



773-74

8-5-2002

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

| | |
|-------------------------------------|--------------|
| <input type="checkbox"/> | Registration |
| <input type="checkbox"/> | Amendment |
| <input checked="" type="checkbox"/> | Other |

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|--|--|---|
| 1. Company/Product Number 773-74 | 2. EPA Product Manager George LaRocca | 3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) Saber Pour On Insecticide | 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 _____ | NOTIFICATION AUG 05 2002 |
| <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 labeling as per PR Notice 98-10. Inclusion of clarification of season-long lice control - Season-long lice control from January-April.

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 |
| * Certification must be submitted | | If "Yes" Unit Packaging wgt. | No. per container | <input type="checkbox"/> Glass | <input type="checkbox"/> Paper |
| | | If "Yes" Package wgt. | No. per container | <input type="checkbox"/> Other (Specify) _____ | |
| 3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container 1 gallon, 30 fl oz | | 5. Location of Label Directions <input checked="" type="checkbox"/> | |
| 6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued 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 Diane deBruin | Title Manager, Regulatory Affairs | Telephone No. (include Area Code) 908.629.3598 |
| 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 Diane deBruin | 5. Date July 22, 2002 | |

2/5



Schering-Plough Animal Health

Schering-Plough Animal Health Corporation
1095 Morris Avenue
PO Box 3182
Union, New Jersey 07083-1982
Telephone (908) 298-4000

Mr. George T. LaRocca
Product Manager Team #13
EPA – OPP-RD-IB
Crystal Mall #2, Second Floor
1921 Jefferson Davis Highway
Arlington, VA 22202

July 22, 2002

SUBJECT: Notification of label change for SABER POUR ON INSECTICIDE
(EPARN 773-74) as per PR Notice 1998-10

COMPANY: Schering-Plough Animal Health
1095 Morris Avenue (U-23-3)
Union, NJ 07083-7143

CONTACT: Diane deBruin
Regulatory Affairs Manager

PRODUCT: Saber Pour On Insecticide EPARN 773-74

Dear Mr. La Rocca:

In compliance with 40 CFR 152.46 please find enclosed a label revision for Schering-Plough's Saber Pour On Insecticide. In this label revision we have added the statement on the back label "– Season- long lice control from January-April" to clarify the claim on the front label "Season-long lice Control with One Application".

As this revision does not increase or modify the use of the product for control of lice on cattle, it is in compliance with 40 CFR 152.56.

This modification is consistent with the provisions of 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 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 section 12 and 14 of FIFRA.

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.....

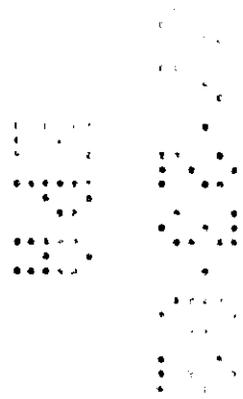
Please provide Schering-Plough with a response that this notification is acceptable (i.e. stamped approved label).

Should you have any questions with this submission, please do not hesitate to contact me by email at diane.debruin@spcorp.com or by phone at (908) 629-3598.

Sincerely,



Diane deBruin B.Sc., M.B.A.
Regulatory Affairs Manager



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3/19/02 • SABER POUR-ON FRONT LABEL • RIC #23590921 • PDR #10539
 5" x 5.5" • OUTPUT @ 100% BY AJU/AM

NOTIFICATION

AUG 05 2002

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: _____



5/5

**3/19/02 • SABER POUR-ON BACK LABEL • RIC #23590824 • PDR #10540
5" x 5.5" • OUTPUT @ 100% BY AJU/AM**

SABER
POUR-ON INSECTICIDE FOR BEEF CATTLE & CALVES

DIRECTIONS FOR USE

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

READY TO USE - No dilution necessary. Do not apply to lactating or dry dairy cows. Do not apply this product to face of beef cattle or calves.

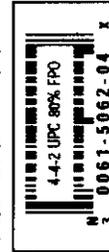
| Apply To | Target Insects | Dosage |
|------------------------|------------------|---|
| Beef Cattle and Calves | Lice, Horn Flies | Apply product down the backline at the rate of Less than 600 lbs 10 mL (1/3 fl oz) Greater than 600 lbs 15 mL (1/2 fl oz) |

Repeat treatment as needed; however, do not apply more than once every 2 weeks and do not apply more often than four times within any 6-month period.

Special Note: SABER™ Pour-On is not recommended for use on weel calves. SABER Pour-On is not effective in controlling cattle grubs. Therefore, this product can be used on cattle at any time of the year without fear of host-parasite reactions commonly associated with grub treatment products. SABER Pour-On should be used in an integrated pest management system, which may involve repeat treatments and the use of other pest control practices. Continual exposure of horn flies to a single class of insecticide, (eg. pyrethroids or organophosphates) may lead to the development of resistance to that class of insecticide. In order to reduce the possibility of horn flies developing resistance, it is important to rotate, on a seasonal basis, the class of insecticide used and/or the method of horn fly control. For advice concerning current control practices with relation to specific local conditions, consult resources in resistance management programs and your Cooperative Agricultural Extension Service.

PRECAUTIONARY STATEMENTS, HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION - Harmful if swallowed, absorbed through the skin, or inhaled. Causes moderate eye irritation. Avoid breathing vapors or spray mist. Avoid contact with skin, eyes, or clothing. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling. Avoid contact with eyes. Wear rubber or nonpermeable protective gloves when applying this product. Data indicate this product to be a contact allergenic. Do not apply product to face of cattle.



FIRST AID

If Inhaled - Move person to fresh air. - If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. - Call a poison control center or doctor for further treatment advice. 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 the poison control center or doctor. - Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER

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

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to fish. Use with care when applying in areas adjacent to any body of water. Do not add directly to water. Do not contaminate water by cleaning of equipment or disposal of rinse water. Apply this product only as specified on the label.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Storage: Keep container sealed when not in use. Do not store near food or feed.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on-site or at an approved waste disposal facility.

Container Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

† Season-long lice control from January-April.

NOTICE OF WARRANTY

SCHERING-PLOUGH ANIMAL HEALTH CORPORATION MAKES NO WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR OTHERWISE EXPRESSED OR IMPLIED, CONCERNING THIS PRODUCT OR ITS USES WHICH EXTEND BEYOND THE USE OF THIS PRODUCT UNDER NORMAL CONDITIONS AND IN ACCORDANCE WITH THE STATEMENTS ON THIS LABEL.



Schering-Plough Animal Health

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PACKAGING COMPONENT APPROVAL

SUBMISSION # **3**

EXAMINE BLACK & WHITE COPY AND ACCOMPANYING COLOR BREAK.

| | APPROVED | NOT APPROVED | DATE |
|----------------|--------------------------|--------------------------|------|
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| 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: _____

