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MAR 21

Mr. Rob Adams
Elite Mfg. & Pkg., Inc.
225-F Horizon Drive
Suwanee, GA 30174

Subject: Move Benzyl Alcohol to Inert Ingredients
Elite Lice Shampoo
EPA Registration No. 51793-34
Your Application Dated October 28, 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 labeling:

- Under Hazards to Humans and Domestic Animals add to the beginning of the paragraph:

"For external use only."
- Revise the beginning of "Crab or Pubic Lice" section with the following:

"Crab or Pubic Lice may be transmitted by sexual contact, therefore, sexual partners should be treated simultaneously to avoid reinfestation, The lice are very small . . . "

Moving Benzyl Alcohol from the active ingredient statement to the inert ingredient statement is acceptable.

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)

CONCURRENCES

SYMBOL	Enclosure						
SURNAME	Helbert						
DATE	3-23-92						

294

ELITE LICE SHAMPOO

FOR USE ON HUMANS ONLY

**Kills Head Lice (Pediculus humanus capitis DeG):
Body Lice (Pediculus humanus humanus L): and
Crab or Pubic Lice (Phthirus pubis L.)**

A non-foaming shampoo

ACTIVE INGREDIENTS:

Pyrethrins	0.3%
*Piperonyl Butoxide, Technical	3.0%
**INERT INGREDIENTS:	<u>96.7%</u>
	100.0%

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

**Contains petroleum distillate

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Side Panel for Additional Precautions

Do not transport or store below 32°F

**MANUFACTURED BY:
ELITE MANUFACTURING & PACKAGING, INC.
225F HORIZON DRIVE, SUWANEE, GEORGIA 30174**

EPA Est. No. 51793-GA-1

EPA Reg. No. 51793-34

NET CONTENTS ___ OZ

BEST AVAILABLE COPY

DIRECTIONS FOR USE

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

**ACCEPTED
with COMMENTS
in EPA Letter Dated**

MAR 31

11/04/91 EL031

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

51793-34

5-74

APPLICATION USE:

- *Shake well! Apply undiluted to dry hair and scalp or any other 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. Do not exceed two consecutive applications within 24 hours.

TO PREVENT REINFESTATION:

To avoid reinfestation with head, public 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 - 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 degrees 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.

494

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.

STORAGE: Do not transport or store below 32 degrees Fahrenheit.

DISPOSAL: Do not re-use container. Wrap and put in trash.

PRECAUTIONARY STATEMENTS

CAUTION

Hazards to Humans & Domestic Animals

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 feed or foodstuffs. Keep out of reach of children.

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 sensitive persons.

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