73049-301

12/03/2001



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 3 _ 2001

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Michael Tichon Regulatory Affairs Valent BioSciences Corporation 870 Technology Way Libertyville, IL 60048

Subject: Label Amendment with language responsive to PR Notices Concerning First Aid and Disposal Statements Permanone Multi-Use Insecticide Spray EPA Reg. No. 73049-301 Your Letter Dated October 4, 2001

Dear Mr. Tichon:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below:

1. In the front panel bullets, change the site that reads, "Bedding" to "Mattresses." The term "bedding" implies application to sheets, pillow cases, etc., which is not an acceptable site.

2. Move the statements under the "Hazards to Domestic Animals" to the directions for use on dogs. You do not need to carry the header "Hazards to Domestic Animals."

Two (2) copies of the finished labeling must be submitted prior to releasing the

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

If you have any questions regarding this action, please let me know. I can be reached at (703) 305-6100.

Sincerely,

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

PERMANOHE-MULTI-USE INSECTICIDE SEPAY

- * Contains the Synthetic Pyrethroid Permanone®
- * Controls Residential, Industrial and Garden Insects
- * For Use on Dogs and on Premises to Control Fleas and Ticks
- * Controls Fleas and Ticks on Dogs for 14 Days
- * A Water-Based Aerosol
- * Controls Pests for up to Four Weeks
- * Kills Lice and Their Eggs on mattresses, furniture, car interiors and other non-washable items.
- * Kills House [Helps Control] Dust Mites in Carpets, Curtains and on Upholstery
- * Controls [Helps Control] House Dust Mites (Dermatophogoides spp.) for up to 8 Weeks [2 months, 60 Days] in Carpets, Curtains and on Upholstery
- * Controls House [Helps control] Dust Mites that may cause Asthma, Hay Fever, Rhinitis, Watery Eyes, Sneezing
- * Permanone is Effective in the Control of Dust Mites
- * Kills Screw Worms on Beef Cattle, Horses, and Sheep
- * For Bedding and Furniture
- * Not For Use On Humans
- * Home Lice Control Spray for Bedding and Furniture
- * 1-2-3 Lice Control System
- * Step 3

ACTIVE INGREDIENT:

Permethrin*	
OTHER INGREDIENTS:	<u>99.50%</u>
TOTAL:	100.00%

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

PRECAUCION AL CONSUMIDOR: Si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente.

(TO THE USER: If you cannot read English, do not use this product until the label has been fully explained to you.)

KEEP OUT OF REACH OF CHILDREN CAUTION

See Back [Side] Panel for Precautionary Statements

EPA Reg. No. 73049-301

NET CONTENTS: _____ [NET Weight: _____ oz. (____ g)

DEC 3

3049

with COMMENTS In EPA Letter Dated:

Under the Federal Insecticide,

Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Rog. No.

2001

301

EPA Est. No.

FIRST	AID
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Call poison control center or doctor immediately for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For MEDICAL and TRANSPORT Emergencies ONLY, call 24 hours a day 1-877-315-9819. For all other information, call 1-800-323-9597

020-0001	[Torn nee phone number language may be modified to in company a poney]
lf 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 eye.
lf 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.
lf on skin or clothing	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

PRECAUTIONARY STATEMENT HAZARDS TO HUMANS [AND DOMESTIC ANIMALS*] CAUTION

Harmful if absorbed through skin. Avoid inhalation of spray mist. Causes eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Avoid contamination of feed and foodstuffs. Remove pets and birds and cover fish aquaria before space spraying or surface applications. **This product is not for 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.

[*For Products that have Animal claims.]

HAZARDS TO DOMESTIC ANIMALS

Do not spray directly in/on eyes, mouth or genitalia of pets. Do not use on dogs under twelve (12) weeks old. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing animals. Sensitivities may occur after using any pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

[Products used exclusively indoors may omit the Environmental Hazards Statement. LRM 9-1]

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.

PHYSICAL OR CHEMICAL HAZARDS

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F (54°C) may cause bursting.

DIRECTIONS FOR USE

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

Not for use on plants being grown for sale or other commercial use, or for commercial seed production, or for research purposes. For use on plants intended for aesthetic purposes or climatic modification and being grown in ornamental gardens or parks, or on golf courses or lawns and grounds.

Do not use in food areas of food handling establishments, restaurants or other areas where food is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Serving areas are areas where prepared foods are served such as dining rooms, but excluding areas where foods may be prepared or held.

