

PM 03

1903-28

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"NOTIFICATION"

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number
265511

Application for Pesticide - Section I

1. Company/Product Number 1903-28	2. EPA Product Manager Mr. Marion J. Johnson, Jr.	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) 8 IN 1 Ear Mite Remedy	PM# 103	
5. Name and Address of Applicant (Include ZIP Code) 8 IN 1 Pet Products, Inc. 2100 Pacific Street Hauppauge, NY 11788-4737 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 1903-28 Product Name 8 IN 1 Ear Mite Remedy	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated	NOTIFICATION JUL - 9 1999
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.	
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.	

Explanation: Use additional page(s) if necessary. (For section I and Section II.) Notification of Label Change per PR Notice 98-10 (IV-A). This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 oz. to 1 gallon		5. Location of Label Directions <input checked="" type="checkbox"/> On Label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled				<input checked="" type="checkbox"/> Other Pressure Sensitive	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Alfred V. Boaro	Title Director of Research & Development	Telephone No. (Include Area Code) (516) 232-1200
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Director of Research & Development	
4. Typed Name Alfred V. Boaro	5. Date June 16, 1999	

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EIGHT IN ONE PET PRODUCTS, INC.
2100 PACIFIC STREET
HAUPPAUGE, NY 11788-4737
TEL: 516. 232.1200 • FAX: 516. 232.1206

June 23, 1999

Document Processing Desk (NOTIFICATION)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460-0001

Subject: 8 IN 1 Ear Mite Remedy
EPA Registration No. 1903-28
Notification Submission

Gentlemen:

Enclosed please find the 8 IN 1 Pet Products, Inc. EPA Application for Pesticide for the subject product.

Included is a copy of the label clearly marking the typographical error which omitted the words "And Ticks" in the DIRECTIONS FOR USE heading. We believe this registration amendment may be accomplished by notification as outlined in PR Notice 98-10 Section IV.A.

If there are any questions, please contact me. Your attention and cooperation would be greatly appreciated in this matter.

Sincerely,

Alfred V. Boaro
Director of Research & Development

AVB/nt
Attachments: EPA Application for Pesticide
Front Label
Back Label with marked changes

3044

NOTIFICATION

JUL - 9 1999

**8 IN 1
EAR MITE REMEDY**

FOR DOGS, PUPPIES, CATS, KITTENS and RABBITS
KILLS EAR MITES
KILLS EAR TICKS
AIDS IN EAR WAX REMOVAL
CONTAINS ALOE AND LANOLIN

ACTIVE INGREDIENTS:

Pyrethrins	0.06%
*Piperonyl Butoxide, Technical	0.60%
INERT INGREDIENTS:	99.34%
Total	100.00%

*Equivalent to 0.48% of Butylcarbityl 6-propylpiperonyl ether and 0.12% of related compounds.

**KEEP OUT OF REACH OF CHILDREN
CAUTION
See Back Panel for Precautionary Statements**

Manufactured by:
8 IN 1 Pet Products, Inc.
Hauppauge, NY 11788-4737
(800) 342-3449

EPA Est. 1903-NY-01

EPA Reg. No. 1903-28

Net Contents: 1 Fl. Oz. (29.5ml)

Ear mites usually induce the formation of a dry, dark brown, waxy exudate with crusts in the ears of pets. Ear mites may be detected by placing some of the ear exudate on a dark surface and carefully watching for the movement of tiny white specks away from the exudate. Inflamed, watery or blocked ear canals indicate a more serious condition which requires the services of a veterinarian.

DIRECTIONS FOR USE

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

**READ ENTIRE LABEL BEFORE EACH USE.
USE ONLY ON DOGS, PUPPIES, CATS, KITTENS AND RABBITS**

To Kill Ear Mites And Ticks: Clean ears to remove build up of wax and dirt. While firmly holding pet, and avoiding contact with pet's eyes, carefully fill the ear canal with approximately 1-10 drops depending on the size of the pet. Massage base of ear for a few minutes to permit penetration of the ear wax by the solution. Allow pet to shake its head to remove as much solution as possible. Wipe excess from the ear with cotton. Repeat treatment every other day until condition has cleared up or as directed by your veterinarian. If no improvement is seen, consult a veterinarian. This solution applied twice monthly will reduce the possibility of ear mite infestation and the accumulation of ear wax.

STORAGE AND DISPOSAL

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

Disposal: Do not reuse empty container. Wrap and put in trash.

**PRECAUTIONARY STATEMENT
Hazards to Humans and Domestic Animals
CAUTION**

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling. Do not apply directly to food or contaminate food or feedstuffs with this product.

For external use only. Do not use for a prolonged period of time. Not for use on puppies, kittens or rabbits less than 12 weeks old. If condition for which this preparation is used persists or if an irritation develops, discontinue use and consult a veterinarian.

Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing or medicated animals. 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 Swallowed: Call a doctor or get medical attention. Do not induce vomiting. Do not give anything by mouth to an unconscious person. Avoid alcohol.

If on Skin: Wash with plenty of soap and water. Get medical attention if irritation persists.

If in Eyes: Flush eyes with plenty of water. See a physician if irritation persists.

If Inhaled: Remove victim to fresh air.