

2382-184

12/27/2011

1/6



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

December 27, 2011

**Michelle Foster
Regulatory Specialist
Virbac AH, Inc.
P.O. Box 162059
Ft. Worth, TX 76161**

Subject: Label Amendment—Adding Agency-mandated mitigation for total release fogger products

Product Name: Zema IGR Total Release Fogger

EPA Reg. No.: 2382-184

Application Dated: September 15, 2011

Decision Numbers: 455922, 458943

Dear Ms. Foster:

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

1. Revise the Precautionary Statements on page 2 by deleting the statement marked with ~~strikethrough text~~, "Not for use in USDA Meat and Poultry Plants." This statement is redundant with the approved statement prohibiting use in food handling establishments and is otherwise not enforceable on its own.

A copy of the label stamped "accepted with comments" is enclosed for your records. You must submit two copies of the final printed label revised in accordance with the comments listed above before the product is released for shipment under this label. If you have any questions, you may contact Clayton Myers at (703) 347-8874 or myers.clayton@epa.gov.

Sincerely,

for Mark Suarez, Product Manager
Insecticide Branch
Registration Division (7505P)

Enclosure:
Stamped Label

2/6

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%
	<u>99.015%</u>

OTHER INGREDIENTS:	100.000%
TOTAL	

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.)

ACCEPTED
With COMMENTS
In EPA Letter Dated:
DEC 27 2011

Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:

2382-184

SIDE/BACK PANEL

READ ENTIRE LABEL BEFORE EACH USE

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
CAUTION

HAZARD TO HUMANS: Harmful if swallowed. Breathing spray mist may be harmful. 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.

~~Not for use in USDA Meat and Poultry Plants.~~

Do not use in food areas or food handling establishments, restaurants or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Serving areas are areas where prepared food is served such as dining rooms but excluding areas where foods may be prepared or held in the home. All food processing surfaces and utensils should be covered during treatment or thoroughly washed before use. Exposed foods should be covered or removed. Non-food areas are areas, such as, garbage rooms, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage (after canning or bottling). 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.
 - Do 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 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.
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- 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.
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- 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.

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.

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

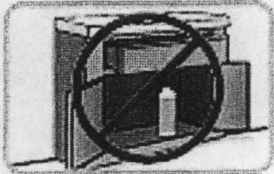
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Does not control bed bugs. (bold)

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.

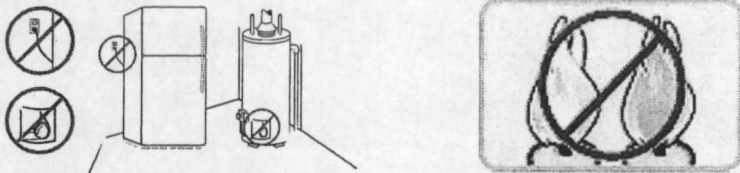
To Use This Product Correctly (bold): DO NOT use more than one fogger per room.



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.



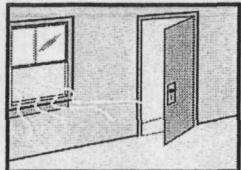
Shut off fans and air conditioners. Put out all flames and pilot lights. Close outside doors and windows. Remove pets and birds but leave pets bedding as this is a primary hiding place for fleas and must be treated for best results. No need to discard pet bedding after treatment. Cover or remove fish 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.

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.