



773-87

1/11/2002

115

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
259579

Application for Pesticide - Section I

1. Company/Product Number 773-87	2. EPA Product Manager George LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Aurimite	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Schering-Plough Animal Health Corp. 1095 Morris Avenue Union, NJ 07083 <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. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<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 to amend label text.

NOTIFICATION

JAN 11 2002

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 checked="" type="checkbox"/> Yes 1 fl. oz. <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 fl. oz. & 16 fl. oz.		5. Location of Label Directions <input checked="" type="checkbox"/> 1 oz- on label accompanying product: 16 oz- on label	
6. Manner in Which Label is Affixed to Product silk screened bottles			<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name W. Stephens Walker	Title Manager, Regulatory Affairs	Telephone No. (Include Area Code) 908.629.3520
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 Manager, Regulatory Affairs	
4. Typed Name W. Stephens Walker	5. Date 20 January 2002	

EPA Form 8570-1 (Page 2 of 2)

Aurimite®

Explanation: This Amendment / Notification of changes the word "Contains" to "Active Ingredients" pursuant to 40 CFR 156.10 (g) (1).and is made pursuant to PR Notice 98-10 and EPA regulations 40 CFR 152.46 and is consistent with both PR Notice 98-10 and EPA regulations 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 this is a violation of 18 U.S.C. Sec 1001 to willfully make any false statements to the EPA. I further understand that if this amendment/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 actions and penalties under sections 12 and 14 of FIFRA.

Signature: _____
Date: _____
Title: _____
Company: _____
Address: _____
City: _____
State: _____
Zip: _____

3/5

10/23/01 • SPAH • 3-1/2" x 1-5/8" • ART IS AT 100% • OUTPUT 100%
 • PDR #10439 • RIC# 13509042 • ELECTRONIC MECH. BY AM

FINAL
 APPROVED
 LASER

NOTIFICATION
 JAN 1 1 2002

13509042
Rev. 3/01

Aurimite[®]
Insecticide E-02

For use as an aid in controlling ear mites in the ears of dogs and cats.
 Active ingredients: 0.04% pyrethrins, 0.45% piperonyl butoxide technical.*
 *Equivalent to 0.332% of (butylcarbyl) (6-propylpiperonyl) ether and 0.098% of related compounds.

Use Only On Dogs and Cats.

KEEP OUT OF REACH OF CHILDREN

 Schering-Plough Animal Health

DO NOT REMOVE CONTAINER FROM CARTON EXCEPT FOR IMMEDIATE USE.

CAUTION: Refer to shelf carton for Caution and Precaution information.

EPA Est. 2808-CA-1 EPA Reg. No. 773-87
 Distributed by Schering-Plough Animal Health Corp., Union, NJ 07093
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DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Shake well before using. Cleanse ear thoroughly. Apply the recommended drops into ears twice daily for 7 to 10 days. Repeat treatment in 2 weeks if necessary.

Body Weight	Dosage
5 to 15 lbs	4 to 5 drops
15 to 30 lbs	5 to 10 drops
30 lbs or over	10 to 15 drops

PACKAGING COMPONENT APPROVAL

SUBMISSION # **3**

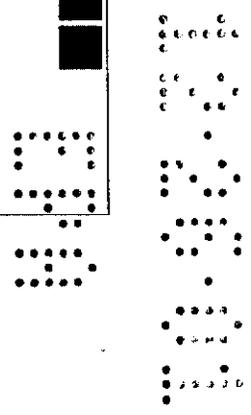
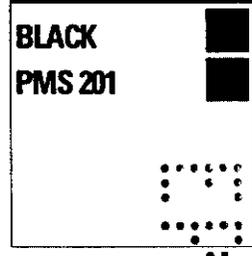
EXAMINE BLACK & WHITE COPY AND ACCOMPANYING COLOR BREAK.

	APPROVED	NOT APPROVED	DATE
DESIGNER	<input type="checkbox"/>	<input type="checkbox"/>
COPY EDITOR	<input type="checkbox"/>	<input type="checkbox"/>
MEDICAL	<input type="checkbox"/>	<input type="checkbox"/>
TRADEMARKS	<input type="checkbox"/>	<input type="checkbox"/>
PACKAGING	<input type="checkbox"/>	<input type="checkbox"/>
SPECIFICATIONS	<input type="checkbox"/>	<input type="checkbox"/>
MARKETING	<input type="checkbox"/>	<input type="checkbox"/>
REGULATORY	<input type="checkbox"/>	<input type="checkbox"/>

ART DUE DATE: INV. LOCATION:

SQA:
 APPROVAL VERIFIED: DATE:

PANTONE COLORS



PANTONE COLORS	
BLACK	
PMS 201	

PACKAGING COMPONENT APPROVAL

SUBMISSION # **2**

EXAMINE BLACK & WHITE COPY AND ACCOMPANYING COLOR BREAK

	APPROVED	NOT APPROVED	DATE
DESIGNER	<input type="checkbox"/>	<input type="checkbox"/>	_____
COPY EDITOR	<input type="checkbox"/>	<input type="checkbox"/>	_____
MEDICAL	<input type="checkbox"/>	<input type="checkbox"/>	_____
TRADEMARKS	<input type="checkbox"/>	<input type="checkbox"/>	_____
PACKAGING	<input type="checkbox"/>	<input type="checkbox"/>	_____
SPECIFICATIONS	<input type="checkbox"/>	<input type="checkbox"/>	_____
MARKETING	<input type="checkbox"/>	<input type="checkbox"/>	_____
REGULATORY	<input type="checkbox"/>	<input type="checkbox"/>	_____

ART DUE DATE: _____ INV. LOCATION: _____

SDA: _____
APPROVAL VERIFIED: _____ DATE: _____

12/22/00 • AURIMITE FC-12
RIC #13511756 • PDR #00680
7-13/16" x 5-1/8" • OUTPUT @ 100%

Aurimite[®] Insecticide

DIE2055

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

CAUTION: Harmful if swallowed. Avoid inhalation of vapors. Avoid contact with skin. Avoid contact with eyes. Flush eyes with plenty of water. Get medical attention if irritation persists. Wash contaminated skin promptly with soap and water. Avoid contamination of food and water.

