

2724-794

12-16-2010

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Nancy Huebl
Wellmark International
1501 East Woodfield Road, Suite 200W
Schaumburg, Illinois 60173

DEC 16 2010

Subject: Notification: Alternate Brand Name
WMI 0.67% Diflubenzuron Cattle Supplement
EPA Reg. No. 2724-794
Date Submitted: December 3, 2010

Alternate Brand Name: ClariFly Larvicide 0.67% Premix

Dear Ms. Huebl:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated December 3, 2010 for the product referenced above. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please contact me at (703) 306-0415 or davis.kable@epa.gov.

Sincerely,

Kable Bo Davis
Entomologist
Insecticide-Rodenticide Branch
Office of Pesticide Programs



United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-794		2. EPA Product Manager John Hebert		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) Wellmark International/WMI 0.67% Diflubenzuron Cattle Supplement		PM # 7			
5. Name and Address of Applicant / Registrant (include ZIP Code) Wellmark International 1501 East Woodfield Road, Suite 200W Schaumburg, Illinois 60173 <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

Amendment - Explain below. Final printed labels in response to Agency letter dated _____

Resubmission in response to Agency letter dated _____ "Me Too" Application

Notification - Explain below. Other - Explain below.

NOTIFICATION
 DEC 16 2010

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

Notification of alternate brand name: ClariFly Larvicide 0.67% Premix
 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:

Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packagin <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Unit Packaging wgt. No. per container

3. Location of Net Contents Information
 Label Container

4. Size(s) Retail Container
1-2000 lbs.

5. Location of Label Directions
 On Label
 On Label Accompanying Product

6. Manner in Which Label is Affixed to Product
 Lithograph
 Paper glued
 Stenciled Other Printed on bag

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Nancy Huebl	Title Senior Registration Specialist	Telephone No. (Include Area Code) (847) 330-5376
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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 statements may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature <i>Nancy Huebl</i>	3. Title Senior Registration Specialist
4. Typed Name Nancy Huebl	5. Date 03-Dec-10

[] and () optional language

WMI 0.67% DIFLUBENZURON CATTLE SUPPLEMENT

Alternate brand name: ClariFly® Larvicide 0.67% Premix

[Prevents the development of Horn flies, Face flies, House flies and Stable flies in the manure of treated cattle (lactating and non lactating beef and dairy cows, slaughter, stocker and feeder cattle and calves including veal calves).]

[A pesticidally active feed concentrate for cattle (lactating and non lactating beef and dairy cows, slaughter, stocker and feeder cattle and calves including veal calves) containing [diflubenzuron) (Dimilin®)]

[Insect Growth Regulator (IGR) for continuous feeding during the fly season]

[(Daily) feed concentrate for (beef and dairy) cattle containing (Dimilin®)(diflubenzuron)(brand name) Insect Growth Regulator (IGR) for continuous feeding during the fly season]

[(Fly larvicide)(fly control) (for beef and dairy cattle)]

[(Stops)(prevents)(growth)(development) of Horn fly, Face fly, House fly and Stable fly larvae in manure (of)(from) treated beef and dairy cattle (lactating and non lactating beef and dairy cows, slaughter, stocker and feeder cattle and calves including veal calves).]

[(Stops)(prevents) development of Horn fly, Face fly, House fly and Stable fly larvae in manure (of)(from) treated beef and dairy cattle]

[(Stops)(prevents) emergence of adult Horn flies, Face flies, House flies and Stable flies from manure (of)(from) treated beef and dairy cattle]

[Contains (diflubenzuron)(Dimilin®)(brand name)(Insect Growth Regulator)(IGR)(chitin synthesis inhibitor)]

[Breaks the (fly)(flies') life cycle]

[Prevents the (formation)(synthesis) of (chitin) fly larvae's exoskeletons (when they molt)(resulting in their death)]

[(Can be used as) part of a (integrated)(total)(complete) fly control (pest management) program]

ACTIVE INGREDIENT (% by weight):

Diflubenzuron* (CAS# 35367-38-5).....0.67%

OTHER INGREDIENTS [**]99.33%

TOTAL100.00%

*contains 3.04 grams of diflubenzuron per pound.
[** Refers only to ingredients which are not larvicidal.]

