

MATA PIOJOS A PEDICULICIDE LOW FOAMING- pyrethrum extract, piperonyl butoxide shampoo

Apex International Mfg

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

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Active Ingredients Purpose

Pyrethrins 0.33%

Piperonyl Butoxide 4%.....Pediculicide

Uses

For the treatment of Head, Body, Pubic (Crab) Lice.

Warnings

For external use only.

Allergy alert:

Use with caution on persons allergic to ragweed.

Do not use

- near eyes or permit contact with mucous membranes, such as inside the nose, mouth, or vagina.

Ask a doctor before use if you have

- Skin irritation or infection
- Infected eyebrows or eyelashes

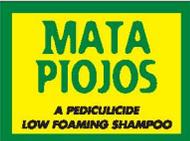
Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center immediately.

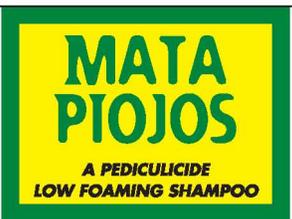
Directions

- **SHAKE WELL BEFORE USE**
- Use on DRY hair.
- Apply to affected area until all hair is thoroughly wet with product
- Allow product to remain on for 10 minutes but no longer.

100%

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150%

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ACTIVE INGREDIENTS:

Pyrethrum Extract equivalent to 0.33% Pyrethrins

Piperonyl Butoxide 4% equivalent to min. 3.2%

(butylcarbityl)(6-propylpiperonyl) ether and 0.8% related compounds.

MATA PIOJOS A PEDICULICIDE LOW FOAMING

pyrethrum extract, piperonyl butoxide shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:5750 1-865
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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PROOF

THIS PROOF IS TO CHECK FOR ACCURACY

Please review and approve: Copy, spelling, copy placement, size, shape, colors, unwind, and dieline. Authorized signature accepts responsibility for accuracy of all copy, color break and artwork. Lofton Label, Inc. is not liable for any discrepancies subsequently identified.

If proof is correct, check "O.K. AS IS", sign and return proof to expedite order. If corrections are necessary, check "Revised Proof Needed".

WE CAN NOT PROCESS THIS ORDER WITHOUT AN AUTHORIZED SIGNATURE

- O.K. AS IS
- REVISED PROOF NEEDED

Signed _____

Date _____

Please Return To: Trish

LOFTON LABEL, INC.

(651) 457-8118 • FAX (651) 457-3709

6290 Claude Way E., Inver Grove Hts., MN 55076

JOB # 50498 DATE 3/3/03

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Size: 2.5" x 4.5" RCR

Dieline does not print.

Unwind:  **ROF-LO**

Rev. #1

Colors:

- 1 - Black
- 2 - PMS 356 Green
- 3 - Process Yellow

Pyrethrum Extract (UNII: ZUM06L90GV) (Pyrethrum Extract - UNII:ZUM06L90GV)	Pyrethrum Extract	.12 g in 60 g
Piperonyl Butoxide (UNII: LWK91TU9AH) (Piperonyl Butoxide - UNII:LWK91TU9AH)	Piperonyl Butoxide	2.4 g in 60 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	39.78 g in 60 g
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	14.2 g in 60 g
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	3.5 g in 60 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57501-865-02	60 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358G	04/23/2010	

Labeler - Apex International Mfg (015226132)

Registrant - Apex International Mfg (015226132)

Establishment

Name	Address	ID/FEI	Business Operations
Apex International Mfg		015226132	manufacture

Revised: 4/2010

Apex International Mfg