

FEB 18 1992

305/5392907

17/11

Mr. Jan Brill
Regulatory Manager
Fairfield American Corporation
809 Harrison Street
Frenchtown, NJ 08825

Dear Mr. Brill:

Subject: Label Amendment - Claims Against Ticks Which May Carry Lyme Disease
Revision of Precautionary Statements
Permanone General Purpose Aqueous Insecticide
EPA Registration No. 4816-696
Permanone General Purpose Aqueous Insecticide II
EPA Registration No. 4816-709
Your Submission Dated April 16, 1991

The recommendations stated below are exclusively for Permanone General Purpose Aqueous Insecticide II, EPA Registration No. 4816-709, except for Item 2.e., which also applies to Permanone General Purpose Aqueous Insecticide, EPA Registration No. 4816-696.

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable provided that you:

1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) or 4(a) 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 the heading "Indoor Application" add the word "feed" to site currently designated as food i.e., . . . Do not use in food/feed areas of food/feed handling establishments etc.

R:63202:C-44:WP5.0-09:Moats:KEVRIC:02/06/92:03/06/92:aw:wo:aw
R:63204:C-44:WP5.0-09:Moats:KEVRIC:02/10/92:03/10/92:aw

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

- b. Food/feed processing plants can imply use in U.S. Department of Agriculture (USDA) Meat and Poultry Plants. Therefore, either add the statement "Not for Use in USDA Meat and Poultry Plants" or submit an application requesting use in these areas. If granted, you can then indicate on the label that the product can be used in these areas. This comment was brought to your attention in our last letter.
- c. Under "Environmental Hazards" change the second sentence to read as follows:

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the high water mark.

- d. On the top of the front label, relocate and revise the statement Recommended for Commercial Agricultural Use to read:

For Commercial Agricultural Use Only

- e. Under the heading "dogs", add the precaution

Do not use on old, sick or debilitated animals.

- f. Under adult mosquito control, revise the sentence to read:

. . . when the wind velocity does not exceed 5 miles per hour but do not apply when wind speeds exceeds 10 miles per hour.

Also, following the last sentence in this paragraph, add:

Not to be used within 100 feet (300 meters) of lakes and streams.

- g. Under indoor application following the last sentence of the first paragraph, add:

In the home, all food processing surfaces and utensils should be covered during treatment or thoroughly washed before use. Exposed food/feed should be covered or removed.

BEST AVAILABLE COPY

h. Under indoor application, add the following precaution:

Do not apply to classrooms while in use.

Also, you may delete the limitation "For space spraying/fogging indoor . . . etc.

The acute toxicity studies in support of the subject products have been reviewed and the following toxicity classifications have been assigned to the products.

<u>Study</u>	<u>Toxic Category</u>	<u>Classification</u>
Acute Oral	IV	Guideline
Acute Dermal	IV	Minimum
Acute Inhalation	IV	Guideline
Eye Irritation	IV	Guideline
Dermal Irritation	IV	Guideline
Dermal Sensitization	Not a sensitizer	Guideline

Please note that the acute dermal toxicity study submitted for the subject products is designated core-minimum data, since the weights of the test animals exceeded the weight range allowed by the Agency (2 to 3 kilograms for rabbits).

Submit five (5) copies of your final printed labeling before you release the product for shipment.

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 bearing the amended labeling constitutes acceptance of these conditions.

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

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosure

BEST AVAILABLE COPY

BEST AVAILABLE COPY

CODE 72055

PERMANONE®

GENERAL PURPOSE AQUEOUS INSECTICIDE

EPA REG. NO. 4816-696AA

EPA EST. NO. 279-NY-1

- * For Domestic Use both indoors and outdoors.
- * A Ready-To-Use PERMANONE® Stable Emulsion Insecticide
- * For Control of Fleas, Brown Dog Ticks and Lice on Premises and on Dogs
- * For Control of Ticks which may cause Lyme disease on Premises
- * Controls Fleas and Ticks on Dogs for 35 Days
- * Aids in Control of Ticks on Dogs for an additional 2 weeks

ACTIVE INGREDIENT:

*Permethrin 0.50%

INERT INGREDIENTS: 99.50%

100.00%

*(3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2,2-dichloroethyl) 2,2-dimethylcyclopropanecarboxylate. Cis/trans ratio: min. 35% (+/-) cis and max. 65% (+/-) trans.

PERMANONE - Registered Trademark of Fairfield American Corporation.

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS CAUTION

Wash thoroughly after handling and before smoking or eating. Avoid contamination of feed and foodstuffs. Remove pets and birds and cover fish aquaria before surface applications. Do not use on humans. Do not allow children or pets to contact treated areas until surfaces are dry.