Discontinue use and consult a veterinarian if infestation persists.

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.

STORAGE AND DISPOSAL: Store in original bottle in locked storage area. Do not reuse bottle. Rinse thoroughly before discarding in trash.

FIRST AID

If on skin or clothing	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 further treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling the poison control center or doctor, or going for treatment. You may also contact the Rocky Mountain Poison Center at 1-303-595-4869 for emergency medical treatment information.

0061-0733-01

Aurimite[®] Insecticide

For use as an aid in controlling ear mites in the ears of dogs and cats.

ACTIVE INGREDIENTS: 0.04% pyrethrins, 0.49% piperonyl butoxide technical.*

OTHER INGREDIENTS: 99.47%

*Equivalent to 0.32% of (butylcarbitol) (8-propylpiperonyl) ether and 0.65% of related compounds.

Read Entire Label Before Each Use. Use Only On Dogs and Cats.

KEEP OUT OF REACH OF CHILDREN
CAUTION: See rear panel for additional precautions and first aid.

EPA Reg. No. 773-87 12-1 FL. OZ BOTTLES EPA Est. No. 29909-CA-1

Schering-Plough Animal Health

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Shake well before using. Cleanse ear thoroughly. Apply the recommended drops into ears twice daily for 7 to 10 days. Repeat treatment in 2 weeks if necessary.

Body Weight	Dosage
5 to 15 lbs	4 to 5 drops
15 to 30 lbs	5 to 10 drops
30 lbs or over	10 to 15 drops

Do not reapply product for 2 weeks. Do not use on dogs or cats under 12 weeks of age.



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LOT CODING AREA
NO VARNISH

NO
VARNISH

GLUE STRIP

NO

VARNISH

NOTIFICATION
JAN 11 2002

4/5

5/5

12/22/00 • AURIMITE LABEL • RIC #13508950 • PDR #00679
7-13/16" x 5-1/8" • OUTPUT 100%

NOTIFICATION

JAN 11 2002

0061-0733-03

Aurimite[®] Insecticide

For use as an aid in controlling ear mites in the ears of dogs and cats.

ACTIVE INGREDIENTS: 0.04% pyrethrins, 0.49% piperonyl butoxide technical.*

OTHER INGREDIENTS: 99.47%

*Equivalent to 0.392% of (butylcarbityl) (6-propyl-piperonyl) ether and 0.098% of related compounds.

Read Entire Label Before Each Use.
Use Only On Dogs and Cats.

KEEP OUT OF REACH OF CHILDREN
CAUTION: See rear panel for additional precautions and first aid.

EPA Reg. No. 773-87

EPA Est. No. Z9309-CA-1

16 FL OZ (1 PT)



Schering-Plough Animal Health

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Shake well before using. Cleanse ear thoroughly. Apply the recommended drops into ears twice daily for 7 to 10 days. Repeat treatment in 2 weeks if necessary.

Body Weight	Drops
5 to 10 lbs	4 to 5 drops
10 to 20 lbs	5 to 10 drops
20 lbs or over	10 to 15 drops

Do not reapply product for 2 weeks.
Do not use on dogs or cats under 12 weeks of age.
Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing animals, or animals on medication.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed. Avoid inhalation of vapors. Avoid contact with skin. Avoid contact with eyes. Flush eyes with plenty of water. Get medical attention if irritation persists. Wash contaminated skin promptly with soap and water. Avoid contamination of food and water.

Seriousness 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 further treatment advice.
NOT RECOMMENDED	
Have the product container or label with you when calling the poison control center or doctor, or going for treatment. You may also contact the Rocky Mountain Poison Center at 1-303-535-4889 for emergency medical treatment information.	

STORAGE AND DISPOSAL: Store in original bottle in locked storage area. Do not reuse bottle. Rinse thoroughly before discarding its contents.

Discontinue use and consult a veterinarian if irritation persists.
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PACKAGING COMPONENT APPROVAL

SUBMISSION # **2**

EXAMINE BLACK & WHITE COPY AND ACCOMPANYING COLOR BREAK

	APPROVED	NOT APPROVED	DATE
DESIGNER _____	<input type="checkbox"/>	<input type="checkbox"/>	_____
COPY EDITOR _____	<input type="checkbox"/>	<input type="checkbox"/>	_____
MEDICAL _____	<input type="checkbox"/>	<input type="checkbox"/>	_____
TRADEMARKS _____	<input type="checkbox"/>	<input type="checkbox"/>	_____
PACKAGING _____	<input type="checkbox"/>	<input type="checkbox"/>	_____
SPECIFICATIONS _____	<input type="checkbox"/>	<input type="checkbox"/>	_____
MARKETING _____	<input type="checkbox"/>	<input type="checkbox"/>	_____
REGULATORY _____	<input type="checkbox"/>	<input type="checkbox"/>	_____

ART DUE DATE: _____ INV. LOCATION: _____

SOA: _____
APPROVAL VERIFIED: _____ DATE: _____

PANTONE COLORS

BLACK

PMS 201

