

JAN 16 1991

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

Dear Mr. Brill:

Subject: Acute Toxicity Studies Conducted on the Amended
Formulation
Permanone Multi-Purpose 10% EC
EPA Registration Number 4816-688
Your Submission Dated August 29, 1990

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, provided that you make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

1. Revise the Precautionary Statements to the following:

Harmful if inhaled. Causes moderate eye injury. Avoid breathing vapor or spray mist and contact with eyes, skin or clothing. Remove contaminated clothing and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling.

2. Revise the Statement of Practical Treatment as follows:

a.) To the If Inhaled, add "Get medical attention." at the end of the statement.

b.) Change the If On Skin as follows:

If On Skin: Wash with plenty of soap and water. Get medical attention if irritation persists.

3. You must submit an acceptable dermal sensitization study on the product formulation or submit additional information to upgrade the current study. The other acute toxicity studies submitted are acceptable and have been assigned to the following categories:

L. M. W. 1/14/91

<u>STUDY</u>	<u>STUDY CLASSIFICATION</u>	<u>TOXICITY CATEGORY</u>	<u>MRID NUMBER</u>
Acute Oral LD-50	Guideline	IV	416280-01
Acute Dermal LD-50	Guideline	IV	416280-02
Acute Inhalation	Guideline	III	416280-03
Primary Dermal Irritation	Guideline	III	416280-04

The dermal sensitization study was rated "supplementary" since the reviewer was unable to reach an objective decision. The data in the report showed that the test material was a weak sensitizer, however, this may or may not be the case since the report did not include data for determining the highest non-irritating concentration. In the absence of data, it is difficult to decide whether the product is a sensitizer or that the highest non-irritating concentration was not chosen for testing. Since the study used Buehler's method, the following excerpt from an article by Edwin V. Buehler and Harry L. Ritz may be helpful (Planning, Conduct & Interpretation of Guinea Pig Sensitization Patch Tests; Current Concepts in Cutaneous Toxicity, Academic Press, 1980):

It is often necessary to determine the primary irritancy of the test substance so that a non-irritating concentration may be chosen for response elicitation. For this purpose as many as four different concentrations of the test material in the appropriate solvent are applied as described for the induction procedure to four naive guinea pigs.

Hence, you must submit all pertinent data for the selection of the highest non-irritating dose as described in the preceding paragraph.

NOTE: Additional labeling changes may be required after the skin sensitization study is submitted.

Submit five copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records.