In the home, all food processing surfaces and utensils should be covered during treatment or thoroughly washed before use. Exposed food should be covered or removed. We recommend that those with asthma or severe allergies consult their doctor before using this product and have someone else apply this product.

Nonfood areas are areas such as garbage rooms, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets and storage (after canning or bottling).

SHAKE WELL BEFORE USING

Remove protective cap, hold container upright and spray from a distance of 12 to 15 inches (8 to 10 inches for clothing, furniture and bedding). Remove birds and cover fish aquariums before spraying.

Houseflies, Fruit Flies, Mosquitoes, Gnats, Black Flies, Skipper Flies, Blow Flies and Small Flying Moths: Close all doors and windows and spray room at the rate of 2 to 3 seconds per 1000 cubic feet. Direct spray to all parts of the room, especially windows and other light sources which attract these insects. Keep nozzle in constant motion. Retreat if infestation occurs, but not more than once every two weeks.

Cockroaches, Waterbugs, Palmetto Bugs, Silverfish, Firebrats, Crickets, Scorpions, Spiders, Millipedes, Centipedes, Sowbugs and Pillbugs: Spray into hiding places such as cracks and crevices, behind sinks, cabinets, along baseboards and floors, around drains and plumbing, hitting insects with spray when ever possible. Spray to the point of dampness but not run-off. Retreat if infestation occurs, but not more than once every two weeks.

Ants: Spray trails, nests and points of entry. Spray on ants where possible. Retreat if infestation occurs, but not more than once every two weeks.

Indian Meal Moths, Angoumois Grain Moths: Close doors and windows, direct spray into all parts of room especially around stored food product containers, pallets and darkened areas. Spray 7 to 10 seconds for each 1000 cubic feet of space. Keep area closed for 15 minutes following treatment. Spray to the point of dampness but not run-off. Retreat if infestation occurs, but not more than once every two weeks.

Exposed stages of Confused Flour Beetles, Saw-Toothed Grain Beetles, Red Flour Beetles, Rice Weevils, Granary Weevils, Grain Mites: Spray into cracks and crevices, around cartons or containers or other areas where these insects tend to congregate. Spray 30 seconds for each 100 square feet of surface. Keep area closed for 45 minutes to 1 hour after treatment. Spray to the point of dampness but not run-off. Retreat if infestation occurs, but not more than once every two weeks. Infested stored food products in the home should be disposed of.

Carpet Beetles: Spray directly on beetles, floors, baseboards, shelves, and carpets. Spray to the point of dampness but not run-off. Retreat if infestation occurs, but not more than once every two weeks.

Bedbugs: Spray mattresses, particularly around tufts and seams. Take beds apart and spray into all joints. Treat baseboards, moldings and floors. If lice infestations should occur on humans, use a product labeled for use on humans. Spray to the point of dampness but not run-off. After mattress is dry, cover with mattress cover and sheet. Do not use mattress without cover. Retreat if infestation occurs, but not more than once every two weeks.

To control *Clothes Moths* and *Carpet Beetles* on wool and other proteinaceous fibers: Remove 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 storage, directing the spray into cracks, joints and crevices. Spray to the point of dampness but not run-off. After airing, infested articles may be treated by spraying lightly, keeping nozzle at least three feet from fabric to avoid staining.

To Control [Kill] [Helps Control] *House Dust Mites (Dermatophagoides spp.):* Permanone Multi-Use Insecticide Spray controls [helps control] house dust mites that may cause asthma, hay fever, rhinitis, watery eyes and sneezing. One treatment lasts for up to 8 weeks [2 months, 60 days]. On **Upholstered Furniture** - test fabric in an inconspicuous area to insure dyes will not bleed. Hold container upright with nozzle away from you. Depress valve and spray from a distance of 8 to 10 inches. Spray all fabric surfaces until damp. Spray to the point of dampness but not run-off. Do not use on delicate fabrics. Allow furniture to dry thoroughly before using. **On Carpets** - Spray over entire carpet until damp. Spray to the point of dampness but not run-off. Hold the nozzle approximately 12 to 18 inches from the carpet surface and spray in a sweeping motion. Use an overlapping pattern to insure total coverage. After application, brush the surface of the carpet with a broom or brush to insure deep penetration. Allow carpet to dry thoroughly before reentering the treated area. Drying time can be accelerated by using a fan. **On Mattresses** - spray the top, bottom and sides of mattresses until damp, paying particular attention to tufts and seams. Allow to dry thoroughly before using. After mattress is dry, cover and sheet. Do not use mattress without cover. Vacuum entire area once dry. Since vacuuming stirs dust up in the air those with allergies should have another person vacuum or should wear a dust mask and use vacuum with a high efficiency particulate (HEPA) filter.

