

Reg # 34875-4

PM-15

1 of 6

US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (75-767) WASHINGTON, DC 20460  <b>NOTICE OF PESTICIDE:</b> <input type="checkbox"/> REGISTRATION <input type="checkbox"/> REREGISTRATION  (Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)	EPA REGISTRATION NO. <b>34875-4</b>	DATE OF ISSUANCE <b>SEP 21 1990</b>
	TERM OF ISSUANCE <b>Until Reregistration</b>	
	NAME OF PESTICIDE PRODUCT <b>Expyre-II</b>	
NAME AND ADDRESS OF REGISTRANT (Include ZIP code)		
<p style="text-align: center;"> <b>Ambix Laboratories</b>  <b>Div. Organics Corporation of America</b>  <b>210 Orchard Street</b>  <b>East Rutherford, NJ 07073</b> </p> <div style="text-align: right; font-size: 2em; font-weight: bold;"> <del>160</del>  <del>17</del> </div>		
<p><b>NOTE:</b> Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.</p> <p>On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.</p> <p>A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.</p> <p>Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</p> <p style="text-align: center;"> <b>This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:</b> </p> <ol style="list-style-type: none"> <li>1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.</li> <li>2. Make the labeling changes listed below before you release the product for shipment:           <ol style="list-style-type: none"> <li>a. Add the phrase, "EPA Registration No. 34875-4."</li> <li>b. Revise Precautionary Statements as follows:                 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 infestation of eyebrows and eyelashes occurs. Avoid contamination of feed or foodstuffs. Not to be used by persons allergic to ragweed.             </li> </ol> </li> </ol> <p><input type="checkbox"/> ATTACHMENT IS APPLICABLE</p>		
SIGNATURE OF APPROVING OFFICIAL		DATE

Handwritten signature and initials at the bottom left of the page.

- c. In General Information under Head Lice add:  
". . . period of about 2 weeks, or sprayed with a product specifically designed for this purpose."
- d. On the front panel add "lice" after "... crab or pubic."
- e. Add your company name, address, and EPA Establishment Number to the front panel.

2. The accelerated storage and stability data for 30 days at elevated storage conditions are acceptable on an interim basis. The results of 12 months storage and stability tests at ambient warehouse conditions must be submitted to this Agency within 15 months after granting the registration.

3. Since this product is applied to humans it is also considered a drug and is therefore co-regulated by The Food and Drug Administration (FDA). You should refer to the Federal Register Notice issued April 3, 1989 (21 CFR Part 358) on "Pediculicide Drug Products for Over-the-Counter Human Use" for further information on data and labeling requirements. For further information you may also contact:

William E. Gilbertson  
Center for Drug Evaluation  
and Research (HFD-210)  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

4. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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

George T. LaRocca  
Product Manager 15  
Insecticide-Rodenticide Branch  
Registration Division (H7505C)

EPA Reg. No. . . . .

EPA Est. No. . . . .

KILLS HEAD LICE (Pediculus humanus capitis DeG); BODY LICE (Pediculus humanus humanus L.) AND CRAB OR PUBIC (Phthirus pubis L.)

NON-FOAMING SHAMPOO

A PYRENONE INSECTICIDE

ACTIVE INGREDIENTS:

Pyrethrins.....	0.3%
*Piperonyl Butoxide, Technical .....	3.0%
INERT INGREDIENTS .....	96.7%
	100.0%

\*Equivalent to min. 2.4% (butylcarbityl) (6-propylpiperonyl) ether and 0.6% related compcunds

KEEP OUT OF REACH OF CHILDREN

CAUTION

See side panel for additional precautions

Do not transport or store below 32 F.

PYRENONE - Registered Trademark of Fairfield American Corporation

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

SEP 21 1990

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

34875-4

### DIRECTIONS FOR USE

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

This Product is For External Use On Humans Only.

#### APPLICATION USE:

- \* Apply undiluted to infested areas until entirely wet. DO NOT USE ON EYELASHES OR EYEBROWS.
- \* Allow treatment to remain 10 minutes, but no longer
- \* Then wash thoroughly with warm water and shampoo or soap.
- \* Dead lice and eggs may require removal with a fine comb.
- \* A second treatment must be made in 7 to 10 days to kill any newly hatched lice.

#### TO PREVENT REINFESTATION:

To avoid reinfestation with head, pubic or body lice, all clothing and bed linen should be disinfected by washing in hot water and drying, using the hot cycle for at least 20 minutes, or by dry-cleaning. Combs and brushes should be soaked in water above 135 F for 5 to 10 minutes. Sexual partners should be treated simultaneously. Rooms inhabited by infested patients should be thoroughly vacuumed.

#### GENERAL INFORMATION

Head Lice, live on the scalp, laying 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, scarves, 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 or sealed in a plastic bag for a period of about 2 weeks. 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 infested patients is recommended.

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

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. All clothing should be disinfected by the same procedure outlined for head lice, clothing should be sealed for at least 30 days in a plastic bag for body lice because the nits (eggs) can remain dormant for a period of up to 30 days.

STORAGE AND DISPOSAL

- Do not contaminate water, food or feed by storage or disposal.
- Do not transport or store below 32 F. Do not reuse container. Wrap container and put in trash collection.

PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS & DOMESTIC ANIMALS

CAUTION

Causes eye irritation. Do not get in eyes. Harmful if swallowed. Do not inhale. Avoid contact with mucous membranes. In case of infection or skin irritation, discontinue use and consult a physician if infestation of eyebrows and eyelashes occurs. Avoid contamination of feed or foodstuffs.

THIS PRODUCT IS FOR EXTERNAL USE ONLY.

**STATEMENT OF PRACTICAL TREATMENT**

**IF SWALLOWED-** Call a physician or Poison Control Center immediately. Drink one or two glasses of water and induce vomiting by touching the back of the throat with finger. Repeat until vomit fluid is clear. Do not induce vomiting or give anything by mouth to an unconscious person.

**IF INHALED-** Remove victim to fresh air. Apply respiration if indicated.

**IF IN EYES-** Flush eyes with plenty of water. Call a physician if irritation persists.

**IMPORTANT:** SHOULD BE USED WITH CAUTION BY RAGWEED SENSITIZED PERSONS.

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