

PAU 13 41-378 21 93

Vectec, Inc.
% Mr. H.R. McLane
H.R. McLane, Inc.
7210 Red Road, Suite 212A
Miami, FL 33143

Dear Mr. McLane:

Subject: Amendments: Dermal sensitization study and label statement; lower minimum amount of active ingredient and additional brand names
FLAK 10-10
EPA Registration No. 42737-6
Your Submission Dated
FLAK 4-4
EPA Registration No. 42737-8
FLAK 2-2 RTU
EPA Registration No. 42737-9
Your Submissions Dated October 26, 1995 and September 29, 1995

This amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(a), is acceptable, provided that you:

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

2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

a. Under "thermal aerosol fogging" we recommend adding the typical dilution rate for thermal fog oil.

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b. The submitted dermal sensitization study (81-6, MRID 43832701) on Flak 10-10 was submitted to supplement a previously rejected study, due to unacceptable re-challenge and positive control sensitization. The submitted data indicated that Flak 10-10 is a mild contact sensitizer. The study is acceptable. There is no change to the signal word. Due to the sensitization property of Flak 10-10, the product label should contain a precautionary statement to warn applicators about the possibility of allergic skin reaction upon repeated or prolonged contact. The statement provided on the submitted label, "May cause contact sensitization following repeated contact with skin in susceptible individuals" is adequate. A copy of the Precautionary Label review is enclosed for your information.

c. The additional brand names; "Skeetermist 10-10", "Skeetermist 4-4", and "Skeetermist 2-2" are acceptable.

With respect to your comment about data support and compensation and use of Vectec data we refer you to CFR 40 Sections 152.80 thru 152.99. Provided an applicant submits an appropriate offer to pay compensation statement under the cite-all or selective methods of support or a combination of these two methods the Agency can approve and register the product without written permission from the data submitter. The Agency is obligated to notify a data submitter prior to approving a registration only when dealing with exclusive use data. Permethrin and PBO are not exclusive use pesticides. Also we bring your attention to CFR section 152.94 regarding citation of published literature studies.

With respect to Vectec, Inc. being listed as a data submitter you can verify this through John Jamula (703-305-6426) of the Program Management and Support Division of EPA.

3. Submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the labels are enclosed for your records.

Sincerely,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosure

BEST AVAILABLE COPY

FLAK® 4-4

For Application only by Public Health Official and Trained Personnel of Mosquito Abatement Districts and Programs. An All Temperature, Quick knockdown, Low Odor, Non-Corrosive Synergized Synthetic Pyrethroid Adult Mosquitoes in Residential And Recreational Areas. Also for Use Against Biting and Non-Biting Mosquitoes.



Contains 0.3344 lbs. A.I. Permethrin / gallon and 0.3344 lbs. A.I. Piperonyl Butoxide / gallon.

ACTIVE INGREDIENTS:

Permethrin (3-phenoxyphenyl)methyl(+/-) cis/trans 3-(2,2-dichloroethenyl) 2,2-dimethyl cyclopropanecarboxylate - - - - 4.0%
 Piperonyl Butoxide Technical Equivalent to 80% (butylcarbityl) (6-propylpiperonyl)ether and 20% related compounds- - - - 4.0%

INERT INGREDIENTS:

* Contains a Petroleum Distillate Solvent. Total 100.0%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

**VECT
6984 VEN
ORLAND**

**FLAK® is a Regi
Vec
Net Center**

EPA Reg. No. 42737-8

PRECAUCION AL USUARIO: Si usted no lee ingles, no use este producto hasta que la etiqueta haya sido explicado ampliamente

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or Poison Control Center immediately. Do not induce vomiting because of aspiration hazard. IF INHALED: Remove victim to fresh air. If not breathing give artificial respiration. IF IN EYES: Flush eyes with plenty of water. Get medical attention if irritation persists. IF ON SKIN: Remove contaminated clothing and wash affected area with soap and water. Get medical attention if irritation persists. NOTE TO PHYSICIAN: *Solvent presents an aspiration hazard. Gastric lavage is indicated if material was taken internally. Vomiting may cause aspiration pneumonia.

SEE BELOW FOR ADDITIONAL PRECAUTIONARY STATEMENTS

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing vapors or spray mist. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after using and before eating or smoking. Avoid contamination of food and feed. May cause contact sensitization following repeated contact with skin in susceptible individuals.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish and aquatic invertebrates. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply when weather conditions favor drift from treated areas. Drift and runoff from treated sites may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwaters. This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.