Sincerely,

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosure

SEE REVERSE FOR SPEC

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APPLICATION SITES	PESTS CONTROLLED	USE DIRECTIONS	DILUENT	DILUTION RATE	APPLICATION RATE	DOSE RATE
AS A SURFACE SPRAY Aircraft, Bakeries, Beverage Plants, Canneries, Flour Mills, Food Processing Plants, Grain Elevators, Granaries, Homes, Hospitals, Hotels, Industrial Installations, Kennels, Meat Packaging Plants, Motels, Office Buildings, Railroad Cars, Restaurants, Schools, Ships' Holds, Supermarkets, Truck Trailers, and Warehouses.		For initial clean up of severe insect infestations: Use a good sprayer adjusted to deliver a coarse wet spray. Direct the spray into hiding places, cracks and crevices, around pallets, around containers of stored foods, around the base of machinery and behind shelves and drawers. Spray bookcases for Silverfish. Spray ant trails, nests and points of entry.	Water	1 part concentrate in 10 parts water (13.8 ounces per gallon)	1 gallon to 750 square feet of surface	
		For normal infestations: Use a good sprayer adjusted to deliver a coarse wet spray. Direct the spray into hiding places, cracks and crevices, under pallets, around containers of stored foods, around the base of machinery and behind shelves and drawers. Spray bookcases for Silverfish. Spray ant trails, nests and points of entry.	Water	From 1 to 2 parts concentrate to 40 parts water (3.25 - 6.50 ounces per gallon)	1 gallon to 750 square feet of surface	
	Carpet Beetles	Spray edges of carpeting and under carpeting and rugs. Make localized application to floor and baseboards. Spray directly into cracks, closets and infested area of shelving. Repeat treatment as necessary.	Water	1 part concentrate to 20 parts water (6.5 fl. ounces per gallon)		
	Bedbugs	Spray mattresses lightly particularly around tufts and seams. Take beds apart and spray in all joints. Treat baseboards, moldings and floors. Allow all treated articles to thoroughly dry before use. Repeat treatment as needed.	Water	1 part concentrate in 20 parts water (6.5 fl. ounces per gallon)		
	Fleas and Ticks (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 localized areas of floor and floor covering. Fresh bedding should be placed in animal quarters following treatment. ON DOGS: To control fleas, ticks - 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 wets thoroughly. Do not spray into eyes and face. Avoid contact with genitalia. Repeat as necessary. Do not use on old, sick or debilitated animals. NOTE: NOT RECOMMENDED FOR USE ON PUPPIES LESS THAN FOUR WEEKS OLD.	Water	From 1 to 2 parts concentrate to 40 parts water (3.25 - 6.50 fl. ounces per gallon)		
Trees and Shrubs	Gypsy moth caterpillars and adults, adult Japanese beetle and Eastern and pest tent caterpillars	Apply to ensure thorough coverage of upper and lower surfaces. On trees and shrubs: Treat trees and shrubs as insects emerge (Usually spring). Treat leaves, branches and tree trunks evenly, making sure to penetrate dense foliage. Repeat application every 7 days or as necessary for control. On roses and in flower gardens: Treat plants and flowers as soon as insects appear. Spray plants and flowers making sure to penetrate dense foliage. Repeat application every 7 days or as necessary for control.	Water	1 part concentrate in 40 parts water (3.2 fl. ounces per gallon of water)		
Walls, ceilings, moldings, screens, door frames, beams, light cords, and similar resting places.	Mosquitoes, Wasps, Gnats, Skippers	Treat surfaces using coarse wet spray. Spray to run off.	Water	1 part concentrate in 20 parts of water (6.5 fl. ounces per 1 gallon of water)		
LIVESTOCK SPRAY: Dairy & Beef Cattle, Sheep, Goats, Swine, Horses and Poultry. (For swine, do not ship animals for slaughter within 5 days of last treatment.)	Horn Flies, House Flies, Mosquitoes And Gnats	Apply to wet the hair thoroughly, with particular attention to topline, underline, flanks, withers, and other infested areas. Repeat treatment at intervals of 5 to 12 days for small insect populations or as needed when flies are emerging in large numbers.	Water	1 part concentrate in 20 parts water (6.5 fl. ounces per gallon)		
	Stable Flies, Horse Flies And Deer Flies	Apply a quart per adult animal to wet the hair thoroughly with particular attention to the legs, flanks, barrel, topline and other body areas commonly attacked by these flies. Repeat treatment as needed.	Water	1 part concentrate in 20 parts water (6.5 fl. ounces per gallon)		
	Face Flies	Apply using spray which produces large wetting droplets. Apply to the face of the animal in the morning before releasing to pasture. Apply sufficiently to wet the face but not more than 1.5 ounces per animal. Repeat daily as needed.	Water	1 part concentrate in 20 parts water (6.5 fl. ounces per gallon)		
	Poultry Lice	Spray roosts, walls and nests or cages thoroughly. This should be followed by spraying over the birds with a fine mist.	Water	1 part concentrate in 20 parts water (6.5 fl. ounces per gallon)		
	Bedbugs and Mites in poultry houses	Spray crevices of roost poles, cracks in walls and cracks in nests where the bedbugs and mites hide.	Water	1 part concentrate in 20 parts water (6.5 fl. ounces per gallon)		
	Sheep "tick" or ked	Thoroughly wet all portions of the body by dipping or by spraying with sufficient pressure and with a nozzle adjustment to give penetration of the wool. Treat at a rate sufficient to wet the animal.	Water	1 part concentrate in 20 parts water (6.5 fl. ounces per gallon)		
	Fleas on Livestock (To kill and to protect against reinfestation)	Wet the animal by dipping or spraying.	Water	1 part concentrate in 20 parts water (6.5 fl. ounces per gallon)		
	Flies, Mosquitoes and Gnats in Barns, Milking Parlors, Milk Rooms, Dairies and Poultry Houses	Apply as a fog or fine mist, directing the spray toward the ceiling and upper corners until the area is filled with mist, using about 2 ounces per 1000 cubic feet of space. For best results, close doors and windows before spraying and keep them closed for ten to fifteen minutes. Vacate the treated area and ventilate before reoccupying. Repeat treatment as necessary.	Water	1 part concentrate in 20 parts water (6.5 fl. ounces per gallon)		

