



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 25, 2018

James McFadden, Ph.D.
Central Garden & Pet
For Four Paws Products LTD.
1501 E. Woodfield Rd. Suite 200 West
Schaumburg, IL 60173

Subject: Amended Reregistration Label
Product Name: FOUR PAWS EAR MITE REMEDY FOR DOGS & CATS
EPA Registration Number: 13799-20
Decision Number: 410345, 412505

Dear Dr. McFadden:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the reregistration of the above referenced product in connection with the Pyrethrins and Piperonyl Butoxide RED, and has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

NOTE: This product is **not** yet being reregistered under section 4(g) of FIFRA.

Please note that the record for this product currently contains the Confidential Statement of Formulation (CSF) listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated 01/23/2014

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

A copy of your label stamped "Accepted" is enclosed. Products shipped after 12 months from the date of this amendment or the next printing of the label, whichever occurs first, must bear the new revised label. Your release for shipment of the product bearing the amended label

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constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions about this letter, please contact Helen Hull-Sanders by phone at 703-347-0243, or via email at hull-sanders.helen@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "EF" followed by a flourish, and the word "for" written to the right.

Elizabeth Fertich, Product Manager 4
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Enclosure

FRONT LABEL
FOUR PAWS EAR MITE REMEDY
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:

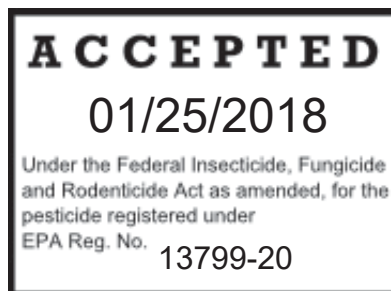
Pyrethrins.....	0.10%
*Piperonyl butoxide,.....	1.05%
Inert Ingredients**:	<u>98.85%</u>
	100.00%

**Contains Petroleum Distillate

* (butylcarbityl) (6-Propyl piperonyl) ether and 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.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: CAUTION: Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before, eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before use.

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.

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: Immediately call a poison control center or doctor. Do not induce vomiting unless told so 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. Note to Physician: Contains petroleum distillate – vomiting may cause aspiration pneumonia.

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.

Environmental Hazards:

This product is toxic to fish, birds and other wildlife. Do not contaminate any body of water with this solution. Do not apply directly into sewers or drains, water bodies, or aquatic habitat can occur. Do not allow the product to enter any drain during or after application.

Physical Hazards:

Do not store or use near heat or open flame.

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.

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.

STORAGE AND DISPOSAL

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

Container Handling: Nonrefillable container. Do not reuse this container. **If empty:** Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Four Paws® Products, Ltd.
1501 E. Woodfield Rd., Ste 200 West
Schaumburg, IL 60173

Item No. 01730
EPA Reg. No. 13799-20
EPA Est. No. _____
Batch/Lot No. _____
Made in U.S.A.