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JUN 16 1986

Mr. Frank P. Bisceglie
Director, Drug Regulatory Affairs
Norcliff Thayer, Inc., Revlon Health Care Group
303 South Broadway
Tarrytown, NY 10591

Dear Mr. Bisceglie:

Subject: Amendment - Formulation and Labeling Revisions
A-200 Pyrinate Liquid Pediculicide Shampoo
EPA Registration No. 39159-2
Your Applications Dated August 27, 1985, January 30 and
February 18, 1986

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:

1. Delete the colon after the signal word and place "For external use only" elsewhere on the front panel or beneath the word "Warning."
2. Add the following Statement of Practical Treatment to the front panel:

Statement of Practical Treatment

If in Eyes: Flush with plenty of water. Get medical attention.

If Swallowed: Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching the back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

3. Add the following referral statement to the front panel:

Refer to back panel for additional precautionary statements.

50572:LaRocca:LR-7:KENC0:6/11/86:6/17/86:dej:vo

CONCURRENCES

SYMBOL ▶							
SURNAME ▶							
DATE ▶							

4. Revise your precautionary paragraph on back panel to read as follows:

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

Warning: May cause eye injury. Do not get in eyes or permit contact with mucous membranes. Harmful if swallowed. Wash thoroughly after handling. Do not leave children unattended with product on their heads. NOT TO BE USED BY PERSONS ALLERGIC TO RAGWEED. If skin irritation or infection is present or develops discontinue use and consult a physician.

5. The Ingredient Statement must appear on the front panel.
6. Refer to comment 3a of our January 15, 1985 letter and delete the phrase "Maximum Strength Formula." Note our comment about the use of the word "new."
7. Add the heading "Storage and Disposal" above your storage and disposal instructions.
8. The names of the inert ingredients are not required to be given in the Ingredient Statement; however, if they are given then all must be listed.
9. Delete the distributor number 37677. The Registration Number as registered by the basic registrant is 39159-2. You may add distributor numbers after the labeling for the basic registrant is accepted.
10. Immediately above the Directions for Use add the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

Please note that the above comments apply both to the carton and container labels.

In regard to the information pamphlet, change the warning instructions to reflect the revisions indicated in comment 4 above. Also, delete the word "safe" as stated in comment 3b of our January 15, 1985 letter.

For your information, the additional toxicity data submitted with your August 27, 1985 letter were assigned EPA Accession Number 259167.

Submit five (5) 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 yours,

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

Enclosure

LABELING COPY FOR 2 FL. OZ. AND 4. FL. OZ. IS IDENTICAL

FOLDING CARTON

FRONT PANEL

NEW IMPROVED
MAXIMUM STRENGTH FORMULA

A-200
PYRINATE®

PEDICULICIDE
SHAMPOO

KILLS
HEAD, BODY & CRAB
LICE
AND THEIR EGGS

Special COMB
& INFORMATION PAMPHLET INSIDE

KEEP OUT OF REACH OF CHILDREN.

WARNING: FOR EXTERNAL USE ONLY.

4 FL. OZ. INSTRUCCIONES EN ESPANOL ADJUNTAS

RECEIVED
with COMMENTS
in EPA Letter Dated

JUN 16 1986

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
39159-2

30 11 7

LABELING COPY FOR 2 FL. OZ. AND 4. FL. OZ. IS IDENTICAL

FOLDING CARTON

BACK PANEL

DIRECTIONS FOR USE: 1. Apply A-200 Pyrinat Shampoo to dry hair and scalp or any other infested areas. Use enough product to completely wet area being treated. Massage in to allow for total contact of product with infested area. (For head lice, avoid getting product into eyes. Helpful hint: When shampooing a child's head, place towel across forehead.) 2. Allow product to remain for 10 minutes, but no longer. 3. Rinse treated area thoroughly with warm water. Towel dry. 4. Use special fine-tooth comb provided to remove dead lice and eggs. (See left side panel for combing suggestions.) 5. Repeat treatment in 7-10 days. Repeat earlier if examination discloses reinfestation has occurred. Do not use more than two applications of A-200 Pyrinat shampoo in 24 hours. When used on children, adult supervision is recommended.

ADDITIONAL CONTROL MEASURES: At time of shampoo treatment, all infested clothing, bed linen and other articles should be laundered in hot water or dry cleaned. Carpets, upholstery and mattresses should be vacuumed thoroughly. Combs and brushes should be soaked in hot water (above 130°F) for 5 to 10 minutes.

