

4691-167

10/18/2005

115

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. 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 4691-167	2. EPA Product Manager George LaRocca	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Clean-up Pour-on Insecticide with IGR	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Boehringer Ingelheim Vetmedica, Inc. 502 S. 15th Street, PO Box 338 Elwood, KS 66024 <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 checked="" type="checkbox"/> Final printed labels in response to Agency letter dated <u>March 10, 2005</u>
<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.

NOTIFICATION  
OCT 18 2005

Explanation: Use additional page(s) if necessary. (For section I and Section II.)  
See following page.

### Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input 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 type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <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 Angela Bishop	Title Regulatory Specialist III, Ectoparasiticides	Telephone No. (Include Area Code) 913-380-3112
<b>Certification</b> 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  <div style="border: 1px solid black; padding: 5px; text-align: center; font-weight: bold;">(Stamped)</div>
2. Signature 	3. Title Regulatory Specialist III, Ectoparasiticides	
4. Typed Name Angela Bishop	5. Date October 11, 2005	

NOTIFICATION

OCT 18 2005

**Clean-up Pour-on Insecticide with IGR, EPA Reg. No. 4691-167****EPA Form 8570-1, Section II, Explanation:**

Notification of the addition of Flies, Lice and Horses in the callouts, addition of "Provides control of chewing and sucking lice" as a bullet, and combination of cattle and horses in the Directions for Use table. Please note that all of these uses have previously been accepted. (See enclosed EPA Stamped "Accepted" label)

In addition, per PR Notice 2001-1, the term HOT LINE NUMER and Note to Physician section have been added since product contains greater than 10% petroleum distillate.

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.

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NOTIFICATION

OCT 18 2005

# Clean-Up™

Pour-on  
Insecticide  
with IGR

- Provides control of chewing and sucking lice.
- Has a zero day pre-slaughter interval and milk discard time.
- May be used as a component of an integrated pest management program, either alone or in combination with other insecticides as an aid to prevent the development of insecticide resistance.

### Active Ingredients

Diflubenzuron (CAS No. 35367-38-5) . . . . .	5.00%
Permethrin (CAS No. 52645-53-1) . . . . .	5.00%
<b>Other Ingredients*</b> . . . . .	<u>90.00%</u>
Total	100.00%

\*Contains petroleum distillate



**Boehringer  
Ingelheim**

NET CONTENTS:  
**2.5 U.S. Gallons**  
(9.5 Liters)

**SHAKE WELL BEFORE USE**

**Keep Out of Reach  
of Children**

**CAUTION**

See back panel for additional  
precautionary statements



**PRECAUTIONARY STATEMENTS**  
**Hazards to Humans and Domestic Animals**

**CAUTION:** Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

**Personal Protective Equipment (PPE) -** Applicators and handlers must wear: 1) Long-sleeved shirt and long pants 2) Shoes and socks 3) Chemical-resistant gloves

FIRST AID		HOT LINE NUMBER
If swallowed	<ul style="list-style-type: none"> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give any liquid to the person.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>	Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-821-7467 for emergency medical treatment information.
If on skin or clothing	<ul style="list-style-type: none"> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>	
If in eyes	<ul style="list-style-type: none"> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>	<b>NOTE TO PHYSICIAN</b> Contains petroleum distillate - vomiting may cause aspiration pneumonia.

**ENVIRONMENTAL HAZARDS**

This pesticide is toxic to fish and other aquatic invertebrates. Do not add directly to water, or areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash waters.

