

2382-184

4/24/2012

1 of 9



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Ms. Michelle Foster
Virbac AH, Inc.
P.O. Box 162059
Fort Worth, TX 76161

APR 24 2012

Dear Ms. Foster:

Subject: Application for Pesticide Notification (PRN 98-10)
Revise per PR Notice 2007-4
ZEMA IGR Total Release Fogger
EPA Reg. No. 2382-184
Your submission dated August 12, 2011

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated August 12, 2011 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds the action requested falls within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

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 non-refillable 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, PhD of my staff at (703) 305-7071 or via e-mail at pilitt.dana@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken".

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

2009

Please read instructions on reverse before completing form.

Form Approved. EPA No. 2070-0060

Print Form



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2382-184	2. EPA Product Manager <i>R. Gebken</i>	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Zema IGR Total Release Fogger	PM# <i>#10</i>	
5. Name and Address of Applicant (Include ZIP Code) Virbac AH, Inc. PO Box 162059 Fort Worth, TX 76161 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical to _____ and labeling to: NOTIFICATION EPA Reg. No. _____ APR 24 2012 Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

For the purposes, content and attachments to this Notification refer to the Cover Letter.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product			<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name <i>Michelle Foster</i>	Title Regulatory Specialist	Telephone No. (Include Area Code) 682-647-3545
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Michelle Foster</i>	3. Title Regulatory Specialist	
4. Typed Name Michelle Foster	5. Date <i>August 15, 2011</i>	



Virbac Corporation
August 12, 2011

Document Processing Desk
Office of Pesticide Programs (7508P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATTENTION: Linda Arrington, Notifications & Minor Formulations Team Leader

Subject: Notification of label change per PR NOTICE 2007-4
ZEMA IGR Total Release Fogger
EPA Reg. No. 2382-184

Dear Ms. Arrington,

In accordance with 40 CFR 152.46, Virbac AH, Inc. submits herewith an application for pesticide notification for subject product. This submission allows for labeling changes per PR Notice 2007-4 to the side/back panel of the label. The labeling changes are noted below and clearly marked on the revised product label (see attachment).

"Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for 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 the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, 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."

Revisions to side/back panel of the label in the "Storage and Disposal" section:

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

Added: Pesticide before Storage

Replace "Disposal" statement with the following:

- Pesticide Disposal and Container Handling: Nonrefillable container. Do not reuse or refill this container. If Empty: Place in trash or offer for recycling, if available.
- If Partly Filled: Call your local solid waste agency for disposal instructions. Never place any unused product down any indoor or outdoor drain."

This product is in compliance with 40 CFR 156.140(a)(4) as the lot number is adhered to the product. This product is exempt from 40 CFR 156.144 through 156.156 due to the product's residential/household use. Additionally, this product is not a dilutable (liquid or solid) formulation.

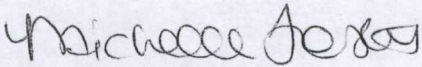
Ms. Linda Arrington
Page 2 of 2
August 12, 2011

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)

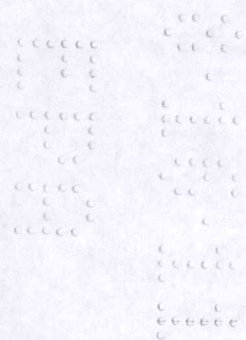
If there are any questions regarding this notification, please contact me at (682)647-3545 or via email at mfooster@virbacus.com.

Sincerely,



Michelle Foster
Regulatory Specialist

Enclosures



FRONT PANEL

ZEMA IGR TOTAL RELEASE FOGGER

- ◆ ZEMA, IGR
- ◆ WITH OR CONTAINS NYLAR^{®3}
- ◆ NYLAR^{®3} INSECT GROWTH REGULATOR
- ◆ TOTAL RELEASE FOGGER
- ◆ KILLS ADULT AND PRE-ADULT FLEAS, INCLUDING FLEA EGGS FOR 7 MONTHS
- ◆ PREVENTS REINFESTATION FOR 7 MONTHS
- ◆ ONE FOGGER (6 FL.OZ.) WILL TREAT A ROOM UP TO 27 FEET X 27 FEET WITH AN 8 FOOT CEILING

ACTIVE INGREDIENT:

³ Pyriproxyfen: CAS #95737-68-1.....	0.100%
Pyrethrins: CAS #8004-34-7.....	0.050%
¹ N-Octylbicycloheptene dicarboximide.....	0.400%
² Permethrin: CAS #52645-53-1	0.400%
Related Compounds	0.035%
OTHER INGREDIENTS:.....	99.015%
TOTAL.....	100.000%

¹ MGK[®] 264 Insecticide Synergist
² Cis/trans isomer ratio: Max. 55% (+/-) cis and Min. 45% (+/-) trans
³ NyLar[®] is a registered trademark of McLaughlin Gormley King and Company.

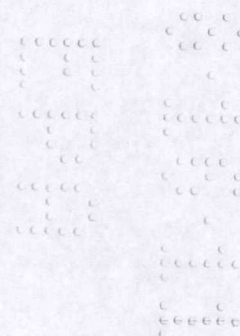
KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE SIDE/BACK PANEL FOR
ADDITIONAL PRECAUTIONARY STATEMENTS

Net Contents: 6 fl. oz. (170 gm.)

NOTIFICATION
APR 24 2012



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.



Highly Flammable Ingredient

Ingrediente Altamente Inflamable

IGR Total Release Fogger contains a combination of three insecticides that stops the flea life cycle in three ways and controls other insects. The first insecticide is pyriproxyfen (NYLAR®), an insect growth regulator that will not allow the flea to reproduce thereby providing long term control. The second insecticide is the botanical, Pyrethrin, which provides effective quick kill of insects upon direct contact and an added benefit of flushing the insects from their hiding place to aid in a more complete control. Permethrin, the third active insecticide, provides activity until the NYLAR® takes effect.