Fleas and Ticks (Adults and Larvae): Remove and thoroughly clean or destroy pet bedding. Spray pet sleeping quarters, bed, entire floor and floor covering, with special attention to cracks and crevices around baseboards and window and door frames. Infested upholstered furniture may also be treated with this product. Spray to the point of dampness but not run-off. A test application should be made to upholstery or drapery fabrics in an inconspicuous place before use.

[XXX Product] is Step 3 in the [xxx Company's] Lice Control System. **Step 1:** Kill lice with [xxx Product]. Re-apply in 10 days. **Step 2:** Comb out eggs & nits with [xxx Product].

Step 3: Clean home. Use [xxx Product] for non-washable items. Washables should be washed in hot water and dried in high heat.

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. Hold container upright with nozzle away from you. Depress valve and spray from a distance of 8 to 10 inches. Spray each square foot for three seconds. Spray only those garments and parts of bedding, including mattresses and furniture that cannot be either laundered or dry cleaned. Spray to the point of dampness but not run-off. Allow all sprayed articles to dry thoroughly before use.

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS

To control *Fleas, Ticks* and *Lice* on dogs. Starting at the tail, stroke against the lay of the hair, spraying the parted fur in short bursts, directly behind the hand to insure penetrating the coat. Dampen the fur up to the head. Retreat if infestation occurs, but not more than once every two weeks.

IN ANIMAL QUARTERS AND MILK ROOMS: For rapid control of *House Flies, Mosquitoes* and *Small Flying Moths*, close windows and doors and spray at the rate of 2 seconds per 1000 cubic feet of space. For best results, keep area closed for 10 minutes after spraying. Do not remain in treated area and ventilate after treatment is completed.

TO TREAT LIVESTOCK: To protect beef cattle, dairy cattle, goats, sheep, hogs and horses from attacks of **Stable Flies, Horse Flies, Deer Flies, Face Flies, House Flies, Horn Flies, Mosquitoes** and **Gnats:** Spray about 3 seconds on each side being careful to spray back, withers and forelegs thoroughly. To protect from *Face Flies*, spray the face and head, but do not spray into eyes. Repeat treatment when flies are troublesome.

To kill **Screw Worms** infesting beef cattle, horses, and sheep, hold can about 4 to 8 inches from area to be treated with nozzle pointed at wound. Spray the area until it is completely wet - three to ten seconds are usually enough. The area surrounding the wound should also be sprayed. This product is not recommended for use in deep wounds. Some strains of screwworms may develop resistance to pyrethroids. This will be observed by lack of response to treatment. Where pyrethroid resistance is known or suspected, this product should not be used.

FOR SWINE: Do not ship animals for slaughter within 5 days of last treatment.

To control **Blood Sucking Lice:** Apply to the infested areas of the animal, using a stiff brush to get the spray to the base of the hair. Repeat every 3 weeks if required.

To control **Poultry Lice:** Spray roosts, walls and nests or cages thoroughly. This should be followed by spraying over the birds with a fine mist. For control of **Bedbugs** and **Mites** in poultry houses, spray crevices of roost poles, cracks in walls and cracks in nests where the bedbugs and mites hide. Spray to the point of dampness but not run-off.

FOR THE 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, Spider Mites, Red Mites* and *Leafminers*.

May be used on plants, as well 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, dogwood, English ivy, euonymus, fuschia, geraniums, crassula, grape vine, Kentia palm, laurel, 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 *Army Worms.* When spraying plants, do not operate closer than 18 inches. Use sweeping motion. Spray in one second bursts. Be cautious about wetting tender foliage, young plants and new growth. Do not spray plants when temperatures exceed 90°F (32°C). Contact insects directly whenever possible. Retreat if infestation occurs, but not more than once every two weeks.

STORAGE AND DISPOSAL

Storage: Store in a cool, dry area. Do not transport or store below 32°F (0°C).
Container Disposal: Do Not Puncture or Incinerate
If empty: Place in trash or offer for recycling if available.
If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions.

Purchaser assumes all responsibility for safety and use not in accordance with directions.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following conditions, disclaimer of warranties and limitations of liability.

CONDITIONS: The directions for use of this product are believed to be adequate and should be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of VALENT BIOSCIENCES CORPORATION. All such risks shall be assumed by the user or buyer.

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[]- Insert Company or Brand Name

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