

JUL 9 1992

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Mr. Joseph A. Conti
 Roussell-Bio Corporation
 170 Beaver Brook Road
 Lincoln Park, NJ 07035

Dear Mr. Conti:

Subject: Amendment - Additional Label Claims for Deer Ticks and
 Lyme Disease Vectors
 Pramex® Insecticide Emulsifiable Concentrate 13.3%
 Formula I
 EPA Registration No. 432-554
 Bioram™ 0.15% + 0.25% Insecticide Aqueous Pressurized
 Spray
 EPA Registration No. 432-582
 Your Submissions Dated October 17, 1991

The amendment referred to above, submitted in connection with registration under FIFRA sec. 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 sec. 3(c)(5) or FIFRA sec. 4 when the Agency requires all registrants of similar products to submit such data.
2. For EPA Reg. No. 432-554, make the following label changes:
 - a. On the front panel add, "For Use and Storage by Pest Control Operators Only". You may then delete the note to pest control operators on the back panel and reference to consulting professional applicators.
 - b. Add a footnote to the label inert ingredient statement indicating: **Contains petroleum distillates.**
 - c. Under the precautionary statements the statement, "Do not use in food handling areas.", should be revised to read as follows:

Do not use in food/feed areas of food/feed handling establishments, restaurants or other areas where							
SYMBOL							
SURNAME	CS.						
DATE	7/18/92						

food/feed 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, cover all food handling surfaces and cover or remove all food and cooking utensils, or wash thoroughly after treatment.

(The above statements could alternatively be placed under the Directions for Use.)

- d. Identify the **Non-Food Areas** on the front label panel as follows:

Non-food/feed areas of food/feed 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).

- e. Revise the Environmental Hazards Statement as follows:

This product is extremely toxic to fish. Do not apply directly to any body of water. Do not contaminate water when disposing of equipment washwaters. Apply this product only as specified on this label.

- f. Under precautionary statements add the following:

- o Do not apply this product in hospital patient rooms while occupied or in any rooms while occupied by the elderly or infirm.
- o Do not apply to classrooms when in use.
- o Do not apply to institutions (including libraries, sports facilities, etc.) in the immediate area when occupants are present.

- g. Under the directions for Fleas, Brown Dogs, etc., add the following precaution: **Do not use this product on old, sick or debilitated dogs.**

Please provide us with an updated Confidential Statement of Formula for your basic formulation.

3. For EPA Reg. No. 432-582, make the following label changes:

- a. Change the precautionary statements beginning with, "Do not use in edible food..." to the following:

Do not use in food/feed areas of food/feed handling establishments, restaurants or other areas where food/feed is commercially prepared or processed. Do not use in serving areas. 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, cover all food handling surfaces and cover or remove all food and cooking utensils, or wash thoroughly after treatment.

(The above statements could alternatively be placed under the Directions for Use.)

- b. Revise the Environmental Hazards Statement as follows:

This product is extremely toxic to fish. Do not apply directly to any body of water. Apply this product only as specified on this label.

- c. Under precautionary statements add the following:

- o Do not apply this product in hospital patient rooms while occupied or in any rooms while occupied by the elderly or infirm.
- o Do not apply to classrooms when in use.
- o Do not apply to institutions (including libraries, sports facilities, etc.) in the immediate area when occupants are present.

- d. Under the directions for Fleas, Brown Dogs, etc., add the following precaution: Do not use this product on old, sick or debilitated dogs.

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 yours,

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

Enclosure

265
BEST AVAILABLE COPY

BIORAM™ 0.15% + 0.25% INSECTICIDE AQUEOUS PRESSURIZED SPRAY

A Combination of Insecticides Offering Quick Knockdown and Residual Kill
of Crawling Insects for up to 4 Weeks.

ACTIVE INGREDIENTS:

*†•Permethrin (3-phenoxyphenyl)methyl(±) cis, trans-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate 0.15%w/w
d-Trans Allethrin 0.25%

INERT INGREDIENTS: 99.60%
100.00%w/w

*Cis/trans isomers ratio: min. 35%(±)cis and max. 65%(±)trans.

†U.S. Patent No. 4,024,163.

