



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MAY 6 2003

Stuart R. Rose, MD
Travel Medicine
369 Pleasant Street
Northampton, MA 01060

Subject: Revised Data Matrix and Label Amendment Removing Scorpions
Fite Bite Permanone Clothing & Gear Repellent
EPA Reg. No. 73876-1
Your Submission Dated March 31, 2003 as Amended by Email May 5, 2003

Dear Dr. Rose:

The revised data matrix and labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, are acceptable subject to the comment below. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

1. The beginning of the Directions for Use (from the "Directions for Use" heading through the Storage and Disposal section) must be placed in a box to indicate that this text is required on all marketed products.

If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely,

A handwritten signature in cursive script that reads "Susan L. Stanton, for".

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

Enclosure

FITE BITE® Clothing & Gear Insect Repellent

MASTER LABEL

- * For Domestic Use Both Indoors & Outdoors
- * General Purpose Aqueous Insecticide
- * A Ready-To- Use Stable Emulsion Insecticide
- * Insect Repellent For Clothing
- * For Treatment Of Dog Bedding
- * For Treatment Of Upholstered Furniture
- * Kills Lice And Their Eggs
- * Kills House Dust Mites In Carpets, Mattresses, Curtains, And On Upholstery
- * Controls House Dust Mites (*Dermatophogoides spp.*) For Up To 8 Weeks [2 months, 60 Days] In Carpets, Mattresses, Curtains, And On Upholstery
- * Controls House Dust Mites That May Cause Asthma, Hay Fever, Rhinitis, Watery Eyes, Sneezing
- * Effective In The Control Of Dust Mites
- * For Treatment of Nets, Tents, Sleeping Bags and Backpacks
- * Controls Fleas & Ticks
- * Repels & Kills Mosquitoes, Ticks, Chiggers & Mites
- * Repels & Kills Ticks Which May Carry Lyme Disease & Rocky Mountain Spotted Fever
- * Provides Long-Lasting Protection: 1 Treatment [On Clothing][On Gear][On Tents][On Sleeping Bags][On Backpacks][On Nets][On Bed Nets] Lasts 2 Weeks
- * Unscented Two-Week Protection Repels & Kills Mosquitoes, Ticks, Chiggers & Mites
- * For Control Of Fleas, Brown Dog Ticks And Lice [On Premises][And] [On Dogs]
- * 3 Ounces Will Treat One Complete Outfit
- * 6 Ounces Will Treat Two Complete Outfits
- * 9 Ounces Will Treat Three Complete Outfits
- * 12 Ounces Will Treat Four Complete Outfits
- * 15 Ounces Will Treat Five Complete Outfits
- * For Control Of Ticks Which May Cause Lyme Disease [On Premises]
- * Controls Fleas And Ticks On Dogs For 14 Days
- * Provides 60-Day (Two Months) Control Of Cockroaches
- * Provides 60-Day (Two Months) Control Of Fleas On Surfaces
- * Provides 60-Day (Two Months) Control Of Stored Product Pests
- * CLOTHING & GEAR INSECT REPELLENT – DO NOT APPLY TO SKIN
- * CLOTHING TREATMENT ONLY – DO NOT APPLY TO SKIN
- * A TREATMENT FOR CLOTHING & GEAR – DO NOT APPLY TO SKIN
- * A TREATMENT FOR CLOTHING – DO NOT APPLY TO SKIN

ACTIVE INGREDIENT:
*Permethrin 0.50%

OTHER INGREDIENTS: 99.50%
..... 100.00%

[(3-phenoxyphenyl) methyl (+/-) cis/trans 3-(2,2-dichloroethenyl) 2,2-dimethyl-cyclopropanecarboxylate. Cis/trans ratio: min. 35% (+/-) cis and max. 65% (+/-) trans.

KEEP OUT OF REACH OF CHILDREN
CAUTION
See Rear Panel For Additional Precautions

EPA REG. NO. 73876-1 EPA EST. NO. 5693-MA-1
NET CONTENTS: 8 fl. oz. (236 ml)

READ ENTIRE LABEL BEFORE EACH USE
[PET USE APPLIES TO USE ONLY ON DOGS]
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 contact with treated surfaces until spray has dried.

FIRST AID

If Swallowed *Call a poison control center or doctor immediately for treatment advice.
 *Have person sip a glass of water if able to swallow.
 *Do not induce vomiting unless told to do so by a poison control center or doctor.
 *Do not give anything by mouth to an unconscious person.

If On Skin *Rinse skin immediately with plenty of water for 15-20 minutes.

If Inhaled *Move person to fresh air, if not already done.
 *If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.

If 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.
 *Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Environmental Hazards
This product is toxic to fish. Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters. This product is toxic to bees exposed to direct treatment. Do not apply this product while bees are actively visiting the treatment area.

Affix trigger pump or the pump sprayer to container for application. Do not transfer to another container.

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

SHAKE WELL BEFORE USING

STORAGE AND DISPOSAL
Do not contaminate water, food or feed by storage or disposal.
If empty: Do not reuse this container. 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. Never place unused product down any indoor or outdoor drain.

*** GENERAL CLOTHING INSTRUCTIONS**
Do not apply to clothing while it is being worn. Do not apply to skin.

For protection against ticks (including those which may carry Lyme disease), chiggers and mosquitoes, apply product as directed below. For further protection, use in conjunction with an insect repellent registered for direct application to the skin and utilize the following primary preventive measures. Avoid walking in areas where the pests are found, wear appropriate protective clothing (light-colored, long sleeved shirt and long pants tucked into socks) and inspect body daily for ticks. Pant cuffs should be worn inside the socks or footwear to ensure full protection against ticks and chiggers.

