

2382-132

12/20/2011

1097



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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

DEC 20 2011

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

Dear Ms. Foster:

Subject: Application for Pesticide Notification (PRN 98-10)  
Revise per PR Notice 2007-4  
Flypel Insecticide Spray for Horses  
EPA Reg. No. 2382-132  
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](mailto:pilitt.dana@epa.gov).

Sincerely,

A handwritten signature in black ink that reads "Richard Gebken".

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



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<br>2382-132  | 2. EPA Product Manager<br>R. Gebken  | 3. Proposed Classification<br><input type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name)<br>Flypel  | PM#<br>#10   |   |
| 5. Name and Address of Applicant (Include ZIP Code)<br>Virbac AH, Inc.<br>PO Box 162059<br>Fort Worth, TX 76161<br><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:<br><b>NOTIFICATION</b><br>EPA Reg. No. <u>DEC 2 0 2011</u><br>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<br><input type="checkbox"/> Yes*<br><input type="checkbox"/> No   | Unit Packaging<br><input type="checkbox"/> Yes<br><input type="checkbox"/> No | Water Soluble Packaging<br><input type="checkbox"/> Yes<br><input type="checkbox"/> No |   | <input type="checkbox"/> Metal | <input type="checkbox"/> Plastic |
| * Certification must be submitted   | If "Yes" Unit Packaging wgt. No. per container                                | If "Yes" Package wgt. No. per container  |   | <input type="checkbox"/> Glass | <input type="checkbox"/> Paper   |
| 3. Location of Net Contents Information<br><input type="checkbox"/> Label <input type="checkbox"/> Container  |   | 4. Size(s) Retail Container  | 5. Location of Label Directions<br><input type="checkbox"/> On Label<br><input type="checkbox"/> On Labeling accompanying product |                                |                                  |
| 6. Manner in Which Label is Affixed to Product<br><input type="checkbox"/> Lithograph<br><input type="checkbox"/> Paper glued<br><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<br>Michelle Foster   | Title<br>Regulatory Specialist    | Telephone No. (Include Area Code)<br>682-647-3545 |
| Certification<br>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<br><br>(Stamped)     |
| 2. Signature<br>  | 3. Title<br>Regulatory Specialist |   |
| 4. Typed Name<br>Michelle Foster  | 5. Date<br>August 15, 2011        |   |



*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  
Flypel Insecticide Spray for Horses  
EPA Reg. No. 2382-132

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.

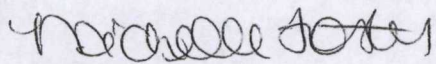
Ms. Linda Arrington  
Page 2 of 2  
August 12, 2011

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)

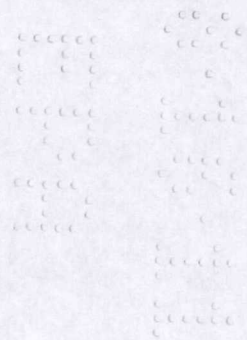
If there are any questions regarding this notification, please contact me at (682)647-3545 or via email at [mfooster@virbacus.com](mailto:mfooster@virbacus.com).

Sincerely,



Michelle Foster  
Regulatory Specialist

Enclosures





6007

SIDE/BACK PANEL

READ ENTIRE LABEL BEFORE EACH USE  
USE ONLY ON HORSES

PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
CAUTION

May cause eye irritation. Do not get in eyes, on skin or clothing. Avoid breathing spray mist. Avoid contamination of food or foodstuffs. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before reuse.

=====

FIRST AID

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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.

- 
- 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 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.

=====

HOT LINE NUMBER

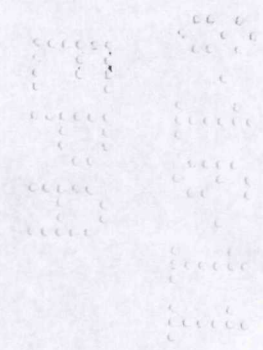
=====

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 HAZARDS

Do not use or store near heat or open flame.



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.

=====
STORAGE AND DISPOSAL
=====

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

Pesticide Storage: Store in original container in a cool dry area away from heat and open flame.

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 unused product down any indoor or outdoor drain.

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)

