

US ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF PESTICIDES PROGRAMS  
REGISTRATION DIVISION (TS-767)  
WASHINGTON, DC 20460

EPA REGISTRATION NO.  
34875-5

DATE OF ISSUANCE  
MAR 27 1991

TERM OF ISSUANCE  
Until Reregistration

NAME OF PESTICIDE PRODUCT  
Blue Gel

NOTICE OF PESTICIDE:  REGISTRATION  
 REREGISTRATION

(Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended)

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Ambix Laboratories  
Division of Organics Corporation of America  
210 Orchard Street  
East Rutherford, NJ 07073

160 5389258  
18,

NOTE: 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.

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.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

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.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) 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. Make the labeling changes listed below before you release the product for shipment:

- a. Add the phrase, "EPA Registration No. 34875-5."
- b. Replace "Kills Crab and Pubic Lice" with:  
"Kills Pubic (Crab) Lice"
- c. Move "Do not transport or store below 32 F" to Storage and Disposal.

ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

DATE

Albert 3-26-91

- d. From the Inert Ingredients statement delete "Petroleum Distillate". If you wish to list inert ingredients you must list all of them. Add this footnote to the Inert Ingredients Statement:

\*\*Contains Petroleum Distillates

- e. Revise Directions for Use as follows:

Apply to affected area until all the 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.

- f. The following statements are required:

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.

- g. Based on the current Confidential Statement of Formula (CSF) your product will not meet the label claim for the active ingredient. Lower limit on the CSF must agree with the label claim in pure active form. Revise the label or CSF so the information agrees.

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

3. 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)

enclosure

BLUE GEL

Proposed Labeling

NDC 10038-049-07

**Blue Gel**

EPA Reg. No. 34875  
Kills Crab and Pubic Lice  
(Pediculus Pubis Linne) and their eggs

**ACTIVE INGREDIENTS:** Pyrethrins, 0.3%, Piperonyl Butoxide,  
Technical, 3.0%.

**INERT INGREDIENTS:** Petroleum Distillate, 1.2 %; Other Inert Ingre-  
dients, 95.5%.

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

**KEEP OUT OF REACH OF CHILDREN CAUTION.** See back panel for additional precautions

Do not transport or store below 32°F.

Net Wt. 1 ounce (28.35 g)

**DIRECTIONS FOR USE:** It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **THIS PRODUCT IS FOR EXTERNAL USE ON HUMANS ONLY.**

Apply undiluted to infested area. 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 REINFECTION:** To avoid reinfection, all clothing and bed linen should be disinfected by washing in hot water and drying, using 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.

**PRECAUTIONARY STATEMENTS—HAZARD TO HUMANS—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. Consult a physician if infestation of eyebrows and eyelashes occurs. Avoid contamination of foodstuffs.

**STATEMENT OF PRACTICAL TREATMENT (FIRST AID):**

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 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.

**STORAGE AND DISPOSAL:** Do not contaminate water, food or feed by storage or disposal. Do not reuse container. Wrap container and put in trash.

AMBIX LABORATORIES, E. Rutherford, NJ 07073 Made in USA

EPA Est. No. 34875 NJ-1

BEST AVAILABLE COPY

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

MAY 21 1977

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