**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**

TARGET ANIMAL	TARGET PEST	APPLICATION INSTRUCTIONS
Lactating and non-lactating dairy cattle, beef cattle, calves and MATURE horses	Sucking Lice, Chewing Lice, Houseflies, Stable Flies, Horse Flies, Black Flies, Horn Flies, Deer Flies, Face Flies and Cattle Ticks	<b>Pour-on:</b> Apply 3 mL per 100 lbs body weight of animal, up to maximum of 30 mL for any one animal. Pour along back line and down face. Product may be either administered directly from graduated tip-and-pour container, graduated applicator gun, or graduated ladle/dipper. Do not use this method of application on foals.
Horses and Foals	Sucking Lice, Chewing Lice, Houseflies, Stable Flies, Horse Flies, Black Flies, Horn Flies, Deer Flies, Face Flies and Cattle Ticks	<b>Wipe-on:</b> Apply 3 mL per 100 lbs body weight of animal up to maximum of 30 mL for any one animal. Dampen an applicator mitt, cloth or towel with Clean-up Pour-on Insecticide with IGR. Rub over hair with special attention to the legs, shoulders, neck and facial areas where pests appear or tend to congregate. Apply directly onto attached ticks.  <b>Ready-To-Use Spray:</b> Use Clean-up Pour-on Insecticide with IGR undiluted in a mist sprayer applying 3 mL per 100 lbs body weight of animal, up to maximum of 30 mL for any one animal. Direct spray to the legs, shoulders, neck and facial areas where pests appear or tend to congregate. Apply directly onto attached ticks.

**Instructions for all methods of application:** Keep away from eyes and mucous membranes of animal being treated. Repeat treatment as needed, but do not apply more than once every two weeks.

Product is not effective in controlling cattle grubs, therefore the product can be used on cattle at any time of the year without fear of host-parasite reactions commonly associated with grub treatment products.

A 64 ounce container will treat up to 63 animals.

A 2.5 gallon container will treat up to 315 animals.

**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 must 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.

**Containers One Gallon and Under:** Do not reuse empty container. Rinse thoroughly, wrap in several layers of newspaper and place in trash.

**WARRANTY AND LIMITATION OF DAMAGES**

Seller warrants that this material conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use and Buyer assumes the risk of any use contrary to such directions. Seller makes no other express or implied warranty of Fitness or of Merchantability, and no agent of Seller is authorized to do so except in writing and with specific reference to this warranty. In no event shall Seller's liability for any breach of warranty exceed the purchase price of the material as to which claim is made.

Boehringer Ingelheim Vetmedica, Inc.  
St. Joseph, Missouri 64505-2002 U.S.A.  
(800) 633-1111

426752L-01-0508



Boehringer  
Ingelheim

S/S

Boehringer Ingelheim  
Vetmedica, Inc.

Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504-C)  
U.S. Environmental Protection Agency  
1801 Bell Street  
Arlington, VA 22202

October 11, 2005

Product Name: Clean-up Pour-on Insecticide with IGR  
EPA Reg. No. 4691-167

Re: Notification of the addition of Flies, Lice and Horses in the callouts, addition of "Provides control of chewing and sucking lice" as a bullet, and combination of cattle and horses in the Directions for Use table. In addition, have added the header "Hot Line Number" and Note to Physician section to the First Aid since product contains greater than 10% petroleum distillate.

Angela Bishop  
Telephone (913) 380-3112  
Telefax (913) 380-3122

15th & Oak Street/P.O. Box 338  
Elwood, Kansas 66024-0338  
Telephone (913) 380-3000  
Telefax (913) 380-3117  
Toll Free 1-800-821-7467

Dear Mr. LaRocca:

Please find enclosed a copy of the final printed label, a second copy of the final printed label with highlighted changes, and a copy of the EPA Stamped "Accepted" copy dated March 10, 2005 for your reference.

Please note that Flies, Lice and Horses have been added to the callouts on the left side of the front label, a bullet has been added to the front panel clarifying lice, and the Directions for Use for cattle and horses have been combined. Each of these pests and animals have been previously accepted by EPA. In addition, a hot line number header and Note to Physician section have been added to the First Aid since the product contains more than 10% petroleum distillates.

If you have any questions or need further clarification, please do not hesitate to contact me at 913-380-3112.

Kind Regards,

Angela Bishop  
Regulatory Specialist III, Ectoparasiticides

Enclosures