NOTIFICATION

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EPA Reg No. 2724-794
EPA Est. No.

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

NET WT: xx lbs. (xx kg.)

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[] and () optional language

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Causes moderate eye irritation. Wear protective eyewear. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Wear long-sleeved shirt and long pants, socks, shoes, and gloves.

FIRST AID	
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. • Call poison control center or doctor for treatment advice.
Emergency Assistance: Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
Wellmark International EMERGENCY PHONE: XXX-XXX-XXXX	

PERSONAL PROTECTIVE EQUIPMENT: Mixers and other handlers must wear long-sleeved shirt and pants, shoes plus socks, and chemical resistant gloves (nitrile rubber, barrier laminate, neoprene rubber or viton). Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS

This pesticide is toxic aquatic invertebrates. Do not contaminate water when disposing of equipment washwaters.

USE INFORMATION

[(WMI 0.67% Diflubenzuron Cattle Supplement)(brand name)(this product)] is intended for blending into (beef and dairy) cattle (lactating and non lactating beef and dairy cows, slaughter, stocker and feeder cattle and calves including veal calves) rations to control horn flies, face flies, house flies and stable flies, which develop in cattle manure. This product prevents emergence of adult flies from the manure of the treated cattle. Use [(WMI 0.67% Diflubenzuron Cattle Supplement)(brand name)(this product)] only in (beef and dairy) cattle supplements.

Use [(WMI 0.67% Diflubenzuron Cattle Supplement)(brand name)(this product)] as part of a(n) [integrated][pest][fly][control][management] program aimed at reducing fly populations in the cattle's environment. Consult your [veterinarian][or][retailer] for program recommendations. In order to achieve optimum fly control, use [(WMI 0.67% Diflubenzuron Cattle Supplement)(brand name)(this product)] in conjunction with [other][Farnam][brand name] premise and on-animal products as well as good management and sanitation practices.

DIRECTIONS FOR USE

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

[] and () optional language

[(WMI 0.67% Diflubenzuron Cattle Supplement)(brand name)(this product)] contains [(Dimilin®)(diflubenzuron)], [an][insect growth regulator][IGR] which prevents the development of horn flies, face flies, house flies, and stable flies in the manure of treated beef and dairy cattle, but is not effective against existing adult flies. Start feeding [(WMI 0.67% Diflubenzuron Cattle Supplement)(brand name)(this product)] early in the spring [(3-4 weeks)(30 days)(1 month)] before flies begin to appear, and continue feeding throughout the summer and into the fall until cold weather (restricts)(stops)(ends) fly activity. In some cases, supplemental fly control measures may be needed in and around pastures, barns, and feedlots to control adult house and stable flies which can breed in other decaying [(organic)(vegetable)] matter or silage in the area, or that migrate in from other locations.

The dosage of [(WMI 0.67% Diflubenzuron Cattle Supplement)(brand name)(this product)] is proportional to the animal's body weight. The recommended feeding rate of [(WMI 0.67% Diflubenzuron Cattle Supplement)(brand name)(this product)] is [0.72 oz (0.04 lb) per 100 lbs of body weight per month (30 days)][(0.10 mg diflubenzuron/kg of body weight) (4.54 mg diflubenzuron/100 lbs. of body weight)] per day]. The product can be fed by any of the following methods.

MIXED WITH FREE-CHOICE MINERALS

Mix [(WMI 0.67% Diflubenzuron Cattle Supplement)(brand name)(this product)] with free-choice-fed minerals to produce a [(WMI 0.67% Diflubenzuron Cattle Supplement)(brand name)(this product)] and mineral mixture as shown in the table below¹.