WARNING: NOT TO BE USED BY PERSONS ALLERGIC TO RAGWEED. DO NOT USE NEAR EYES OR PERMIT CONTACT WITH MUCOUS MEMBRANES. IF PRODUCT SHOULD GET INTO EYES, DO NOT RUB AND IMMEDIATELY FLUSH WITH PLENTY OF CLEAR WATER. CONTACT WITH EYES MAY CAUSE TEMPORARY IRRITATION. DO NOT LEAVE CHILDREN UNATTENDED WITH PRODUCT ON THEIR HEADS. HARMFUL IF SWALLOWED. DO NOT INHALE. IF SKIN IRRITATION OR INFECTION IS PRESENT OR DEVELOPS, DISCONTINUE USE AND CONSULT A DOCTOR.

Store at room temperature. Do not reuse empty bottle. Wrap and put in trash. See bottom of carton for lot number and expiry date.

ACTIVE INGREDIENTS: Pyrethrins 0.33%, Piperonyl butoxide technical 4%*.

INERT INGREDIENTS: Benzyl Alcohol, Butyl Stearate, Fragrance, Octoxynol-9, Oleic Acid, Oleoresin Parsley Seed, Petroleum Distillate, Water.

*Equivalent to 3.2% (butylcarbityl)(6 propylpiperonyl) ether and 0.8% related compounds.

EPA REG. NO. 39159-2-37677

EPA EST. 39159-PR-1

Manufactured by USV (P.R.) Development Corp., Manati, P.R. 00701
Distributed by NORCLIFF THAYER INC., Tarrytown, NY 10591

20804 2/1

LABELING COPY FOR 2 FL. OZ. AND 4. FL. OZ. IS IDENTICAL

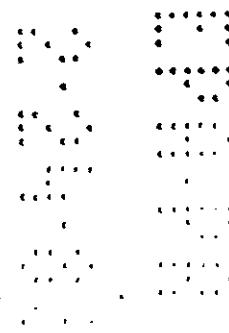
FOLDING CARTON

LEFT SIDE PANEL

A-200
P Y R I N A T E

EFFECTIVE REMOVAL
OF LICE EGGS FROM HAIR:

1. After shampooing with A-200 Pyrinate, towel dry hair.
2. Use regular comb to remove tangles.
3. Using special, precision comb enclosed in this package, comb small sections of hair at a time. Use repeated strokes to remove all nits.
4. To clean comb, use a small brush under forceful stream of hot water.
5. As added sanitary aid, soak combs and brushes in hot water (above 130°F) for 5 to 10 minutes.

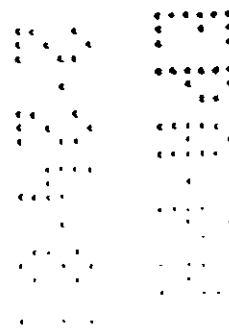


LABELING COPY FOR 2 FL. OZ. AND 4. FL. OZ. IS IDENTICAL

FOLDING CARTON

RIGHT SIDE PANEL

A-200
P Y R I N A T E



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LABELING COPY FOR 2 FL. OZ. AND 4. FL. OZ. IS IDENTICAL

IMMEDIATE CONTAINER LABEL - FRONT

A-200
PYRINATE ©

PEDICULICIDE
SHAMPOO

KILLS HEAD, BODY AND CRAB LICE
AND THEIR EGGS

KEEP OUT OF REACH OF CHILDREN
WARNING: FOR EXTERNAL USE ONLY

4 FL. OZ.

5 5

LABELING COPY FOR 2 FL. OZ. AND 4. FL. OZ. IS IDENTICAL

IMMEDIATE CONTAINER LABEL - BACK

DIRECTIONS FOR USE: 1. Apply A-200 Pyrinat Shampoo to dry hair and scalp (or other infested areas) to completely wet area being treated. Massage in. (For head lice, avoid getting product into eyes. Helpful hint: When shampooing a child's head, place towel across forehead.) 2. Allow product to remain for 10 minutes, but no longer. 3. Rinse treated area thoroughly with warm water. Towel dry. 4. Comb hair with fine-tooth comb to remove dead lice and eggs. 5. Repeat treatment in 7-10 days. Repeat earlier if examination discloses reinfestation has occurred. Do not use more than 2 applications of A-200 Pyrinat Shampoo in 24 hours. When used on children, adult supervision is recommended.

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*Equivalent to 3.2% (butylcarbityl)(6 propylpiperonyl) ether and 0.8% related compounds.

EPA REG. NO. 39159-2-37677

EPA EST. 39159-PR-1

Manufactured by USV (P.R.) Development Corp., Manati, P.R. 00701
Distributed by NORCLIFF THAYER INC., Tarrytown, NY 10591

La solución al problema de los piojos

con el uso de
A•200
PYRINATE®
champú pediculicida



**Mata a los piojos
y sus huevos**

La presencia de las *ladillas* se manifiesta por picazón en el pubis. Algunas veces se notan marcas azuladas de picaduras en estas mismas partes del cuerpo.

