

11-09-2010

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 PREVENTIC L.A. IGR, EPA Reg. No. 2382-124 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, nd leekk

Richard J. Gebken Product Manager (10) Insecticide Branch Registration Division (7504P)

002382-00124 D441123

					(N		100 NO 12
)	an muana hafam annaia		Form An	oround			Pr	int Foi	[]]] 255
\$epa	United EPA Environmental Pro Washington,		States Direction Agency		Registration Amendment X Other		OPP Identifier Number		
		Application for	Pesticide - Se	ction I					
. Company/Product Nu	mber		2. EPA Product Ma	enager	- 	3. Pr	oposed Cl	assifica	ation
2382-124			None					Restricte	
4. Company/Product (Name) Preventic L.A. IGR									
5, Name and Address o	f Applicant (Include ZIP Co	ode)	6. Expedited Re	eviëw.	In accordan	ce with	FIFRA S	ection	3(c)(3)
Virbac AH, Inc.			(b)(i), my product to:	t is simi	lar or identic	al in co	mpositio	n and	labeling
PO Box 162059 Fort Worth, TX 7616	51		EPA Reg. No.						
Check i	f this is a new address								
		Se	Product Name						
Amendment - Ex			l	tad labet	in fesponse	**			
	Agency is	etter date	d _		TIEIA				
	response to Agency letter	dated	"Me Too" Application.				NOTIFICATION		
Notification - Ex	plain below.		Other - E	xplain bel	iow.	NC)V - 9	2010	
	ditional page(s) if necessar			tter date	d Septembe	r 23, 20	10.		
		o this Notification re		ter date	d Septembe	r 23, 20	10.		
	ntent and attachments t	o this Notification re	fer to the Cover Let	ter date	d Septembe	r 23, 20	10.		
For the purposes, co	ntent and attachments t t Will Be Packaged in:	o this Notification re	fer to the Cover Let	ter date	d Septembe	Container			
For the purposes, co 1. Material This Produc Child-Resistent Packagi Yes*	ntent and attachments t R Will Be Packaged In: ing Unit Packaging Yes	o this Notification re	fer to the Cover Let Ction - III or Soluble Packaging Yes	ter date					
For the purposes, co	ntent and attachments t It Will Be Packaged in: ing Unit Packaging Yes No If "Yee"	to this Notification re	fer to the Cover Let Ction - III or Soluble Packaging Yes No			Container Metal Plastic Glass			
For the purposes, co 1. Material This Produc Child-Resistent Packagi Yes*	ntent and attachments t It Will Be Packaged in: ing Unit Packaging Yes No If "Yee"	o this Notification re Sec Wate No. per 11 "Y	fer to the Cover Let C tion - III Ir Soluble Packaging Yes No			Container Metal Plastic Glass Paper			
For the purposes, co 1. Material This Produc Child-Resistant Packagi Yes* No * Certification must	ntent and attachments t It Will Be Packaged In: ing Unit Packaging Yes No If "Yes" Unit Packaging wgt.	o this Notification re Sec Wate No. per 11 "Y	fer to the Cover Let ction - III or Soluble Packaging Yes No es" No. pe age wgt contair	n ner	2. Type of C	Container Metal Plastic Glass Paper Other (S	Specify)		
For the purposes, co 1. Material This Produc Child-Resistant Packagi Yes* No * Cartification must be submitted	ntent and attachments t It Will Be Packaged In: ing Unit Packaging Yes No If "Yes" Unit Packaging wgt.	o this Notification re Sec Wate No. per conteiner	fer to the Cover Let ction - III or Soluble Packaging Yes No es" No. pe age wgt contair	n ner	2. Type of C	Container Metal Plastic Glass Paper Other (S	Specify)	product	
For the purposes, co 1. Material This Produc Child-Resistant Packagi Ves* No Certification mus be submitted 3. Location of Net Cont Label	ntent and attachments t t Will Be Packaged In: ing Unit Packaging Yes No If "Yes" Unit Packaging wgt. ents Information	No. per container 4. Size(s) Retail Cont	fer to the Cover Let ction - III or Soluble Packaging Yes No es" No. pe age wgt contair l ainer	n ner	2. Type of C	Container Metal Plastic Glass Paper Other (S	Specify)	product	
For the purposes, co 1. Material This Produc Child-Resistant Packagi Ves* No Certification mus be submitted 3. Location of Net Cont Label	ntent and attachments t It Will Be Packaged In: Ing Unit Packaging Yes No If "Yes" Unit Packaging wgt. ents Information Container	No. per Container 4. Size(s) Retail Cont Lithograph Paper glued Stenciled	fer to the Cover Let ction - III or Soluble Packaging Yes No es" No. pe contair ainer Oth	fr mer 5. Loc	2. Type of C	Container Metal Plastic Glass Paper Other (S	Specify) ons npanying (
For the purposes, co 1. Material This Produc Child-Resistant Packagi Ves* No Certification mus be submitted 3. Location of Net Cont Label 6. Manner in Which Lat	ntent and attachments t It Will Be Packaged In: Ing Unit Packaging Yes No If "Yes" Unit Packaging wgt. ents Information Container	to this Notification re Sec No. per conteiner 4. Size(s) Retail Cont Lithograph Paper glued Stenciled Sec	fer to the Cover Let ction - III r Soluble Packaging Yes No es" No. pe age wgt contair ainer I ainer Other ction - IV	fr ner 5. Loc her	2. Type of C	Container Metal Plastic Glass Paper Other (S I Direction ng accon	Specify) ons npanying (