See rear panel for additional precautions.

NET CONTENTS:



FAIRFIELD
AMERICAN
CORPORATION

201 ROUTE 12 NORTH, RUTHERFORD, NJ 07070

DIRECTIONS FOR USE

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

Affix trigger, pump or other type sprayer to container for application. Do not transfer to another container.

SHAKE WELL BEFORE USING

INDOOR APPLICATION

For spot application only. Do not use as a space spray indoors.

SURFACE SPRAYING:

To control Cockroaches, Waterbugs, Palmetto Bugs, Scorpions, Millipedes, Centipedes, Sowbugs, Pillbugs, Ants, Silverfish, Firebrats, Spiders, Crickets, Clover Mites, Cheese Mites, Granary Weevils, Rice Weevils, Confused Flour Beetles, Rust Red Flour Beetles, Drugstore Beetles, Meal Worms, Grain Mites and Caddisflies: Direct the spray into hiding places, cracks and crevices, and behind shelves and drawers. For silverfish, spray bookcases. For ants, spray trails, nests and points of entry.

To control Carpet Beetles: Spray edges of carpeting and under carpeting and rugs. Make localized application to floor and baseboards. Spray directly into cracks, crevices and infested areas of shelving. Repeat treatment as needed.

To control Bedbugs: Spray mattresses lightly, particularly around tufts and seams. Take beds apart and spray in all joints. Treat baseboards, moldings and floors. Repeat treatment as needed.

To control Fleas (adults and larvae) and Ticks, including Ticks which may carry Lyme disease (adults and larvae): Thoroughly spray infested areas, pet beds, resting quarters, nearby cracks and crevices, along and behind baseboards, moldings, window and door frames, and entire areas of floor and floor covering. Fresh bedding should be placed in animal quarters following treatment. Repeat treatment as needed. Allow to dry thoroughly before allowing pets to contact treated areas.

To control Clothes Moths: Remove any infested articles from storage, brush thoroughly, and air for several hours in sunlight, if possible. Apply spray liberally to empty chests, closets, bureaus and other storages directing the spray into cracks, joints and crevices. After airing, infested articles may be treated lightly, keeping nozzle at least three feet from fabric to avoid staining.

To Kill Lice and Louse Eggs: Spray in an inconspicuous area to test for possible staining or discoloration. Inspect again after drying, then proceed to spray entire area to be treated. Spray from a distance of 8 to 10 inches. Treat only those garments and parts of bedding, including mattresses and furniture that cannot be either laundered or dry cleaned. Allow all treated articles to dry thoroughly before use.

ON LIVESTOCK

To protect cattle (beef and dairy), from Horn Flies, Face Flies, and Gnats: Apply a light mist sufficiency. For face flies, spray face and head.

To control Stable Flies, Horse Flies: Apply at rate of 2 ounces per adult animal. Spray thoroughly. Repeat treatment daily to give continued protection.

To control Blood-sucking Lice: Apply to animal, using a stiff brush to get into the hair. Repeat every 3 weeks if required.

To control Poultry Lice: Spray thoroughly. This should be followed with a fine mist.

To control Bedbugs and Mites in roost poles, cracks in walls, and other places where bedbugs and mites hide.

ON DOMESTIC ANIMALS

To control Fleas, Ticks, and Lice: Move the dispenser rapidly and spray the entire body is covered, including spraying, fluff the hair so that the spray reaches the skin. Make sure spray wets thoroughly. Do not spray into eyes or face. Avoid protective gloves or mitts when necessary.

NOTE: Not recommended for use on animals less than 6 weeks old. DO NOT USE ON CATS.

OUTDOOR APPLICATION

TO CONTROL TICKS, INCLUDING LYME DISEASE (PERIMETER TREATMENT): Use Permanone® General Purpose Insecticide as a residual treatment to control Ticks (including the Lone Star Tick (Amblyomma americanum), Dog Tick (Rhipicephalus sanguineus), and Western Ticks (Dermacentor variabilis) and Western Ticks (Dermacentor pacificus)).

For each area listed below, apply approximately 1 gal/750-1000 ft².

Treat around windows and doors, garages, under stairways and in other areas where insects may enter.

Treat a band of vegetation and lawn around the outside of buildings to help prevent insects from entering.

CONTINUED

ON DOGS:

To control *Fleas, Ticks, and Lice*: Start spraying at the tail, moving the dispenser rapidly and making sure that the animal's entire body is covered, including the legs and underbody. While spraying, fluff the hair so that the spray will penetrate to the skin. Make sure spray wets thoroughly, but do not saturate animal. Do not spray into eyes or face. Avoid contact with genitalia. Use protective gloves or mitts when applying product. Repeat as necessary.