La presencia de *piojos del cuerpo* se manifiesta por la picazón intensa en el cuerpo, las piernas o los brazos de la persona infestada. A menudo, pequeñas marcas rojizas de picazón en los hombros, entre éstos o alrededor del talle.

COMO TRATAR TODOS LOS TRES TIPOS DE PIOJOS CON EL USO DEL CHAMPÚ A-200 PYRINATE.

La eliminación sin riesgo de los piojos se consigue con un tratamiento de 10 minutos con el champú A-200 Pyrinate. Este producto mata los

TIPOS DE PIOJOS QUE INFESTAN A LOS SERES HUMANOS

El piojo de la cabeza es el tipo de piojo más común. Generalmente se encuentra en los cabellos finos de la cabeza y en el cuero cabelludo. Millones de niños de edad escolar se contagian de piojos todos los años. No hay por qué avergonzarse ni turbarse. Los piojos de la cabeza no son señal de falta de limpieza de su hijo ni de su casa. La infestación puede eliminarse fácilmente con el champú A-200 Pyrinate: un efectivo y seguro tratamiento de champú.

Las ladillas se posan en el pubis. *El piojo del cuerpo* se encuentra generalmente en las costuras de la ropa.

CONTAGIO

Los piojos de la cabeza se con-

tactan físicamente entre personas o por contacto con objetos de uso personal (como decir peines, cepillos, sombreros, bufandas, ropa de cama y tapizado de los muebles) que han estado en contacto con una persona infestada.

Las ladillas generalmente se contagian por relaciones sexuales y, a veces por la ropa de cama o por el asiento del inodoro.

Los piojos del cuerpo se contagian por contacto entre una persona y otra o por contacto con ropa personal o ropa de cama infestadas.

CÓMO DESCUBRIR LOS PIOJOS QUE INFESTAN A LOS SERES HUMANOS

La presencia de los piojos en la cabeza se manifiesta general-

mente por la picazón en la cabeza, picazón en las pequeñas marcas azules en el cuerpo, los brazos y las piernas. Es probable que usted pueda ver a simple vista los piojos o los huevos, que son pequeños granos de azúcar surtidos de los cuernos de los cuernos cabelludos.



Huevos de piojo sobre los cabellos ven a través de los puntos de pote-

Instrucciones para el uso:

1. Aplíquese el champú A-200 Pyrinate al cabello y el cuero cabelludo o cualquier otras partes infestadas cuando están secas. Use suficiente cantidad del producto para mojar completamente la zona tratada. Además obteniendo contacto completo del producto con la zona infestada por medio de masajes. (Para piojos de la cabeza evite contacto del producto con los ojos. Consejo útil: aplicando el champú a la cabeza de un niño póngale una toalla cruzando la frente.)
2. Déje que el champú permanezca por 10 minutos cuanto más.
3. Enjuague cuidadosamente con agua caliente la zona tratada. Séquese con una toalla. Use un peine común para desenredar el cabello.
4. Use el peine de precisión especial suministrado, peinando secciones pequeñas cada vez. Repita las pasadas del peine para remover todos los huevos. Limpie el peine con un cepillo pequeño bajo una

corriente de agua caliente, remoje el peine en agua caliente (de más de 130°F o 54,4°C) de 5 a 10 minutos

5. Repita el tratamiento en 7 a 10 días.

No use más de dos tratamientos de champú A-200 Pyrinate en 24 horas. Cuando es usado por niños la supervisión de un adulto es aconsejable.

Medidas adicionales de control: Cuando descubre piojos en un miembro de la familia, los otros miembros de la familia deben examinarse inmediatamente, y recibir tratamiento si es necesario. Durante el tratamiento todas las vestimentas, ropas de cama y otros artículos personales deben lavarse en agua caliente (aproximadamente 130°F o 54,4°C) o limpiados a seco. Alfombras, tapizados y colchones deben limpiarse bien con una aspiradora eléctrica. Para los piojos de cabeza, peines y cepillos deben enjuagarse en agua caliente (aproximadamente 130°F o 54,4°C) de 5 a 10 minutos.

Advertencia: No debe ser usado por personas alérgicas al polen de Ambrosía.

Mantenga este producto fuera del alcance de los niños. Evite el contacto con los ojos, nariz y boca. No permita contacto con las mucosas.

Irritación temporal: Si el producto permanece en la piel por mucho tiempo, puede causar irritación. Lave con mucha agua por mucho tiempo. No se debe aplicar en las heridas o en las irritaciones de la piel. Evite la infección con el uso de este producto.

Para uso externo: (Guárdese a la temperatura ambiente en su caja original)