For the purposes, co 1. Material This Product Child-Resistant Packagi Yes* No * Certification mustication for the submitted 3. Location of Net Cont Label 6. Manner in Which Lat 1. Contact Point /Com	ntent and attachments t t Will Be Packaged In: ing Unit Packaging Yes No If "Yes" Unit Packaging wgt. ents Information Conteiner Del is Affixed to Product	No. per No. per conteiner 4. Size(s) Retail Cont Lithograph Paper glued Stenciled Sec for identification of ind	fer to the Cover Let ction - III or Soluble Packaging Yes No es" No. pe contair age wgt contair iner Ction - IV ividual to be contacter	fr ner 5. Loc her	2. Type of C	Container Metal Plastic Glass Paper Other (S I Direction ng accon cess this Felephon	Specify) ons npanying 	000 000 0/f.f	
For the purposes, co 1. Material This Product Child-Resistent Packagi Yes* No * Cartification mustication 3. Location of Net Continues 6. Manner in Which Late 1. Contact Point (Compared to the continues)	ntent and attachments t t Will Be Packaged In: ing Unit Packaging Yes No If "Yes" Unit Packaging wgt. ents Information Conteiner Del is Affixed to Product	No. per No. per conteiner 4. Size(s) Retail Cont Lithograph Paper glued Stenciled Sec for identification of ind	fer to the Cover Let ction - III r Soluble Packaging Yes No es" No. pe age wgt contair ainer I ainer Other ction - IV	fr ner 5. Loc her	2. Type of C	Container Metal Plastic Glass Paper Other (S I Direction og accon	Specify) ons npanying 	000 000 0/f.f	
For the purposes, co	ntent and attachments t A Will Be Packaged In: ing Unit Packaging Yes No If "Yes" Unit Packaging wgt. ents Information Conteiner Del is Affixed to Product plete items directly below for statements I have made on at any knowingly false or r	No. per Container 4. Size(s) Retail Cont Lithograph Paper glued Stenciled Sec for identification of ind Title Regula Certification this form and ell attace	fer to the Cover Let ction - III or Soluble Packaging Yes No es" No. pe age wgt contair l einer Ction - IV Twidual to be contacte atory Affairs Spec.	her	2. Type of C	Container Metal Plastic Glass Paper Other (S Direction ng accon cess this Felephon 682-647	Specify) ons npanying (e No. (Inc '-3545 c C Recei	<u>o o c</u> <u>o o c</u> <u>o c c</u> Audo A	rea Code c c ation ^{c c}
For the purposes, co	ntent and attachments t A Will Be Packaged In: ing Unit Packaging Yes No If "Yes" Unit Packaging wgt. ents Information Conteiner Del is Affixed to Product plete items directly below for statements I have made on at any knowingly false or r	No. per Container 4. Size(s) Retail Cont Lithograph Paper glued Stenciled Sec for identification of ind Title Regula Certification this form and ell attace	fer to the Cover Let ction - III or Soluble Packaging Yes No es" No. pe age wgt contair l einer Ction - IV Twidual to be contacte atory Affairs Spec.	her	2. Type of C	Container Metal Plastic Glass Paper Other (S Direction ng accon cess this Felephon 682-647	Specify) ons npanying e No. (Inc -3545 -3545 -3545 -3545 -3545 -3545 -3545 -3545 -3545 -3545 -3545 -3545 -3545 -3545 (1)	o c c o c c o c c o c c o c o c o	rea Code c c ation ^{c c} ed) ^{c c}
For the purposes, co	ntent and attachments t A Will Be Packaged In: ing Unit Packaging Yes No If "Yes" Unit Packaging wgt. ents Information Conteiner Del is Affixed to Product plete items directly below for statements I have made on at any knowingly false or r	No. per No. per container 4. Size(s) Retail Cont Lithograph Paper glued Stenciled Stenciled Certification of ind Title Regula Certification o this form and all attac misleading statement n 3. Title	fer to the Cover Let ction - III or Soluble Packaging Yes No es" No. pe age wgt contair l einer Ction - IV Twidual to be contacte atory Affairs Spec.	ner 5. Loc her nd, if necs	2. Type of C	Container Metal Plastic Glass Paper Other (S Direction ng accon cess this Felephon 682-647	Specify) ons npenying (e No. (Inc -3545 c c Recei c (c c c c c c c c c c c c c c c c c c		rea Code c c ation ^{c c}
For the purposes, co	ntent and attachments t A Will Be Packaged In: ing Unit Packaging Yes No If "Yes" Unit Packaging wgt. ents Information Conteiner Del is Affixed to Product plete items directly below for statements I have made on at any knowingly false or r	No. per No. per container 4. Size(s) Retail Cont Lithograph Paper glued Stenciled Stenciled Certification of ind Title Regula Certification o this form and all attac misleading statement n 3. Title	fer to the Cover Let ction - III r Soluble Packaging Yes No es" No. pe age wgt contair ainer Ction - IV ividual to be contacte atory Affairs Spec. chments thereto are to hay be punishable by	ner 5. Loc her nd, if necs	2. Type of C	Container Metal Plastic Glass Paper Other (S Direction ng accon cess this Felephon 682-647	Specify) ons npenying (e No. (Inc -3545 c c Recei c (c c c c c c c c c c c c c c c c c c	<u>ο ο ο ο</u> <u>ο</u> <u>ο</u> <u>ο</u> <u>ο</u> <u>ο</u> <u>ο</u> <u>ο</u> <u></u>	rea Code c e c stion ^{c c}

