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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 25 1991

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Judith M. Babo
Barre-National Inc.
7205 Windsor Blvd.
Baltimore, MD 21207

Dear Mr. Babo:

Subject: Label Amendment (Update Labeling Plus Combination Package Label)
Pyrinyl II Liquid
EPA Registration No. 56387-1
Pyrinyl II Lice Control Spray
EPA Registration No. 56387-6
Your Letter Dated May 14, 1991

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 label:

Unless otherwise noted the following label comments pertain to Pyrinyl II Liquid.

- 1. "Crab" lice must be prefaced with pubic anywhere it appears on the label as follows:

"For the treatment of head, pubic (crab), and body lice."

- 2. The following are required statements:

Head Lice: Head lice live on the scalp and lay small white eggs (nits) on the hair shaft close to the scalp. The nits are most easily found on the nape of the neck or behind the ears. All personal headgear, scarfs, coats, and bed linen should be disinfected by machine washing in hot water and drying, using the hot cycle of a dryer for at least 20 minutes. Personal articles of clothing or bedding that cannot be washed may be dry cleaned, sealed in a plastic bag for a period of about 2 weeks, or sprayed with a product specifically designed for this

CONCURRENCES

SYMBOL	<i>Helvest</i>						
SURNAME	<i>9-25-91</i>						
DATE							

purpose. Personal combs and brushes may be disinfected by soaking in hot water (above 130 °F) for 5 to 10 minutes. Thorough vacuuming of rooms inhabited by infected patients is recommended.

Pubic (Crab) Lice: Pubic lice may be transmitted by sexual contact, therefore, sexual partners should be treated simultaneously to avoid reinfestation. The lice are very small and look almost like brown or grey dots on the skin. Pubic lice usually cause intense itching and lay small white eggs (nits) on the hair shaft generally close to the skin surface. In hairy individuals, pubic lice may be present on the short hairs of the thighs and trunk, underarms, and occasionally on the beard and mustache. Underwear should be disinfected by machine washing in hot water; then drying, using the hot cycle for at least 20 minutes.

Body Lice: Body lice and their eggs are generally found in the seams of clothing, particularly in the waistline and armpit area. They move to the skin to feed, then return to the seams of the clothing where they lay their eggs. Clothing worn and not laundered before treatment should be disinfected by the same procedure as described for head lice, except that sealing clothing in a plastic bag is not recommended for body lice because their nits (eggs) from these lice can remain dormant for a period of up to 30 days.

(Note: Comments 1 and 2 are taken from the Federal Register Notice issued April 3, 1989 (21 CFR Part 358) on "Pediculicide Drug Products for Over-the-Counter Human Use." Refer to the FR Notice for further information on data and labeling requirements).

- 3. Under IF SWALLOWED in the Statement of Practical Treatment add "Repeat until vomit is clear." after ". . . throat with finger."
- 4. Delete "Elimination" from the name of your kit. Claims which imply total eradication of pests are not acceptable.

We do not object to the packaging of your product in a kit.

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 13
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosure
cc: Dick Montfort
PM-10

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Barro

Barro[®] **PYRINYL II** **LIQUID**

ACTIVE INGREDIENTS:
Pyrethrin..... 0.3%
Pyrethrin Ester technical..... 3.0%
(equivalent to 2.40 percent (Deltamethrin) (0-propyl-
phenyl) ether and 0.60 percent related compounds)
INERT INGREDIENTS*..... 96.7%
TOTAL..... 100.0%

*Contains Petroleum Distillate.

PRECAUTIONARY STATEMENTS **HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS**

CAUTION: Harmful if swallowed. Do not inhale. Keep out of eyes and avoid contact with mucous membranes. If product should get into eyes, immediately flush with plenty of water. If skin irritation or infection is present or develops, discontinue use and consult a doctor. Consult a doctor if infection of eyes and eyelashes occurs. Avoid contamination of food or feedstuffs. Not to be used by persons allergic to pyrethrin.

STATEMENT OF PRACTICAL TREATMENT

If Swallowed - Call a doctor or Poison Control Center immediately. Drink one or two glasses of water and induce vomiting by touching the back of throat with a finger. Do not induce vomiting or give anything by mouth to an unconscious or convulsing person.

If Inhaled - Remove victim to fresh air. Apply artificial respiration if indicated.

If On Skin - Remove contaminated clothing and wash affected areas with soap and water.

If In Eyes - Flush eyes with plenty of water. Call a doctor if irritation persists.

STORAGE AND DISPOSAL: Do not transport or store below 50°F (10°C). Do not reuse empty container. Weep and put in trash. See bottom of box for lot number and expiration date.

EPA EST. 80374-1
EPA REG. NO. 80377-1

4 FL OZ (118 mL)

Barro[®]

DIRECTIONS FOR USE

It is a violation of Federal Law to use these products in a manner inconsistent with their labeling.

PYRINYL II **LIQUID** **AND COMB**

In order to prevent reinfestation with body lice all clothing must be sterilized concurrent with the application of this preparation.

SHAKE WELL BEFORE USING.

Apply to infested area until hair is thoroughly wet with product. Allow product to remain on area for 10 minutes but no longer. Wash area thoroughly with warm water and soap or shampoo. A fine toothed comb may be used to help remove dead lice or their eggs (nits) from hair. A second treatment must be made in 7 to 10 days to kill any newly hatched lice. Use no more than two times in 24 hours.

See accompanying bilingual circular for additional important information.

INSTRUCCIONES EN ESPAÑOL
ADJUNTAS.

PYRINYL II **LICE CONTROL** **SPRAY**

For Bedding & Furniture

SHAKE WELL BEFORE EACH USE.

Remove protective cap. Aim spray opening away from person. Push button to spray.

To kill lice and their 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 3 seconds. Spray only parts of bedding (including mattresses), furniture and those garments that cannot be either laundered or dry cleaned.

Allow all sprayed articles to dry thoroughly before use.

Repeat treatment as necessary.

Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herewith.

Distributed by
BARRO-NATIONAL INC.
Baltimore, MD 21207 USA

SEP 25 1991

Use...
EPA Reg. No. 56387-1