IGR Total Release Fogger contains a combination of ingredients that kill both adult and hatching fleas. NYLAR®, the Insect Growth Regulator in this fogger continues to kill hatching fleas for 7 months by preventing their development into adults. The fogger reaches fleas (and other insects) hidden in carpets, rugs, drapes, upholstery, pet bedding, floor cracks and open cabinets. Occasionally adult fleas may be present in treated areas when reintroduced from infested animals.

DIRECTIONS FOR USE

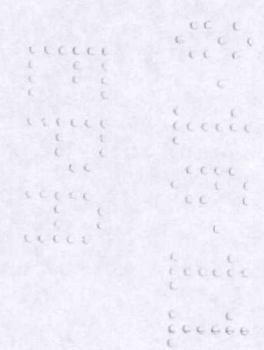
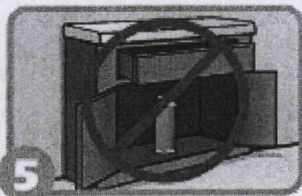
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Does not control bed bugs. (bold)

For use only when building has been vacated by human beings and pets. Ventilate treated area for 30 minutes before re-entry. For best results treat all infested areas. One fogger will treat a room up to 27 feet by 27 feet with an 8 foot ceiling. Use additional units for remote rooms or where the free flow of fog is not assured.

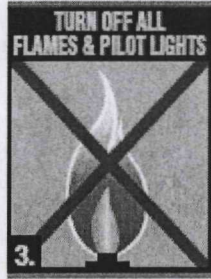
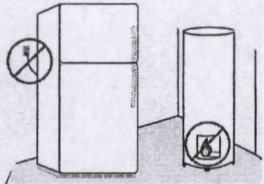
To Use This Product Correctly (bold): DO NOT use more than one fogger per room.



DO NOT use in small, enclosed spaces such as closets, cabinets or under counters or tables. Use of a fogger in an enclosed space may cause the product to explode, resulting in injury to people or damage to property.



Do not use in rooms 5 ft. x 5 ft. or smaller; instead, allow fog to enter from other rooms. Turn off ALL ignition sources such as pilot lights (shut off gas valves), other open flames or running electrical appliances that cycle off and on (i.e., refrigerators, thermostats, etc.).



Call your gas utility or management company if you need assistance with your pilot lights.

Before You Fog (bold): Remove or cover exposed food and drinking water before application. Remove or cover dishes, utensils, food processing equipment, and food preparation surfaces or wash them before use.

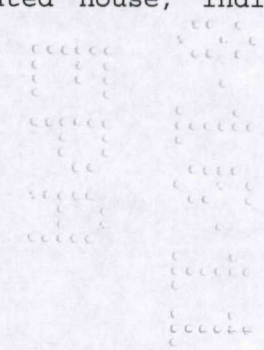


Shut off fans and air conditioners. Put out all flames and pilot lights. Close outside doors and windows. Remove pets and birds but leave pets bedding as this is a primary hiding place for fleas and must be treated for best results. No need to discard pet bedding after treatment. Cover or remove fish tanks and bowls. Leave rugs, drapes and upholstered furniture in place. This product will not harm furniture when used as directed. Open interior closet doors and cabinets or areas to be treated. Cover waxed furniture and wood floors in the immediate area surrounding the fogger.

For more effective control of storage pests and cockroaches open all cupboard doors and drawers for better penetration of fog. Remove all infested foodstuffs and dispose of in outdoor trash.

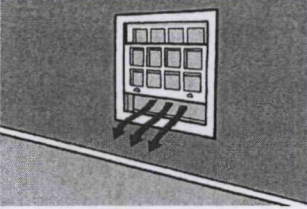
For flea and tick control, thoroughly vacuum all carpeting, upholstered furniture, along baseboards, under furniture and in closets. Put vacuum bag into a sack and dispose of in outside trash. Mop all hard floor surfaces.

READ ALL DIRECTIONS AND CAUTIONS BEFORE USING: TO START FOGGING, SHAKE FOGGER WELL BEFORE USING. Hold can at arms length with top of can pointing away from the face and eyes. Push down on finger pad until it locks. This will start fogging action. Set canister in an upright position on a table, stand, etc. (up to 30" in height in the center of the area) and place several thickness of newspaper under the canister to prevent marring of the surface. Treat the whole dwelling using multiple units in homes with more than one level and numerous rooms. Vacate the treated house, individual apartment unit, or other structure immediately.



9099

DO NOT RE-ENTER THE BUILDING FOR TWO HOURS. Airing Out:



Wait two (2) hours after application, then open windows, vents and doors for two hours. If an odor is still detected, additional ventilation is required. If additional units are used for remote rooms or where free flow of fog is not assured, increase airing-out time accordingly.

STORAGE AND DISPOSAL

Do not contaminate water, food, feed, by storage and disposal. Pesticide Storage: Store in a cool dry place inaccessible to children and away from heat and open flame. Store away from food and pet food. Pesticide Disposal and Container Handling: 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.

EPA Reg. No.: 2382-184

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)

DOOR KNOB HANG TAG

A FOGGER HAS BEEN USED ON THIS PREMISES

DO NOT ENTER UNTIL _____ ON _____

Directions for Door Knob Hang Tag: Fill out and place hang-tag on the door to the treated area to alert family and others with access to the treated area not to enter for X hours.

All label statements will include both English and Spanish text. Virbac AH, Inc. certifies that the Spanish language text will be a true and accurate translation of the English text.

Handwritten scribbles and marks in the bottom right corner.