INITIAL TREATMENT INSTRUCTIONS:
A test application should be made to fabric in an inconspicuous place [area] before use.

1. Select a well-ventilated outdoor area protected from wind and lay out [or hang] the clothing to be treated (a complete outfit is shirt, pants [trousers] and socks).
2. Hold container about 6-8 inches from surface of the clothing and spray to lightly moisten the entire surface of the fabric.
3. Continue spraying over entire outfit, until the outer surface of the fabric is moist enough to cause a slight color change or darkening. Pay special attention to socks, pant [trouser] cuffs, and shirt cuffs.

[Optional language [text]]
* Optional bullet points and directions for use

Boxed text must be present on label plus minimum of one direction for use

ACCEPTED
with COMMENTS
In EPA Letter Dated:
MAY 6 2003
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
73876-1

- 4. Turn clothing over and treat the other side as described in Steps 2 & 3.
- 5. Hang the treated clothing and allow to dry for at least 2 hours (4 hours under humid conditions) before wearing.
- 6. Three ounces will treat one complete [an average] outfit.

INITIAL TREATMENT INSTRUCTIONS ON NETS, TENTS, SLEEPING BAGS AND BACKPACKS: Do not treat inside of sleeping bag. Spray exterior surfaces of tent only.

Select a well-ventilated outdoor area protected from wind and lay out [or hang] article to be treated. Hold container upright about 6-8 inches from surface of the article and spray to lightly moisten the surface of the fabric. Continue spraying over entire article, until the outer surface of the article is moist enough to cause a light color change or darkening. Turn the article over and treat the other side as described above. Hang the treated article and allow to dry for at least 2 hours (4 hours under humid conditions) before using.

RETREATMENT INSTRUCTIONS:

This product contains an active ingredient which actually binds to the fabric being treated, providing residual protection which lasts a minimum of two weeks, and holds up through several machine washings. **DO NOT RETREAT CLOTHING (OR ARTICLES) MORE THAN ONCE EVERY TWO WEEKS. LAUNDRY CLOTHING AT LEAST ONCE BEFORE RETREATING.** For re-treatment, follow instructions for initial treatment.

*** INDOOR APPLICATION**

For spot application only. Do not use as a space spray indoors. 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. Do not use in commercial food/feed handling establishments, restaurants, or other establishments where food/feed is commercially prepared, processed, or served.

For protection against Ticks, Chiggers, Fleas and Mosquitoes: Spray around windows, doors, porches, patios, and screens until surface area is damp.

SURFACE SPRAYING: For 60-day [Two Months] control of Cockroaches, Waterbugs, Palmetto Bugs, Millipedes, Centipedes, Sowbugs, Pillbugs, Ants, Silverfish, Firebrats, Crickets, Clover Mites, Cheese Mites, Granary Weevils, Rice Weevils, Confused Flour Beetles, Rust Red Flour Beetles, Drugstore Beetles, Meal Worms, Grain Mites and Cadellles: 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.

To Control Bedbugs: Spray mattresses lightly, particularly around tufts and seams. After mattress is dry, cover with mattress cover and sheet. Do not use mattress without cover. Take beds apart and spray in all joints. Treat baseboards, moldings, and floors.

To Control Clothes Moths and Carpet Beetles on wool and other proteinaceous fibers: 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: **NOT FOR USE ON HUMAN HAIR.** 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 8-10 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.

To Control House Dust Mites (*Dermatophagoides* spp.): This product controls 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 sprayer away from you. Spray from a distance of 8-10 inches. Spray all fabric surfaces until damp. Do not use on delicate fabrics. Allow furniture to dry thoroughly before using.

On Carpets—Spray over entire carpet until damp. Spray from a distance of 12-18 inches from the carpet surface and with a slow, 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. Using a fan can accelerate drying time.

On Mattresses—Spray the top, bottom, and sides of mattresses until damp, paying particular attention to tufts and seams. After mattress is dry, cover with mattress 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 a vacuum with a high efficiency particulate (HEPA) filter.

*** DOGS, DOG BEDDING AND PREMISES:** Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant or nursing animals. Do not use on dogs under 12 weeks old. 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.

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 application every two weeks, if necessary, but not more than twice per month. **DO NOT USE ON CATS OR KITTENS.**

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. Allow to dry thoroughly before allowing pets to contact treated areas. Upholstered furniture may also be treated to control fleas and ticks in these areas. A test application should be made to upholstery in an inconspicuous place before use. Spray upholstery paying particular attention to tufts and seams. Allow to dry before reuse.

*** OUTDOOR APPLICATION**

To Control Ticks (including Ticks which may carry Lyme disease) [Ticks including the Deer Tick (*Ixodes Scapularis*), Lone Star Tick (*Amblyomma americanum*), Brown Dog Tick (*Rhipicephalus sanguineus*), American Dog Tick (*Dermacentor variabilis*) and Western Black-legged Tick (*Ixodes pacificus*)], mosquitoes, chiggers, and mites (Perimeter Treatment): Use this product as a residual treatment. 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 the outside of buildings to help control ticks occurring there. To help control ticks [pest] 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 ON ORNAMENTAL PLANTS:**

For use on roses, dahlias, asters, and other ornamentals to kill *Japanese Beetles* hit by spray as well as *Whiteflies*, *Aphids*, *Exposed Thrips*, *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, eunonymus, 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. Not for use on plants grown for sale or other commercial or research purposes. Not for use in commercial greenhouses.

Buyer assumes all responsibilities for safety and use, not in strict accordance with directions.

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