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

Yellow - Applicant Copy

27



NOTIFICATION

NOV - 9 2010

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

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.

Ms. Linda Arrington Page 2 of 2 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,

Michola Joster

Michelle Foster Registration Specialist

Enclosures

FRONT PANEL

PREVENTIC L.A. IGR

NOTIFICATION

NOV - 9 2010

RESIDUAL FLEA OVISTERILANT AND TICK KILLER SPRAY FOR DOGS
LONG ACTING FLEA & TICK SPRAY WITH NYLAR[©]² IGR FOR DOGS
QUICK ACTING/IMMEDIATE FLUSHING RESIDUAL FLEA & TICK SPRAY FOR DOGS
LONG ACTING FLEA & TICK SPRAY WITH PERMETHRIN AND PYRIPROXYFEN
KILLS FLEAS FOR 2 MONTHS
KILLS TICKS, INCLUDING LYME VECTORS, FOR 1 MONTH

 ${\rm IGR}\ {\rm STERILIZES}\ {\rm FLEAS}\ ({\rm KILLS}\ {\rm FLEA}\ {\rm EGGS})\ {\rm FOR}\ {\rm 3}\ {\rm MONTHS}$

ACTIVE INGREDIENT: 2.00% 'Permethrin: CAS #52645-53-1 2.00% Pyriproxyfen: CAS #95737-68-1 (NYLAR[®]2) 0.05% OTHER INGREDIENTS: 97.95% TOTAL. 100.00%

 1 cis/trans isomer ratio: Min 35% (+/-) cis and Max 65% (+/-) trans

² NYLAR is a Registered Trademark of McLaughlin Gormley King & Company

KEEP OUT OF REACH OF CHILDREN

λ.

CAUTION

SEE SIDE/BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Net Contents: 8 fl. oz. (237 mL) 16 fl. oz. (473 mL)

Page 1 of 3 September 23, 2010

. .

. .

SIDE/BACK PANEL

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS DO NOT USE ON CATS PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

HAZARD TO HUMANS: Caused moderate eye irritation. Avoid contact with eyes or clothing. Avoid breathing spray mist. Use only in a well ventilated area. Avoid contamination of food. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove contaminated clothing and wash before reuse.

HAZARDS TO ANIMALS:

. .

...

DO NOT USE ON CATS. DO NOT USE ON DOGS UNDER 6 MONTHS OF AGE. Do not spray in eyes, face or genitalia. Until dry do not confine treated dog in area without adequate cross ventilation.

Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant, or nursing animals.

Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap or a non-pesticidal shampoo and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

· ·	FIRST AID
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
==================	***************************************
or doctor, o	duct container or label with you when calling a poison control center or going for treatment. You may also contact 1-800-345-4735 for emergency tment information.
^	

PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame.

Page 2 of 3 September 23, 2010

с

С

SIDE/BACK PANEL

DIRECTIONS FOR USE

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

Spray over entire haircoat making sure the coat is thoroughly wetted to the skin. Spray against the lay of the hair, ruffling the coat on long-haired dogs. Weight of dog, length of hair, and density of coat will determine amount of spray to be applied to wet the skin (average dose approximately 7.5g/kg). Eight ounces (8 oz.) of product should be sufficient for two applications at a two month interval to an average 30-35 lb. dog. Lighter applications will reduce period of effectiveness and require more frequent treatments. Allow dog to air dry or blow dry. Do not towel dry. Do not spray in eyes, face or genitalia. Do not use on dogs under 12 weeks of age. Do not apply more often than once a month.

STORAGE AND DISPOSAL

Storage: Store in an area away from heat and open flame.

Disposal: If empty: Do not reuse 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.

EPA Reg. No.: 2382-124

. .

. •

EPA Est. No.: 67517-M0-1

Deleted: or 1-800-CLEANUP

Manufactured By Virbac AH, Inc. Fort Worth, TX 76161 800-338-3659

AVAILABLE THROUGH LICENSED VETERINARIANS ONLY

(lot number statements as needed) Mfg. & Printed in U.S.A. (label revision number) (product number)

Page 3 of 3 September 23, 2010

