

US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (75-767) WASHINGTON, DC 20460 NOTICE OF PESTICIDE: <input type="checkbox"/> REGISTRATION <input type="checkbox"/> REREGISTRATION <i>(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)</i>	EPA REGISTRATION NO. 4816-727	DATE OF ISSUANCE 01 29 1991
	TERM OF ISSUANCE Until Reregistration	
	NAME OF PESTICIDE PRODUCT Pyrenone Lice Killing Shampoo	

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

18 5405815
18 5405814

Fairfield American Corporation
 809 Harrison Street
 Frenchtown, NJ 08825

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) since you have agreed to submit additional information/data for acute dermal toxicity and acute irritation toxicity by January 1, 1992. If the precautionary labeling review classifies your product as toxicity category III (or lower) then you must add appropriate precautionary language to your label and 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 following label changes:
 - a. Add the phrase, "EPA Registration No. 4816-727."
 - b. We have no objection to inclusion of the word public on your package insert only, provided you revise (or delete) the present instructions and add the following information regarding control of head, crab and body lice:

ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL	DATE
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Helbert 10-28-91

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 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.

- c. On the labeling's front panel identify your product as a "pediculicide" or "lice treatment."

(Note: Comments b and c 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).

- e. The claim on the packaging insert should read as follows:

"Pyrenone Lice Killing Shampoo's principal active ingredient, pyrethrins, is derived from a ..."

3. The insert claim ". . .should kill virtually 100% . ." is too promising. The claim may read ". . will kill adult lice but . ."

4. We consider the claim "improved" equivalent to the word "new." Thus for a period of six months after registration you may use the claim "improved."

5. 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

PYRENONE®

LICE KILLING SHAMPOO

- * **NEW IMPROVED FORMULA**
- * **KILLS LICE AND THEIR EGGS (Head lice, crab lice and body lice)**
- * **EASY TO FOLLOW INSTRUCTIONS**
- * **EXCLUSIVE 100% EFFECTIVE NIT (EGG) REMOVAL COMB***

ACTIVE INGREDIENTS:

Pyrethrins 0.33%
 **Piperonyl Butoxide, Technical 4.00%

INERT INGREDIENTS:

C13-C14 Isoparaffin, Fragrance, Isopropyl Alcohol, PEG-25 Hydrogenated Castor Oil, Water, Xanthan Gum..... 95.67%
 TOTAL 100.00%

*Scientifically tested in a laboratory device.
 **Equivalent to min. 3.2% (butylcarbityl) (6-propylpiperonyl) ether and 0.8% related compounds.

PYRENONE - Registered Trademark of Fairfield American Corporation.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See side panel for additional information (Vis.rockines en Espanol Adjuntas)

NET CONTENTS: _____



FAIRFIELD AMERICAN CORPORATION
 201 ROUTE 19 NORTH, RUTHERFORD, NJ 07070

727 18108A

DIRECTIONS FOR USE

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

1. Shake well. Apply undiluted product to dry hair and scalp or any other infested areas and wet entirely. Do not use on eyelashes or eyebrows.
2. Allow product to remain on area for 10 minutes but no longer.
3. Rinse thoroughly with warm water. If desired, follow with your regular shampoo or soap.
4. Dead lice and eggs should be removed with special nit comb provided.
5. Repeat treatment in 7-10 days to kill any newly hatched lice. Do not exceed two consecutive applications within 24 hours.

To prevent reinfestation, it is important to wash all clothing and bedding of infested person at time of treatment (See package insert).

STORAGE AND DISPOSAL

Do not store below 32 °F or above 120°F. Do not reuse original container. Securely wrap original container in several layers of newspaper and discard in trash.

BEST AVAILABLE COPY

CODE FE

**PRECAUTIONARY STATEMENTS
 HAZARDS TO HUMANS AND DOMESTIC ANIMALS
 CAUTION**

Avoid contact with eyes. If contact occurs, flush eyes with plenty of water. Get medical attention if irritation persists. Avoid contact with mucous membranes. If skin irritation, discontinue use and consult a physician. Consult a physician if irritation of eyebrows or eyelashes occurs.

THIS PRODUCT IS FOR EXTERNAL USE ONLY ON HUMANS ONLY.

IMPORTANT: Should be used with caution on ragweed sensitized persons.

PHYSICAL AND CHEMICAL PROPERTIES

Do not use or store near food.

