



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

May 23, 2024

Karen VanLare
Senior Regulatory Manager
Virbac AH, Inc.
PO Box 162059
Fort Worth, TX 76161

Subject: Label Amendment - Registration Review Mitigation for Permethrin and
Pyriproxyfen
Product Name: Zema IGR Total Release Fogger
EPA Registration Number: 2382-184
Application Dates: 4/26/2021 and 5/16/2024
Decision Numbers: 573492 and 595867

Dear Karen VanLare:

The Agency, in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with the Permethrin and Pyriproxyfen Interim Decisions and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

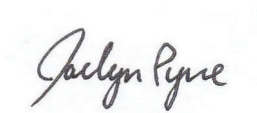
Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling and must be used at your next label printing. You must

submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 12 months from the date of this letter. After 12 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

If you have any questions about this letter, please contact Carolyn Smith by email at smith.carolyn@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Jaclyn Pyne". The signature is written in a cursive style with a large, stylized "J" and "P".

Jaclyn Pyne, Team Leader
Risk Management and Implementation Branch 3
Pesticide Re-Evaluation Division
Office of Pesticide Programs

ENCLOSURE: Stamped label

FRONT
PANEL

KNOCKOUT® (ZEMA) IGR TOTAL RELEASE FOGGER

- ◆ ZEMA IGR
- ◆ WITH OR CONTAINS NYLAR
- ◆ NYLAR (PYRIPROXYFEN) 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
- ◆ FOR INDOOR USE ONLY

For Residential Use

ACTIVE

INGREDIENTS

Pyriproxyfen	0.10%
Pyrethrins	0.05%
N Octyl bicycloheptene dicarboximide*	0.40%
Permethrin**	0.40%
	<u>99.05%</u>
OTHER	100.00%

OTHER

INGREDIENTS

TOTAL

* MGK 264 Insecticide Synergist

** C1s/trans isomer ratio Max 55% (±) cis and Min 45% (±) Trans

Nylar and MGK are registered trademarks of McLaughlin Gormley King Company.

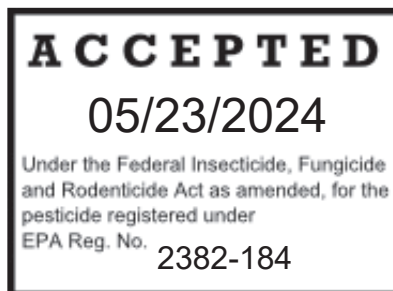
KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE SIDE/BACK PANEL FOR

ADDITIONAL PRECAUTIONARY STATEMENTS

Net Contents 6 oz. (170 g)



SIDE/BACK
PANEL

READ ENTIRE LABEL BEFORE EACH

**USE PRECAUTIONARY STATEMENTS
HAZARDS TO
HUMANS CAUTION**

HAZARD TO HUMANS Harmful If absorbed through skin. Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID

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.
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 Polson control center or doctor for treatment advice.
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 breathingcall 911 or an ambulancethen 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.

**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

Ingredient Altamente Inflammmable

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 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 Insect Growth Regulator takes effect.

IGR Total Release Fogger contains a combination of ingredients that kills both adult and hatching fleas. NYLAR Insect Growth Regulator 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, draperies, 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

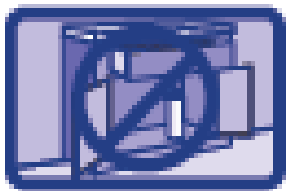
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Does not control bed bugs.

For use only when building has been vacated by human beings and pets. Ventilate treated Area for two (2) hours before reentry. 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 unit for remote rooms or where the free flow of fog is not assured.

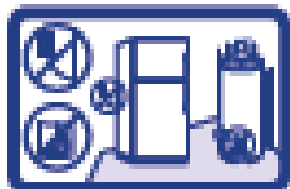


DO NOT use more than one fogger per room

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.



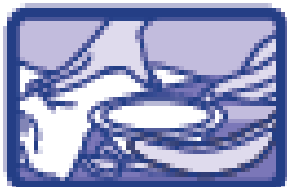
Do not use in a room 5 ft. X 5 ft. or smaller instead allow fog to enter from other rooms. Turn off ALL ignition sources such as pilot lights (shut off gas valves) other open flames or running electrical appliances that cycle off and on (i.e. refrigerators thermostats etc.).



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

Before You Fog Remove or cover exposed dishes, utensils, food surfaces or wash them before use.

Food and drinking water before application processing equipment and food preparation.



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 holding place for fleas and must be treated for best results. No need to discard pets bedding after treatment. Cover or remove fish tanks and bowls. Leave rugs draperies 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 arm s length with top of can pointing away from the face and eyes. Push down on finger pad until it locks. T h i s Will start fogging action. S e t canister in an upright position on a table, s t a n d , 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 HOME IMMEDIATELY**



Wait **two (2) hours** after application then open windows vents and doors for **two (2) Hour**. 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. Do not allow adults children or pets to enter until mist and aerosols have dispersed and the treated area has been thoroughly ventilated.

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STORAGE AND DISPOSAL

Do not contaminate water food or 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.

Do not allow the product to enter any indoor or outdoor drain during or after application. Call your local solid waste Agency for local disposal.

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EPA Reg No 2382 184

EPA Est No 47000 IA 1

Manufactured For
Virbac AH Inc
Fort Worth TX 76161
800- 338-3659

(lot number statements as needed)

(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.

April 26, 2021

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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.