4 OZ. PER DAY FEEDING RATE

WMI 0.67% Diflubenzuron Cattle Supplement	13	lbs	6.10%
Free-Choice Minerals	200	lbs	93.90%
Total	213	lbs	100.00%

2 OZ. PER DAY FEEDING RATE

WMI 0.67% Diflubenzuron Cattle Supplement	13.5	lbs	11.89%
Free-Choice Minerals	100.0	lbs	88.11%
Total	113.5	lbs	100.00%

1. These calculations are based on a 1,000 pound animal.

Place the [(WMI 0.67% Diflubenzuron Cattle Supplement)(brand name)(this product)] + mineral mixture in feeders close to water sources and/or resting areas. Use one feeder for each 15 to 20 head. Fill the feeders with no more than a 5 to 7 day supply of the mixture at one time, and protect the mixture from rain.

MIXED-RATION FEEDING

Use the table below as a guide for mixing [(WMI 0.67% Diflubenzuron Cattle Supplement)(brand name)(this product)] with grain or a feed supplement.

Body Weight (lbs.)	Feed Intake as a % body wt.	Feed Intake (lbs. /head /day)	WMI 0.67% Diflubenzuron Cattle Supplement [(oz./ton)] [(lbs./ton)]	
100-200	See table below: "For Formulating Calf Starters (and Milk Replacers)			
250	1.50%	3.75	[31.9]	[2.0]
500	1.50%	7.50	[31.9]	[2.0]
750	1.50%	11.25	[31.9]	[2.0]
1000	1.50%	15.00	[31.9]	[2.0]
1500	1.50%	22.50	[31.9]	[2.0]
250	2.00%	5.00	[23.9]	[1.5]
500	2.00%	10.00	[23.9]	[1.5]
750	2.00%	15.00	[23.9]	[1.5]
1000	2.00%	20.00	[23.9]	[1.5]
1250	2.00%	25.00	[23.9]	[1.5]
250	2.50%	6.25	[19.1]	[1.2]
500	2.50%	12.50	[19.1]	[1.2]
750	2.50%	18.75	[19.1]	[1.2]
1000	2.50%	25.00	[19.1]	[1.2]
1500	2.50%	37.50	[19.1]	[1.2]
250	3.00%	7.50	[15.9]	[1.0]
500	3.00%	15.00	[15.9]	[1.0]
750	3.00%	22.50	[15.9]	[1.0]
1000	3.00%	30.00	[15.9]	[1.0]
1250	3.00%	37.50	[15.9]	[1.0]

[] and () optional language

$$\frac{\text{Inclusion of WMI 0.67\% Diflubenzuron Cattle Supplement (lbs/ton)}}{\frac{\text{Body Weight (lbs)}}{100} \times 3} = \text{Average Daily Feed Intake (lb)}$$

Thoroughly mix [(WMI 0.67% Diflubenzuron Cattle Supplement)(brand name)(this product)] with grain or a feed supplement. The mixing and feeding rates in the above table will provide the recommended daily intake of [(0.10 mg diflubenzuron/kg of body weight)(4.54 mg diflubenzuron/100 lbs. of body weight)] per day.

FOR FORMULATING CALF STARTERS (AND MILK REPLACERS)

For formulating calf starters and milk replacers to be fed to calves weighing between 100 and 200 pounds, use the following table:

CALF WEIGHT	FEED INTAKE lb/head/day	INCLUSION RATE	
		lb of (Brand name)/ton	g of Diflubenzuron/ton
100 – 150 lbs	1.0 – 1.49	4.5	13.6
100 – 180 lbs	1.5 – 1.99	3.6	10.9
100 – 200 lbs	≥2.0	3.0	9.1

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.
STORAGE: Store in a cool, dry place. Do not contaminate with pesticides or fertilizer.
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: Completely empty bag by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into mixing equipment. Offer for recycling if available, then dispose of bag in a sanitary landfill or by incineration, or if allowed by state and 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. To the extent consistent with applicable law, 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.

Wellmark International
 1501 East Woodfield Road 200 W
 Schaumburg, IL 60173
 [URL]