

13799-20

05/15/2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

MAY 15 2003

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Haley Birk  
Four Paws Products, Ltd.  
50 Wireless Blvd.  
Hauppauge, NY 11788

Dear Sir or Madam:

Subject: Four Paws Ear Mite Remedy  
EPA Reg. No. 13799-20  
Submission dated 2/14/03

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. One copy of the finished labeling must be submitted prior to releasing the product for shipment.

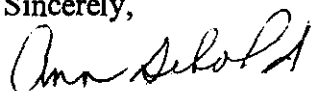
Add a footnote to the ingredient statement as follows:  
Contains petroleum distillate.

The If Swallowed first aid statement must be revised as follows:  
If Swallowed: Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.

Add a Note to Physician as follows:  
Contains petroleum distillate – vomiting may cause aspiration pneumonia.

If you have questions, please call Ann Sibold at 703 305-6502.

Sincerely,

  
for Marion J. Johnson, Jr.

Product Manager 3  
Insecticide Branch  
Registration Division (7505C)

FRONT LABEL  
FOUR PAWS EAR MITE REMEDY  
EPA REG. NO. 13799-20

ACCEPTED  
with COMMENTS  
In EPA Letter Dated:  
**MAY 15 2003**

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
13799-20

Four Paws®  
Ear Mite Remedy  
For Dogs & Cats

Contains the Grooming Ingredient Aloe Vera

Effective in Killing Ear Mites

**Active Ingredients:**

Pyrethrins.....	0.10%
*Piperonyl butoxide, technical.....	1.05%

**Inert Ingredients:**.....

98.85%
100.00%

\*Equivalent to 0.84% (butylcarbityl) (6-Propyl piperonyl) ether and 0.21% related compounds.

**KEEP OUT OF REACH OF CHILDREN.  
CAUTION**

Net . Wt. 3/4 oz. (22 cc)

BACK LABEL  
FOUR PAWS EAR MITE REMEDY  
EPA REG. NO. 13799-20

**READ ENTIRE LABEL BEFORE EACH USE  
USE ONLY ON DOGS AND CATS**

Four Paws®  
EAR MITE REMEDY  
For Dogs and Cats  
Contains the Grooming Ingredient Aloe Vera

**FOUR PAWS EAR MITE REMEDY KILLS EAR MITES AND CONTAINS THE GROOMING INGREDIENT ALOE VERA. IT ALSO AIDS IN WAX REMOVAL.**

**DIRECTIONS FOR USE** It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**FOR EXTERNAL USE ONLY  
SHAKE WELL BEFORE USING**

**To Kill Ear Mites and Aid in the Removal of Ear Wax:** Apply 5 drops of solution in ear and gently massage base of ear for 3-5 minutes. Leave solution in ear for another few minutes and the allow dog or cat to shake its head to remove as much solution as possible. Wipe the remainder of the liquid from the ear with cotton. Repeat treatment every other day until condition is relieved. Improvement is usually noted after two applications. This solution applied twice monthly will reduce the possibility of ear mite infestation and the accumulation of ear wax. Do not use on puppies or kittens under 12 weeks of age. Consult a veterinarian before using this product on debilitated, aged, pregnant or nursing animals, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

**DIAGNOSIS**

Ear mites normally cause a dry, dark, brown, waxy, exudate with crust in the ears of dogs. The mites are easily observed by placing some of the ear exudate on a dark surface and watching carefully for white specks walking away. DO NOT probe, swab or injure the delicate tissue of the ear when removing exudate. Inflamed, watery or blocked ear canals indicate a more serious condition which requires the services of a veterinarian.

**PRECAUTIONARY STATEMENTS**

**Hazards to Humans and Domestic Animals:** Harmful if swallowed. Avoid contact with skin and eyes. Do not contaminate food or feedstuffs with this solution. Do not use for prolonged periods of time. If condition persists or if irritation develops, discontinue use and consult a veterinarian.

**Environmental Hazards:** This product is toxic to fish, birds and other wildlife. Do not contaminate any body of water with this solution.

**Physical Hazards:** Do not store or use near heat or open flame.

**FIRST AID**

**If on skin or clothing:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

**If in eyes:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**If swallowed:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. In case of emergency or for product use information, call (631) 434-1100 9AM-5PM EST, Monday through Friday.

**STORAGE AND DISPOSAL**

**Storage:** Store in a cool, dry area away from heat or open flame.

**Disposal: If empty:** Do not reuse this container. Place in trash or offer for recycling if available.

**If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

**THIS IS ANOTHER QUALITY PRODUCT FROM:  
STEPHEN'S PHARMACEUTICAL CO., A DIVISION OF**

Four Paws® Products, Ltd.  
Hauppauge, NY 11788-USA  
Item No. 01730  
EPA Reg. No. 13799-20  
EPA Est. No. 43395-NY-1

UPC CODE

Made in U.S.A.