packaging  Yes  No  If "Yes" Unit Packaging wgt.  No. per Unit Packaging wgt.			Water Soluble Packaging  Yes  No  If "Yes"  No. per Package wgt  Container		f Container  Metal Plastic Glass Paper Other (Specify)				
3. Location of Net Contents Information 4. Size(s) Ret			iteil Container 5. Location of Label Direct						
Label Container									
			tion - IV	······································					
1. Contact Point (Complet	e items directly below	for identification of ind	ividual to be contacted,	if necessary, to p	rocess this	applicacion.\$			
Name Michelle Foster			Title Regulatory Affairs Spec.  Telepho 682-64			ne No. (Include Area Code)			
-	ny knowingly false or i		On Il attachments thereto are true, accurate and complete. nent may be punishable by fine or imprisonment or			6. Date Application Repolved: ((Stamped)			
2. Signature  YOUR SOURCE  TO THE STATE OF T			itory Affairs Specialis	6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6	, , , , , , , , , , , , , , , , , , ,				
4. Typed Name Michelle Foster			5. Date 9123110			0 0 0 C C			



| Virbac Corporation

September 23, 2010

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

**ATTENTION: Linda Arrington** 

NOTIFICATION

NOV - 9 2010

Subject:

Notification of removal of 1-800-CLEANUP number

Dear Ms. Arrington:

According to the Label Review Manual, Chapter 13: Storage and Disposal; "use of a toll-free number or website is optional"; therefore, 1-800-CLEANUP has been removed from our labels. We understand notification is not required for such a change, but we wanted to maintain a record.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Enclosed are the following revised products labels.

Ecto-Soothe® 3X Flea and Tick Shampoo for Dogs and Cats, EPA Reg. No. 2382-117 FlyPel, EPA Reg. No. 2382-132 Zema IGR Premise Spray, EPA Reg. No. 2382-183 Preventic L.A. IGR, EPA Reg. No. 2382-124 Otomite® Plus, EPA Reg. No. 2382-116 Permethrin-Pyriproxyfen Residual Shampoo for Dogs #1, EPA Reg. No. 2382-155 Pet-Guard Gel Forte, EPA Reg. No. 2382-92 Pyre-sect Dip, EPA Reg. No. 2382-89 Yard Spray Concentrate, EPA Reg. No. 2382-122

One additional change was made to the Pyre-sect Dip label. This label was submitted on May 7 2009 in response to an MGK-326 RED reregistration deficiency letter. The word, 'Pesticide' was inadvertently left off and has been added before 'Storage' in the STORAGE AND DISPOSAL section to comply with the required verbiage in PR Notice 2007-4.

September 23, 2010

The contents and attachments to this notification include the following:

- 1) Cover Letter
- 2) Application for Pesticide Notification (EPA FORM 8570-1)
- 3) Revised Product Label with Changes Marked (one copy)
- 4) Revised Product Label (one copy)

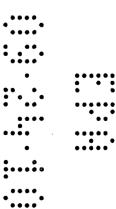
If there are any questions regarding this notification, please contact me at 682-647-3545 or via email at mfoster@virbacus.com.

Sincerely,

Michelle Foster

**Registration Specialist** 

**Enclosures** 



# FRONT PANEL

#### ZEMA IGR PREMISE SPRAY

# NOTIFICATION

NOV - 9 200

- ♦ PARASITOLOGY
- IGR, INSECT GROWTH REGULATOR
- ♦ KNOCKOUT AREA TREATMENT
- ♦ KILLS ADULT FLEAS AND TICKS AND CONTROLS PRE-ADULT FLEAS (LARVAE) FOR 120 DAYS
- ♦ KILLS ADULT AND PRE-ADULT FLEAS
- ♦ KILLS TICKS
- ♦ ONE TREATMENT GIVES CONTINUOUS FLEA PROTECTION FOR 120 DAYS
- ♦ WITH NYLAR® (PYRIPROXYFEN) INSECT GROWTH REGULATOR
- ♦ CONTAINS NYLAR®

### ACTIVE INGREDIENT:

¹Pyriproxyfen: CAS #95737-68-1	0.015%
Tetramethrin: CAS #7696-12-0	
Phenothrin: CAS #26002-80-2	0.300%
OTHER INGREDIENTS:	99.285%
TOTAL	100.000%

¹Nylar® is a registered trademark of McLaughlin Gormley King and Company.

## KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE SIDE/BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Net Weight: 16 fl. oz. (473 mL.)

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# SIDE/BACK PANEL

# READ ENTIRE LABEL BEFORE EACH USE PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

HAZARD TO HUMANS: Harmful if swallowed or absorbed through the skin. Avoid breathing spray mist or vapor. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Avoid contamination of feed and foodstuffs.

Do not use in commercial food processing, preparation, food storage or serving areas. In the home, all food processing surfaces and utensils should be covered during treatment, or thoroughly washed before use. Exposed food should be covered or removed.

Remove pets, birds, and cover fish aquariums before spraying.

### 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.
  - On not induce vomiting unless told to do so by a poison control center or doctor.
- ° Do not give anything by mouth to an unconscious person. \_\_\_\_\_

If On Skin or o Take off contaminated clothing.

Clothing

- $^{\circ}$  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 eyes.
- ° Call a poison control center or doctor for treatment advice.

If Inhaled

- Move person to fresh air.
- ° If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
- ° Call a poison control center or doctor for further 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 1-800-345-4735 for emergency medical treatment information.

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# SIDE/BACK PANEL

#### PHYSICAL AND CHEMICAL HAZARDS

Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. [PICTURE OF FLAME]

#### DIRECTIONS FOR USE

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

FOR INDOOR USE ONLY

ZEMA IGR Premise Spray kills fleas and ticks. This product contains a unique combination of ingredients that kills both adult and pre-adult fleas, and even kills fleas before they grow up to bite. NYLAR®, a unique ingredient in the flea spray, continues to kill fleas for 120 days (4 months) by preventing their development into the adult biting stage. It reaches fleas hidden in carpets, rugs, drapes, upholstery, pet bedding, and floor cracks. Protects your home from reinfestation and buildup. Protects your pets and family from bites. One treatment with this spray gives continuous flea protection for 120 days. Leaves no objectionable or sticky mess and when used as directed, does not stain furnishings.

FLEAS & TICKS: SHAKE WELL BEFORE EACH USE: Hold can 2 or 3 feet from surfaces to be treated. Be sure to apply uniformly using a sweeping motion to carpets, rugs, drapes and all surfaces of upholstered furniture. Be sure to treat pet bedding as this is a primary hiding place for fleas. No need to remove pet bedding after treatment.

DO NOT TREAT PETS: Use a registered flea control product on your pets in conjunction with this treatment. Repeat as necessary. Avoid wetting furniture and carpeting. A fine mist of spray applied uniformly is all that is necessary to kill fleas and ticks.

#### STORAGE AND DISPOSAL \_\_\_\_\_\_\_

Storage: Store in a cool dry place inaccessible to children and away from heat and open flame.

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 Deleted: or 1-800-CLEANUP disposal instructions.

EPA Reg. No.: 2382-183

EPA Est. No.: 47000-IA-1

Manufactured For Virbac AH, Inc. Consumer Brands Division Fort Worth, TX 76161

800-338-3659

(lot number statements as needed)

Mfg. & Printed in U.S.A. (label revision number) (product number)

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