EPA Reg. No. 4816-TET
 EPA Est. No. 42615-CT-1
 EPA Est. No. 54487-GA-1

ACCEPTED with COMMENTS
 by EPA Letter Dated:

OCT 29 1991

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide...

KILLS LICE AND THEIR EGGS

EPA Reg. No. 4816-TET

This booklet will tell you about human lice and how to treat infestations effectively with PYRENONE LICE KILLING SHAMPOO. Lice are parasitic insects the size of a pinhead. They can infest people at all social levels; no one is immune. There are 3 types of lice which infest humans; head lice, which live mainly on the scalp; pubic or crab lice, that infest the pubic area; and body lice, which live on the clothes and therefore, infest primarily a person's trunk or limbs. Lice are easily transmitted from person to person by shared personal articles such as hats, hair ribbons, combs, towels and bedding, and by physical contact.

Infestations of lice are easily treated today, especially with PYRENONE LICE KILLING SHAMPOO. This package of PYRENONE LICE KILLING SHAMPOO, with its special patented comb, is a complete product designed to kill and remove lice and their eggs rapidly and effectively. (PYRENONE LICE KILLING SHAMPOO's principal active ingredient is derived from a species of the chrysanthemum flower.)

TREATMENT OF LICE INFESTATION

STEP 1: Shampoo with PYRENONE LICE KILLING SHAMPOO

- ☐ Shake well. Apply undiluted PYRENONE LICE KILLING SHAMPOO to dry hair and scalp or any other infested areas and wet entirely. Do not use on eyelashes or eyebrows.
- ☐ Allow PYRENONE LICE KILLING SHAMPOO to remain on the area for 10 minutes but no longer.
- ☐ Rinse with warm water and, if desired, follow with your regular shampoo or soap.

PYRENONE LICE KILLING SHAMPOO should kill virtually 100% of the adult lice but not all their eggs. All eggs must be removed to prevent reinfestation. To ensure that all eggs are removed, it is very important to properly use the special comb provided with PYRENONE LICE KILLING SHAMPOO.

- ☐ Clip or pin back nit-free strands. Continue combing and pinning until the entire section is free of nits and lice. Wipe nits from the PYRENONE LICE KILLING SHAMPOO comb frequently with a tissue.
- ☐ Comb remaining hair sections as directed above. Always comb away from the top of the head to prevent irritation of combed hair. This may take some time if hair is long and thick. If hair dries during combing, wet with water.
- ☐ When entire head is combed, rinse thoroughly with water.
- ☐ After hair is dry, recheck entire head for stray nits and comb out any remaining nits.

STEP 3: Prevent Reinfestation

- ☐ Soak comb in either the PYRENONE LICE KILLING SHAMPOO solution or hot soapy water (130°F) for 10 minutes.
- ☐ Repeat treatment with PYRENONE LICE KILLING SHAMPOO in 7-10 days to kill any hatched lice which may have been missing during the initial treatment. Do not exceed two consecutive applications within 24 hours.

Since there is no immunity from lice, personal cleanliness and the avoidance of infested persons and their bedding and clothes will aid in preventing infestation. These additional steps are important in order to minimize the chance of possible reinfestation.

- ☐ Inspect all family members daily for a least two weeks, and if they become infested, treat with PYRENONE LICE KILLING SHAMPOO.
- ☐ Wash all personal clothing, nightwear and bedding of any infested person in hot water, at least 130°F, or by dry cleaning.
- ☐ Thoroughly soak all personal articles such as combs, brushes, etc. in PYRENONE LICE KILLING SHAMPOO solution or hot soapy water (at least 130°F) for ten minutes.
- ☐ Tell children not to use any borrowed combs or brushes, nor to wear anyone else's clothes.
- ☐ For carpets, bedding, furniture, and other objects which become infested with lice, but which are not easily laundered or dry cleaned, ask your pharmacist for PERMANONE MULTI-USE INSECTICIDE SPRAY (not for use on humans or animals).

PYRENONE LICE KILLING SHAMPOO should not be swallowed or inhaled. PYRENONE LICE KILLING SHAMPOO should be kept out of the eyes. If PYRENONE LICE KILLING SHAMPOO should come in contact with the eyes, immediately flush eyes with water. PYRENONE LICE KILLING SHAMPOO may be used on children, but only with adult supervision.

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