

2382-132

10/18/2010

1/7



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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Ms. Michelle Foster  
Virabac AH, Inc.  
P.O. Box 162059  
Fort Worth, Texas 76161

OCT 18 2010

Subject: Label Notification(s) for Pesticide Registration Notice 98-10

Dear Ms. Foster:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated September 23, 2010 for the following product(s):

**Flypel**

**EPA Registration Number 2382-132**

The Registration Division (RD) has conducted a review of this request for applicability under PR Notice 98-10 and finds that the label change(s) requested falls within the scope of PRN 98-10. The label has been date-stamped "Notification" and will be placed in our records.

If you have any questions, please contact Linda A. DeLuise at 703-305-5428..

Sincerely,

A handwritten signature in cursive script, appearing to read "Linda A. DeLuise".

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

Print Form

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 2382-132	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Flypel	PM# 13	
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 in composition and labeling to: <b>NOTIFICATION</b> EPA Reg. No. _____ Product Name _____ OCT 8 2010	

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 dated September 23, 2010.

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	If "Yes" Unit Packaging wgt. No. per container		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		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 Michelle Foster	Title Regulatory Affairs Spec.	Telephone No. (Include Area Code) 682-647-3545
<b>Certification</b> 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 	3. Title Regulatory Affairs Specialist	
4. Typed Name Michelle Foster	5. Date 9/23/10	



*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**

Subject: Notification of removal of 1-800-CLEANUP number

Dear Ms. Arrington:

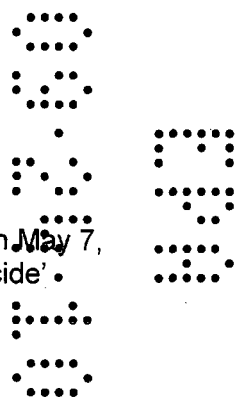
According to the Label Review Manual, Chapter 13: Storage and Disposal; "use of a toll-free number or website is optional"; therefore, 1-800-CLEANUP has been removed from our labels. We understand notification is not required for such a change, but we wanted to maintain a record.

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)

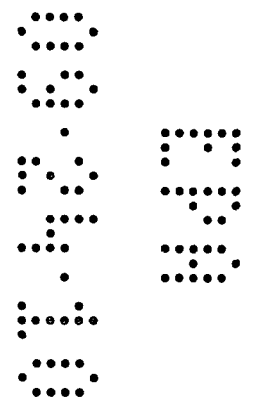
If there are any questions regarding this notification, please contact me at 682-647-3545 or via email at [mfooster@virbacus.com](mailto:mfooster@virbacus.com).

Sincerely,



Michelle Foster  
Registration Specialist

Enclosures



5/7

**FRONT PANEL**

**FLYPEL**

**INSECTICIDE SPRAY FOR HORSES  
DO NOT USE ON HORSES INTENDED TO BE SLAUGHTER FOR FOOD**

**NOTIFICATION  
OCT 18 2010**

- ◆ PROTECTS CONTINUOUSLY FOR HOURS AGAINST BITING AND NUISANCE INSECTS, TICKS, MOSQUITOES AND GNATS
- ◆ WITH SUNSCREEN AND SILICONE
- ◆ CONTAINS SUNSCREEN
- ◆ DRIES QUICKLY
- ◆ SILICONE CONFERS A HIGH GLOSS TO THE COAT

**ACTIVE INGREDIENT:**

*Permethrin: CAS #52645-53-1 .....	2.0%
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<b>OTHER INGREDIENTS:</b> .....	<u>98.0%</u>
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<b>TOTAL:</b> .....	100.0%
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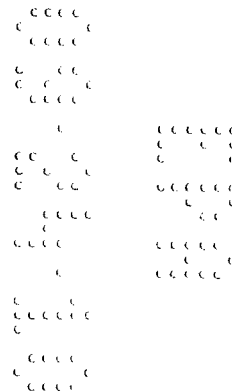
\* cis/trans isomer ratio: Min 35% (+/-) cis and Max 65% (+/-) trans

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**SEE SIDE/BACK PANEL FOR  
ADDITIONAL PRECAUTIONARY STATEMENTS**

**NET CONTENTS: 16 fl. oz. (473 mL.)**





SIDE/BACK PANEL

DIRECTIONS FOR USE

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

Do not use on horses intended to be slaughtered for food. Spray in well ventilated area. Spray areas of hide that are subject to attack by nuisance and biting flies. Wet hair thoroughly. Avoid spraying onto horse's face, eyes and genitalia. Control ticks by spraying around the ears and areas on which ticks attach. Repeat treatment as necessary.

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STORAGE AND DISPOSAL
=====

Storage: Store in original container in a cool dry 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.

Deleted: or 1-800-CLEANUP

EPA Reg. No.: 2382-132

EPA Est. No.: 67517-M0-1

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)