•Roussel Bio's Pramez® brand of permethrin insecticide.

Roussel Bio Corporation, 400 Sylvan Avenue, Englewood Cliffs, N.J. 07632

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 SIDE PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS AND
STATEMENT OF PRACTICAL TREATMENT**

Can be used in non-food areas of food handling establishments such as garbage rooms, lavatories, floor drains (to sewers), entries, vestibules and hallways, offices, locker rooms, machine rooms, basements, boiler rooms, garages, utility rooms, mop closets and storage rooms (after canning or bottling).

EPA Est.: See Lot No. For Correlation

EPA Reg. No. 432-582

A 42545-MO-1

P-1/18/91

F 10370-TX-1

P 655-GA-1

NET WEIGHT:

LOT NO.

ROUSSEL BIO
CORPORATION

P.O. Box 1077 400 Sylvan Avenue
Englewood Cliffs New Jersey 07632

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Avoid contact with eyes, skin or clothing. Harmful if swallowed. Do not use in or near areas of food processing plants, restaurants, or other areas where food is prepared or processed. Do not use in serving areas while food is being prepared. All food handling surfaces and cover or remove all food thoroughly after treatment.

STATEMENT OF PRACTICAL TREATMENT
If in eyes or on skin: Flush with plenty of water. Get medical attention.

ENVIRONMENTAL HAZARDS
This pesticide is highly toxic to fish. Do not apply directly to marshes, and potholes). Drift from treated areas may be harmful to aquatic sites.

PHYSICAL AND CHEMICAL HAZARDS
Contents under pressure. Do not use or store near heat or open flame. Incinerate container. Exposure to temperatures above 130°F may cause container to rupture. Do not apply this product in conduits, motor housings, junction boxes, or electrical equipment because of possible shock hazard. Do not use on surfaces that may be harmed or stained by water.

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

STORAGE: Do not store near heat or open flame. Keep in cool, dry place. Do not store in water-based formulation at temperatures below 32°F (0°C).
CONTAINER DISPOSAL: Replace cap and wrap container. Discard in trash.

Shake well before each use. Remove protective cap. Aim nozzle and push button to spray.

FOR USE IN NON-FOOD AREAS INDOORS AND OUTDOORS: MOTELS, HOMES, PRESCHOOLS, NURSERIES, DAYCARE CENTERS, LATHHOUSES, REED HOUSES, FOOD HANDLING ESTABLISHMENTS, PROCESSING PLANTS, COMMERCIAL, INDUSTRIAL, STORAGE BUILDINGS, DAIRIES, MILK STORAGE ROOMS, SUPERMARKETS, RESTAURANTS, BOTTLING PLANTS, MILLS, BAKERIES, AND HOSPITALS. IN HOSPITALS, PAINTS, PRIOR TO TREATMENT. ALSO FOR USE IN CAMPS, AUTOMOBILES, TRUCKS, AND BOXCARS. ALSO FOR HORSE STABLES. IN HORSE STABLES, NOT FOR APPLICATION TO FEED FOR FOOD.

DIRECTIONS FOR USE (Continued on next page)

PESTS INDOORS

For residual and contact control of cockroaches (waterbugs), crickets, silverfish (firebrats), clover mites, millipedes, centipedes, earwigs, scowbugs (pillbugs), spiders, ants, clothes moths, carpet beetles, boxelder bugs, scorpions, spider beetles, grasshoppers, house flies, mosquitoes, gnats, fruit flies, cluster flies, flying moths, confused flour beetles, saw-toothed grain beetles, shiny spider beetles, grain mites, red flour beetles, angoumois grain moths, grain weevils, Indian meal moths, Mediterranean flour moths, lesser grain borers, cigarette beetles, drug store beetles, chocolate moths. Spray thoroughly into hiding places such as cracks, crevices, moist areas, openings around pipes and sinks, under refrigerators, baseboards, and storage areas. Spray directly on insects where possible.

