

61483-91

09/28/2011

1/6



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 28 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Hubert R. O'Neal, PhD
KMG-Bernuth, Inc.
9555 W Sam Houston Pkwy S. Ste 600
Houston, TX 77099-2145

Subject: Correction of Label Language due to Typographical Error

Dear Dr. O'Neal:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated August 29, 2011 for:

EPA Reg. No. 61483-91

Clean-Up Pour-On Insecticide with IGR

The Registration Division (RD) has conducted a review of this request for applicability under PRN 98-10 and finds that the label change(s) requested falls within the scope of PRN-98-10. The label has been date-stamped "Notification" and will be placed in our records.

If you have any questions, call me at 703 305-5409 or electronically at daniel.dani@epa.gov.

Sincerely,

Dani Daniel
Registration Division (7504P)
Insecticide/Rodenticide Branch

NOTIFICATION

Please read instructions on reverse before completing form

Form Approved OMB No. 2070-0040 Approval expires 2-28-98

United States SEP 28 2011 EPA Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration	OPP Identifier Number
	<input type="checkbox"/> Amendment	
	<input checked="" type="checkbox"/> Other	

Application for Pesticide - Section 1

1. Company/Product Number 61483-91	2. EPA Product Manager Richard Gebken	3. Proposed Classification
4. Company/Product (Name) Clean-Up Pour-On Insecticide with IGR	PM# 10	<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
5. Name and Address of Applicant (Include Zip Code) KMG-Bernuth, Inc. 9555 W Sam Houston Pkwy S. Ste 600 Houston, Texas 7709-2145 <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 March 10, 2006
<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.)

Submission of label to correct inadvertent typographical omission of "Face Flies" in the Targe Pest list under Directions for Use on page 2 of the label.

Removal of "A 64 ounce container will treat up to 63 animals" wording. The product is no longer marketed in a 64 ounce container.

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	
* Certification must be submitted		If "Yes" Unit Packaging Wt.	No. per container	If "Yes" Package Wt	No. per container
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (specify _____)	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions	
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 Dr. Hubert R. O'Neal	Title Regulatory Consultant	Telephone No. (Include Area Code) (713) 819-3932
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 Regulatory Consultant	
4. Typed Name Dr. Hubert R. O'Neal	5. Date August 29, 2011	



August 29, 2011

Document Processing Desk (NOTIF)
Office of Pesticides Programs (7504P)
U. S. Environmental Protection Agency
ATTN: RICHARD GEBKEN PM 10
Ariel Rios Building
1200 Pennsylvania Avenue, N. W.
Washington, D.C. 20460-0001

Re: Label Correction Notification
Clean-Up Pour-On Insecticide With IGR
EPA Registration No. 61483-91

Dear Mr. Gebken:

Enclosed are the following documents in accordance with notification of correction of label language due to an inadvertent typographical error and to remove extraneous language related to container size no longer marketed.

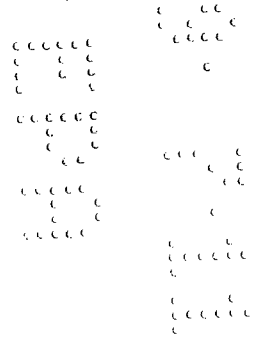
- . EPA Form 8570-1 (Rev 3-94),
- . One (1) copy of the label marked to show the changes,
- . Two (2) copies of the label unmarked.

“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.”

If you have any questions, please contact me 713-819-3932 or hroneal@suddenlink.net.

Sincerely

Hubert R. O'Neal, PhD



NOTIFICATION

SEP 28 2011

CLEAN-UP™ POUR-ON INSECTICIDE WITH IGR

4/6

Ready-to-Use Suspension for Control of Flies and Lice on Lactating and Non-Lactating Dairy Cattle, Beef Cattle, Calves and Horses

Provides control of chewing and suckling 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 # 35367-38-5)	5.00%
Permethrin (CAS # 52645-53-1)	5.00%

OTHER INGREDIENTS*	90.00%
Total	100.00%

* Contains petroleum distillate

EPA Reg. No 61483-91

EPA Est. No. 61483-KS-001

SHAKE WELL BEFORE USE

Keep Out of Reach of Children

CAUTION

See Back Panel for Additional Precautionary Statements

FIRST AID	
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Do not induce vomiting unless told 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.
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 treatment advice.
HOTLINE 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 1-800-322-8177 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Contains petroleum distillate – vomiting may cause aspiration pneumonia.	

**Net Contents: 2.5 U.S. Gallons
(9.5 Liters)**

Manufactured by: KMG-Bernuth, Inc.
9555 W. Sam Houston Pkwy S., Ste 600
Houston, TX 77099-2168 1-800-322-8177

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.

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.	Pour-On: 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.	Wipe-On: 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 toweling 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. Ready-To-Use Spray: 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: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling, if available, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by local authorities, by burning. If burned, stay out of smoke.

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.

EPA NOTIF 8-26-2011