PHYSICAL AND CHEMICAL HAZARDS

Do not use, pour, spill or store near heat or open flame.

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

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. **STORAGE:** Store product in its original labeled container in a cool, dry, locked place designated for such insecticides and out of reach of children. Avoid exposure to extreme temperatures. In case of spillage, soak up with absorbent material such as sawdust, or fuller's earth, sweep up and place in labeled container and dispose of as follows. **PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **CONTAINER DISPOSAL:** (Metal) Triple rinse or equivalent. Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or by other approved state and local procedures. (Plastic) Triple rinse or equivalent. Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

THERMAL AEROSOL FOGGING

TRUCK MOUNTED: Apply diluted with Thermal Fog Oil and suitable Thermal Fogging equipment. Use at the recommended rates of 0.001 to 0.007 pounds of Permethrin per acre and the same amount, 0.001 to 0.007 pounds of the synergist Piperonyl Butoxide per acre. Use higher flow rate in heavy vegetation or when insect populations are high. Do not exceed the maximum rates. May be applied at speeds of 5 m p h. up to 20 m p h. To reduce oil requirement and sludge buildup in equipment, use 100 second viscosity mineral fog oil. For use with hand carried and/or lawn mower foggers, use same rates of A.I. per acre. Do not wet foliage since certain oil base formulations may be phytotoxic. Do not fog when wind conditions exceed 3 miles per hour. Use clean, well maintained and properly calibrated fogger. Fog Down wind.

AS A BARRIER SPRAY USE A "BACKPACK" ULV UNIT

For use in non thermal ULV portable backpack equipment apply FLAK® 4-4 with equipment adjusted to deliver ULV particles of 50 to 100 microns mass median diameter. Use 38.3 fl. oz. of the undiluted spray per acre (equal to 0.1 lb. A.I. per acre) as a 50 ft (15.2 m) swath while walking at a speed of 2 m p h. (3.2 k p h.) May also be applied diluted; make sure that the same amount of A.I. (0.1 lb.) is applied per acre.

NON-THERMAL AEROSOL (U.L.V.)

FLAK® 4-4 is recommended for application as an ultra low volume (U.L.V.) non thermal aerosol in residential and recreational areas where these insects are a problem. Do not apply this product within 100 feet of campsites, woodlands, athletic fields, golf courses, residential areas, and recreational areas and overgrown waste areas. Do not allow spray treatment to drift on pastureland, cropland, poultry ranges, or other areas where mosquitoes are most active and weather conditions are conducive to keep temperatures and wind speed not greater than 10 m p h. Applications during cooler weather conditions are preferable. Repeat treatment as needed.

FLAK® 4-4 U.L.V. Non-Thermal Aerosol (Cold Fog) Applications: To control Mosquitoes in residential and recreational areas use FLAK® 4-4 using any standard U.L.V. ground applicator with an accurate flow meter or flow rate indicator. Apply the product at the rate of producing a non-thermal aerosol spray with droplets ranging in size from 5 to 10 microns (MMD) of 10 to 20 microns using a spread factor of 0.85. Apply the product under conditions of 10 m p h. with a swath width of 300 feet. Use higher flow rate in heavy vegetation or when populations are high.

NON-THERMAL AEROSOL CONDITIONS AND RATES TO CONTROL MOSQUITOES

Permethrin/PBO lbs. A.I./Acre	Application Rates - Fluid Ounces	
	5 mph	10 mph
0.007 / 0.007	8.1	6.3
0.0035 / 0.0035	4.0	8.1
0.00175 / 0.00175	2.5	4.1
0.001 / 0.001	1.1	2.3

AERIAL APPLICATION

The use of specially designed aircraft capable of applying ULTRA LOW VOLUME (U.L.V.) sprays may be considered necessary when conducted at the discretion of Public Health Officials and other trained personnel engaged in OUTDOOR Mosquito & Biting Insect Control Programs. This use is specifically authorized by the Bureau of Entomology, Florida Department of Agriculture. **PROHIBITION ON AERIAL USE:** This use is specifically authorized by the Bureau of Entomology, Florida Department of Agriculture.

NOTICE: Buyer and user assume all risk and liability of use, storage and/or handling of this product with the terms of this label. (42-8AMD PM5EPA accepted 04-11-81)

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