GRAIN INSECTS: For residual use, to control confused flour beetles, saw-toothed grain beetles, spider beetles, shiny spider beetles, grain mites, red flour beetles, angoumois grain moths, grain weevils, Indian meal moths, Mediterranean flour moths, lesser grain borers, cigarette beetles, drug store beetles, chocolate moths, carpet beetles. Avoid contamination of other food and foodstuffs in the areas by removing before spraying. Spray directly on exposed stages and into cracks and crevices where grain insects may be hiding. Dispose of all infested products. The shelves and drawers should be cleaned and thoroughly sprayed so as to contact all pests, and covered with shelf paper after allowing shelves to dry. Any utensils that are contacted with spray should be washed before using. Repeat as necessary.

SPIDERS: Spray directly on these pests and use repeated applications to the webbing and all cracks and crevices which harbor spiders.

ANTS: To kill ants, spray trails, nests and points of entry within buildings and homes. Spray directly on ants where possible. Repeat as necessary.

WASPS, HORNETS, YELLOW JACKETS, BEES: Application should be made in the late evening when insects are at rest. Spray liberally into hiding and breeding places, especially under attic rafters, contacting as many insects as possible. Repeat as necessary.

HOUSE FLIES, MOSQUITOES, CLUSTER FLIES, GNATS, FRUIT FLIES, FLYING MOTHS: Close off all doors and windows. Point nozzle upward. Direct spray mist to all parts of the room, especially windows and other light sources which attract these insects. Fill the room with mist, then leave the treated area. Keep the room closed for at least 15 minutes. Ventilate the room when treatment is completed.

CARPET BEETLES AND CLOTHES MOTHS: To Treat Carpets- Hold container 14-18 inches (36-46 cm) from carpet. Apply spray evenly, covering the entire surface until slightly moist. Spray underside of carpet when possible. Avoid wetting or soaking. To Treat Garments, Blankets, Carpets and Other Fabrics Before Storage- Dry clean or wash before treatment and after storage. Apply spray evenly, covering the material on both sides until slightly moist. For best results, place treated materials in plastic bags after drying, and store in a dark place. Also spray floor and baseboards, closets, cracks, crevices, infested areas of shelving and/or wherever these insects are seen or suspected.

CONTACT APPLICATION ONLY: (Not For Residual Control Of Fleas, Ticks and Bedbugs)

FLEAS, BROWN DOG AND LONE STAR TICKS ON DOGS, CATS AND PREMISES: Spray animals along back, under forelegs and on other areas, except scrotum and anus. Part hair to contact skin

and insure good coverage. Hold nozzle about one foot (30 cm) away while spraying. Apply until hair is thoroughly moist. Do not spray directly in eyes, mouth or nose of animal. To prevent reinfestation, thoroughly spray the animals' bedding and other resting areas until the surface is slightly moist contacting as many insects as possible. Treat the floor areas, cracks and crevices in the floor and along baseboards at the rate of 2 seconds per linear foot (30 cm) at a distance of 12 to 18 inches (30-45 cm). Also spray the entire inside surface of dog houses.

FOR BEDBUGS: Apply as a spot treatment to cracks and crevices, around baseboards, floorboards, bedboards and walls. First thoroughly clean and air mattresses and springs. Then spot treat only areas that may harbor bedbugs, concentrating on tufts, folds and seams. Repeat as necessary. For persistent infestations, consult professional applicator.

PESTS OUT-OF-DOORS

PESTS ON OUTSIDE SURFACES OF BUILDINGS: Use this product to control ants, clover mites, crickets, earwigs, millipedes and sowbugs (pillbugs) on the outside surfaces of buildings. To help prevent infestation of buildings treat the building foundation to a height of 2 to 3 feet (0.5 to 1 m), where pests are active and may find entrance. Also, apply as a residual spray to outside surfaces of buildings, including porches, screens, window frames, eaves, patios, garages, refuse dumps, and other areas where these pests congregate or have been seen. Repeat treatment as needed to maintain effectiveness.

HOUSE FLIES, MOSQUITOES, CLUSTER FLIES, GNATS, FLYING MOTHS: For outdoor use only as an aid in reducing annoyance from these insects. Spray outside surfaces of screens, doors, window frames or wherever these insects may enter the room. Also treat surfaces around light fixtures on porches, in garages, and other places where these insects alight or congregate. Repeat as necessary.

