



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:
2382-132

Date of Issuance:
MAY 28 1996

NOTICE OF PESTICIDE:
 Registration
 Reregistration

Term of Issuance:
Conditional

(under FIFRA, as amended)

Name of Pesticide Product:
FlyPel

Name and Address of Registrant (include ZIP Code):

Virbac Inc.
P.O. Box 162059
Fort Worth, Texas 76161

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the following label changes:

a. Revise the EPA Registration Number to read, "EPA Reg. No. 2382-132".

b. The flash points on the CSFs for the basic and alternate formulations should be corrected to "109°F" and "131°F" respectively to be consistent with the flammability data submitted in product chemistry data MRID No.437967-01. We note that the basic formulation contains a solvent which is a List 2 Potentially Toxic Inert with High Priority for Testing. The Agency encourages registrants to substitute other ingredients in place of the List 2 Inerts.

Signature of Approving Official:

Date:

c. In reference to the label:

i. The chemical name for Permethrin should be corrected as follows: (3-Phenoxyphenyl)methyl (±) cis-trans-3-(2,2-dichloroethyl)-2,2-dimethylcyclopropanecarboxylate; both on the ingredient statement on the label as well as on page 5 of the product chemistry data. The cis/trans isomer ratio in the report should be corrected to be consistent with the label and the upper and lower certified limits for Permethrin should be corrected to 2.1% and 1.9% respectively to be consistent with the CSF.

ii. Add the following sub-heading and statement under "Precautionary Statements"

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

iii. The "Description of Formulation Process" mentions the use of a fragrance in the formulation (stated in Confidential Appendix A). However, no fragrance is used in the basic or alternate formulations. Please comment.

iv. Please provide sample GC curves with supporting calculations which shows that the product contains 2.0% Permethrin.

It is noted that the Efficacy Data (MRID No. 437967-02) are adequate to support the claim for effectiveness in repelling flies in stalled and pasture environments when the product is applied as a fine spray mist to horses so as to cover areas of hide that are subject to attack by nuisance and biting flies or to thoroughly wet hair.

3. Submit two copies of the revised final printed label for the record. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

- A stamped copy of the label is enclosed for your records.

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virbac®

FLYPEL™

Insecticide Spray for Horses

**Protects continuously for hours
against biting and nuisance
insects, ticks, mosquitoes and
gnats
With Sunscreen and Silicone**

ACTIVE INGREDIENT:

Permethrin: [(3-phenoxyphenyl) methyl (+/-) cis-trans-3-(2,2-dichloroethenyl) 2,2-dimethylcyclopropane-carboxylate]*..	2.0%
INERT INGREDIENTS.....	98.0%
TOTAL.....	100.0%

*cis-trans isomer ratio: Min. 35% (+/-) cis
Max. 65% (+/-) trans

CAUTION

KEEP OUT OF REACH OF CHILDREN

See back panel for additional precautionary statements and directions

Net Contents: 16 fl. oz. (474 mL)

FLYPEL™ insecticide Spray provides hours of continuing protection from biting and nuisance insects, ticks, mosquitoes and gnats. Contains sunscreen. Dries quickly. Silicone confers a high gloss to the coat.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labelling.

SHAKE WELL. Spray in a 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 and eyes, treating these areas by wiping with a spray-moistened cloth or sponge. Control ticks by spraying around the ears and areas on which ticks attach. Do not apply to horses to be used for food. Repeat treatment as necessary.

PRECAUTIONARY STATEMENT HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

HAZARDS TO HUMANS: May cause eye irritation. Do not get in eyes or on skin or clothing. Avoid breathing spray mist. Avoid contamination of food. Wash hands after using. Remove contaminated clothing and wash before reuse. Do not use on horses intended to be slaughtered for food.

STATEMENT OF PRACTICAL TREATMENT

If in Eyes: Flush with plenty of water. Call a physician if irritation persists.

STORAGE AND DISPOSAL

STORAGE: Store in a cool dry area, away from heat and open flame

DISPOSAL: Do not reuse empty container. Wrap in several layers of newspaper and discard in trash.

EPA Reg. No. 2382- EPA Est. No. 2382-IN-1

Virbac Inc.,
P. O. Box 162059, Fort Worth, TX 76161

Lot no. on bottom of container 95/08

ACCEPTED
with COMMENTS
Re EPA Letter Dated

MAY 28 1996

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2382-132