NOTE: Not recommended for use on puppies less than four weeks old. DO NOT USE ON CATS OR KITTENS.

OUTDOOR APPLICATION

TO CONTROL TICKS, INCLUDING TICKS WHICH MAY CARRY LYME DISEASE (PERIMETER TREATMENT):

Use Permanone® General Purpose Aqueous Insecticide II as a residual treatment to control *Ticks* including the *Deer Tick* (*Ixodes dammini*), *Lone Star Tick* (*Amblyomma americanum*), *Brown Dog Tick* (*Rhipicephalus sanguineus*), *American Dog Tick* (*Dermacentor variabilis*) and *Western Black-legged Tick* (*Ixodes pacificus*).

For each area listed below, apply until surface is wet (approximately 1 gal/750-1000 ft²).

Treat around windows and doors, porches, screens, eaves, patios, garages, under stairways and in crawl spaces where these pests may enter.

Treat a band of vegetation and leaf litter 6 to 10 feet wide around and the outside of buildings to help control ticks occurring there.

To help control ticks in outdoor activity areas, treat a band of vegetation and leaf litter 6-10 feet wide and adjacent to activity areas, especially where dense vegetation occurs.

FOR CONTROL OF GARDEN INSECTS:

For use on roses, dahlias, asters and other ornamentals to kill *Japanese Beetles* hit by spray as well as *Whiteflies*, *Aphids*, *Exposed Thrips*, *Spiders*, *Red Mites* and *Leafminers*. May be used on plants as a multi-purpose spray in small gardens and for spot treatments of incipient insect infestations to prevent spreading in large garden areas.

May also be used on other plants such as African violets, asters, azaleas, begonias, camellias, carnations, chrysanthemums, dahlias, delphiniums, dogwoods, English ivy, euonymus, fuschia, geraniums, crassula, grape vines, Kentia palms, laurels, marigolds, rhododendrons, roses, rubber plants, snapdragons, stocks, wandering Jews and zinnias.

Effective when used as directed against *Whiteflies*, *Aphids*, *Spider and Red Mites*, *exposed Thrips*, *Lace Bugs*, *Japanese Beetles*, *Pavement Ants*, *Clover Mites* and *Armyworms*:

When spraying plants, do not operate closer than 18 inches. Use sweeping motion. Be cautious about wetting tender foliage, young plants and new growth. Do not spray plants when temperatures exceed 90 °F. Contact insects directly whenever possible. Repeat treatment as infestations occur.

ADULT MOSQUITO CONTROL:

Apply as a fine mist to thoroughly treat the entire area. For best results, treat when the wind velocity does not exceed 5 miles per hour. Treat shrubbery or vegetation where mosquitoes may rest. Apply at a rate of 2.5 pints per acre (0.9 ounce per 1000 square feet). Using truck-mounted conventional misting equipment such as Rotomist models 51C, 91 or 100 HT traveling at 5 mph to treat a 300 foot swath, calibrate equipment to deliver 0.95 gallon per minute. Under no conditions should open water be treated with this product.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE AND SPILL PROCEDURES: Store upright at room temperature. Avoid exposure to extreme temperatures. In case of spill or leakage, soak up with an absorbent material such as sand, sawdust, earth, fuller's earth, etc. Dispose of with chemical waste.

PESTICIDE DISPOSAL: Pesticide or rinse water that cannot be used according to label instructions must be disposed of at or by an approved waste disposal facility.

CONTAINER DISPOSAL:

CONTAINERS ONE GALLON AND SMALLER: Do not reuse container. Wrap container in several layers of newspaper and discard in trash.

CONTAINERS LARGER THAN ONE GALLON:

Metal Containers - Triple rinse or equivalent. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.

Plastic containers - Triple rinse or equivalent, then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Glass Containers - Triple rinse or equivalent, then dispose of in a sanitary landfill or by other approved state and local procedures.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS CAUTION

Wash thoroughly after handling and before smoking or eating. Avoid contamination of feed and foodstuffs. Remove pets and birds and cover fish aquaria before space spraying or surface applications. Do not use on humans. Vacate room after treatment and ventilate before reoccupying. Do not allow children or pets to contact treated areas until surfaces are dry.

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not apply directly to any body of water. Do not contaminate water when disposing of equipment washwaters.

Buyer assumes all risks of use, storage or handling of this product not in strict accordance with directions given herewith.

2/18/92

BEST AVAILABLE COPY

UP BARCODE

CAS