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APPLICATION SITES	PESTS CONTROLLED	USE DIRECTIONS	DILUENT	DILUTION RATE	APPLICATION RATE	DOSE RATE
ASA SPACE SPRAY Bakeries, Beverage Plants, Canneries, Flour Mills, Food Processing Plants, Granaries, Homes, Hospitals, Hotels, Industrial Installations, Kennels, Meat Packaging Plants, Motels, Office Buildings, Railroad Cars, Restaurants, Schools, Ships' Holds, Supermarkets, Truck Trailers, Warehouses.	House Flies, Fruit Flies, Gnats, Mosquitoes, Skipper Flies, Wasps, Hornets, Bees, Blackflies, Small Flying Moths.	<p>Apply with mechanical or compressed air equipment (non thermal) adjusted to deliver a fine mist. Close doors and windows and shut off ventilating systems. When using an oil dilution for space spraying, extinguish all flames and pilot lights when applying.</p> <p>For rapid control of Houseflies, Fruit Flies, Gnats, Mosquitoes, Skipper Flies, Wasps, Hornets, Bees, Blackflies, Small Flying Moths, direct spray at an upward angle distributing it uniformly through the entire area at a rate of 1 ounce per 1000 cubic feet of space. Keep area closed for at least 10 minutes. Vacate areas after treatment and ventilate and sweep up dead insects before reoccupying.</p> <p>For rapid kill of exposed or accessible stages of other insects named on this label, apply using conventional, mechanical or compressed air equipment (non-thermal) following directions for space spraying.</p>	Oil or Water	1 part concentrate in 20 parts oil or water (6.5 fluid ounces per gallon)	1 ounce per 1000 cubic feet	
Animal Houses, Corrals, Drive in Restaurants, Drive in Theaters, Feedlots, Gardens, Golf Courses, Parks, Playgrounds, Recreational Areas, Urban Areas, Zoos, Etc.	Mosquitoes, Gnats, biting and non-biting Midges, Blackflies, and other biting Flies.	<p>Apply using vehicle mounted ULV equipment to create an insecticidal swath. For best results apply when there is a light breeze (ie. about 5 mph) and apply in direction of breeze to obtain maximum swath and better distribution. Do not exceed 10 mph.</p> <p>The target dose rate to be applied is up to 0.007 lb. ai. per acre. This can be achieved under different conditions by altering the flow of insecticide from the equipment and/or the speed of the vehicle. Apply 3.5 to 7.0 fluid ounces per minute at vehicle speeds of 5-10 miles per hour using swath widths of 150-300 feet as appropriate to local conditions.</p> <p>At higher vehicle speeds flow rates should be increased proportionately to achieve the target dose rate.</p> <p>Not to be used within 100 feet (30 meters) of lakes and streams.</p> <p>In treatment of corrals, feed lots, animal lots and zoos, cover any exposed drinking water, drinking fountains and animal feed before application.</p> <p>Allow 24 hours before retreating. Do not apply more than once in a 24 hour period.</p>	Oil or Water	1 part concentrate with 1 part suitable oil solvent, or at proportional oil dilutions calculated on the basis of vehicle speed and swath width to achieve the target dose.	Dependent of swath width, flow rate and speed of vehicle.	Up to 0.007 lbs. of active ingredient per acre.
BARRIER SPRAY Perimeter of residential yards, public facilities, paths, and recreational areas.	As an aid in reducing mosquito annoyance. To kill and control biting and non-biting midges, deer flies and other biting flies.	<p>Apply when walking at a speed of approximately 2 mph or a swath of 50 feet treating approximately 0.2 acre/minute.</p>	Oil or water	1 part concentrate to 1 part of a suitable diluent, or at proportional dilutions calculated on the basis of applicator speed and swath width to achieve the target dose.	Apply 17.5 fluid ounces of diluted material per acre.	Approx. 0.1 lb. per acre.