

pm 13

432 - 554

1 of 6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 9 1992

305 / 407 100
18 / 3

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	(G+)					
DATE	7/8/92					

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.

4 of 6

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

5 of 6

PRAMEX® INSECTICIDE EMULSIFIABLE CONCENTR FORMULA I CRAWLING INSECT SPRAY

AN INSECTICIDE OFFERING RESIDUAL KILL OF CRAWLING INSECTS FOR UP TO 4
Contains 1 lb/gal (120 g/L) of Pramex® Insecticide

ACTIVE INGREDIENTS:

*†•Permethrin (3-phenoxyphenyl)methyl (±) Cis, trans-3-(2,2-dichloro-
ethenyl)-2,2-dimethylcyclopropanecarboxylate 13.30%w/w

INERT INGREDIENTS: 86.70%

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 Pramex® brand of permethrin insecticide.

Roussel Bio Corp., 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
WARNING**

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

EPA Est.: See Lot No. For Correlation

EPA Reg. No. 432-554

A 425/5-MO-1

P-1/17/91

F 10370-TX-1

P 655-GA-1

NET CONTENTS

Gallons (Liters)
LOT NO.:

.....

**ROUSSEL BIO
CORPORATION**

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



PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS WARNING

Causes eye irritation. Do not get in eyes. Avoid contact
swallowed. Avoid breathing vapor. Wash thoroughly after
handling areas.

STATEMENT OF PRACTICAL TREATMENT
If swallowed: Call a physician or Poison Control Center. Do not
contains aromatic petroleum solvent. Aspiration may be a
if in eyes: Flush with plenty of water. Get medical attention
If on skin: Wash with soap and plenty of water. Get medical attention

ENVIRONMENTAL HAZARD
This product is extremely toxic to fish. Do not contaminate
d'sposal of wastes. Keep out of lakes, streams or ponds, etc.
product only as specified on this label.

PHYSICAL AND CHEMICAL HAZARD
Do not use or store near heat or open flame. Flashpoint n

DIRECTIONS FOR USE
It is a violation of Federal Law to use this product in a ma

STORAGE & DISPOSAL

Do not contaminate water, food or feed by storage or disposal.
STORAGE: Store product in original container in a locked
PESTICIDE DISPOSAL: Pesticide wastes are toxic. Improper
spray mixture, or rinsate is a violation of Federal Law. If the
use according to label instructions, contact your State F
Agency, or the Hazardous Waste representative at the
guidance.

CONTAINER DISPOSAL: For Containers One Gallon
container. Wrap container and put in trash. For Containers
equivalent). Then offer for recycling or reconditioning, or for
landfill, or by other procedures approved by State and Local

**ACCEPTED
with COMMENTS
in EPA Letter Dated** Directions For Use (Continued on I

JUL 9 1992

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

432-554

DIRECTIONS FOR USE (Continued)

FOR USE IN NON-FOOD AREAS INDOORS AND OUTSIDE PREMISES OF HOTELS, MOTELS, HOMES, PRESCHOOLS, NURSERIES, DAY CAMPS, GREENHOUSES, LATHHOUSES, SEED HOUSES, FOOD HANDLING ESTABLISHMENTS, PACKAGING AND PROCESSING PLANTS, COMMERCIAL, INDUSTRIAL, OFFICE, INSTITUTIONAL AND STORAGE BUILDINGS, DAIRIES, MILK STORAGE ROOMS, EGG PROCESSING PLANTS, SUPERMARKETS, RESTAURANTS, BOTTLING PLANTS, CANNERIES, FLOUR AND FEED MILLS, BAKERIES, AND HOSPITALS. IN HOSPITALS, PATIENTS SHOULD BE REMOVED PRIOR TO TREATMENT. ALSO FOR USE IN CAMPERS, MOBILE HOMES, BUSES, AUTOMOBILES, TRUCKS, AND BOXCARS. ALSO FOR USE IN DOG KENNELS AND HORSE STABLES. IN HORSE STABLES, NOT FOR APPLICATION IF HORSES WILL BE USED FOR FOOD.

NOTE TO PEST CONTROL OPERATORS:

One gallon of finished spray is sufficient to treat 1580 linear feet (482 m) with a 6 inch (15.2 cm) spray band.

For contact and residual sprays, mix PRAMEX with water in the following manner:

FINISHED SPRAY	PRAMEX EC (fluid ounces)	WATER
0.25%	2-2/3 (79 ml)	1 gallon (3.79 L)
0.25%	2/3 (20 ml)	1 quart (0.95 L)
0.50%	5-1/2 (163 ml)	1 gallon (3.79 L)
0.50%	1-1/3 (39 ml)	1 quart (0.95 L)

For heavy infestations, use the 0.50% dilution. For lighter infestations and for maintenance purposes, use the 0.25% dilution.

PESTS INDOORS

For residual and contact control of cockroaches (waterbugs), crickets, silverfish (firebrats), clover mites, millipedes, centipedes, earwigs, sowbugs (pillbugs), spiders, brown dog ticks, lone star ticks, ants, fire ants, clothes moths, carpet beetles, fleas, boxelder bugs, scorpions, spider beetles, bed bugs, 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.

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.

Grain Insects: 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 - remove infested grain, cereal or flour and destroy. 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. In homes, 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 (including Fire 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.

DEER, BEAR, BLACK LEGGED TICKS (VECTOR LYME DISEASE)
Fleas, Brown Dog and Lone Star Ticks on Dogs, Cats, and Premises: Spray animals along back, under forelegs and on other areas, except scrotum, face and anus. Part hair to contact skin and insure good coverage. Hold sprayer 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.

House Flies, Mosquitoes, Cluster Flies, Gnats, Fruit Flies, Flying Moths: Close off all doors and windows. Point sprayer upward. Direct spray mist to all parts of the room, especially windows and other light sources which may 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. **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

EPA Reg. No. 432-554

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.

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 Outdoors: 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.

DEER, BEAR, BLACK LEGGED TICKS (VECTOR LYME DISEASE)
Ants, Lone Star Ticks, Crickets, Fleas, and Earwigs Outdoors: For treatment of localized infestations of these insects in outdoor areas where there are weeds or brush, 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.

TO CONTROL FIRE ANTS Dilute 2 tablespoons (30 ml) of this product in 1 gallon (3.79 L) of water. Apply 1 gallon (3.79 L) of solution as a gentle rain to each fire ant mound using a sprinkler can. Thoroughly wet the mound and surrounding area to a 4 foot diameter (1.22 m). For best results, apply in cool weather, 65-80°F (18.5-27°C), or in early morning or late evening hours. Treat new mounds as they appear. Do not disturb the mound prior to treatment. If possible, treat all mounds in the vicinity, and treat all colonies which may not as yet have constructed a mound. Larger quantities of solution can be prepared for multiple mound treatments. Equipment to deliver the diluted product as a gentle rain at the rate of 1 gallon (3.79 L) per mound is still required. Do not use equipment that produces a pressurized spray as pressurized sprays may disturb fire ants and cause migration, reducing product effectiveness.

WARRANTY STATEMENT

Our recommendations for the 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.