ANTS, LONE STAR TICKS, CRICKETS, FLEAS, AND EARWIGS: For treatment of localized infestations of these insects in outdoor areas where there are weeds or bushy non-crop areas, spray infested areas thoroughly. For ants, thoroughly wet hills and runways. Repeat application as infestations warrant and as reinfestations occur.

WASPS, HORNETS, YELLOW JACKETS, BEES: Application should be made in late evening when insects are at rest. Aim spray at nest openings in ground, bushes, and in cracks and crevices which may harbor nests, saturating nest openings and contacting as many insects as possible.

FOR USE ON PLANTS

CONTACT AND RESIDUAL SPRAY- Apply spray to plants covering all foliage. Avoid heavy wetting.

INDOORS: To protect plants in greenhouses and lathouses, and for indoor landscaping- Spray directly on insects to kill leafrollers, armyworms, cutworms, cabbage worms on chrysanthemums; fungus gnats on velvet plants. Spray as directed above. Spray as directed above to control aphids, armyworms, corn earworms, fall cankerworms, inchworms, Japanese beetles, leafminers, leafrollers, and whiteflies on the following plants.

Ageratum
Ardisia
Aster
Azalea

English Ivy
Fuchsia
Glaucolus
Grape Ivy

Piggy-back plant
Poinsettia
Portulaca
Pothos

Baby's breath
Begonia
Birds-nest fern
Bleeding heart
Carnation
Coleus
Crown of thorns
Cockscomb
Cyclamen
Dracaena
Dumbcane

Hypoestes
Ivy
Juniper
Lily
Marigold
Orchid
Palms
Pansy
Piperomia
Petunia
Philodendron

Prayer Plant
Purple Passion
Rabbits foot fern
Rose
Schefflera
Snapdragon
Snake Plant
Statice
Velvet Plant
Verbena
Zinnia

If application is to be made indoors, remove infested plants from living areas prior to application. Spray plants in an area not likely to be occupied by children or pets (particularly fish). When leaves dry, plants can be returned to original location.

Use with CAUTION on ferns, palms and fuchsia. As with all plants listed above, especially carnations, chrysanthemums and roses, there exists a wide variety of species and cultivars, and therefore, a wide variety of susceptibility to injury. To ascertain possible phytotoxicity, spray a few plants as described above, wait 24 hours, and check for possible injury.

Repeat applications may be necessary to control citrus black flies on non-bearing citrus; adult Japanese beetles on roses.

OUTDOORS: Spray as described above in the late afternoon or evening, when the temperature ranges from 50°F to 75°F and when there is little or no wind. Spray at the first indication of insect pests. On those plants that will flower during the season, the spray schedule should be completed before blossom formation. Repeat as necessary; use intervals of 4 to 8 days. PRAMEX application can be made up to the day of collection.

Spray as directed above to control aphids, cicadas, corn earworms, fall cankerworms, inchworms, leafminers, leafrollers, mealybugs, spider mites, exposed thrips and whiteflies on the following plants:

Ageratum
Aster
Azalea
Begonia
Coleus
Common ninebark
Common snowberry
Exacum
Euonymus
English Ivy
Glaucolus

Gold bells
Hypoestes
Ivy
Juniper
Lilac
Marigold
Mock Orange
Nannyberry
Orchid
Palm
Pansy

Pea shrub
Petunia
Philodendron
Poinsettia
Rhododendron
Rose
Snapdragon
Taxus
Wax plants
Weeping fig
Zinnia

TO KILL TENT CATERPILLARS: Application should be made when caterpillars are young and tents are first noticed (usually late spring). For best results, apply in the late afternoon or evening when caterpillars have returned to their tents. Aim spray directly at tents, and saturate on all sides. Repeat as necessary.

WARRANTY STATEMENT

Our recommendations for use of this product are based upon tests believed to be reliable. The use of this product being beyond the control of the manufacturer, no guarantee, expressed or implied, is made as to the effects of such or the results to be obtained if not used in accordance with directions or established safe practice. The buyer must assume all responsibility, including injury or damage resulting from its misuse as such, or in combination with other materials.

→ DEER, BEAR, BLACK LEGGED - which VECTOR Lyme Disease -