

# 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, IL 60173

Subject: Notification of Alternative Brand Name/Trademark per PR Notice 98-10 EPA Registration No. 2724-795 Submission Date: March 15, 2011

Dear Ms. Huebl:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated <u>March 15, 2011</u> for product <u>EPA Reg</u> <u>No. 2724-795</u>. The Registration Division (RD) has conducted a review of this request 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 regarding this label, please contact Gene Benbow at (703) 347-0235 or via email at benbow.gene@epa.gov.

Sincerely,

Gene Benbow Wildlife Biologist Insecticide-Rodenticide Branch Registration Division (7505P)

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NOTIFICATION

MAR 3 0 2011

	everse before completin(			Form Ar ved.	ONID NO. 2070	-0060. Approval expires 2-28-99		
🗘 EPA		United States Intal Protection A shington, DC 20460	gency	X Other		OPP Identifier Number		
		Applicatio	n for Pesticide - Sectio	n I	······································			
1. Company/Product Number Wellmark International/272	4-795		2. EPA Product Manager Venus Eagle		3.	Proposed Classification		
4. Company/Product (Name) Wellmark International/WMI 0.04% Diflubenzuron Cattle Supplement		on Cattle	PM# 1			X None Restricted		
5- Name and Address of Applicant / Registrant (Include ZIP Code)			6. Expedited Review.	6. Expedited Review. In accordance with FIFRA Section 3(C)(3)				
Wellmark International			(b)(i), my product is similar or identical in composition and labeling to:					
1501 East Woodfield Road, Suite 200W			EPA Reg. No.	EPA Reg. No.				
Schaumburg, Illinois 60173								
r1			Product Name		,			
Check if this is	a new address							
			Section - II					
Amendment - Explain bel	ow.			inted labels in respo	nse to			
Resubmission in response to Agency letter dated				Agency letter dated				
Resubmission in respons	e to Agency letter dated			"Me Too" Application				
X Notification - Explain belo	₩.	,	Other -	Explain below.				
Explanation: Use addition		East agestian L and agesti	an II )					
• • • • • • • • • • • • • • • • • • • •	onal page(s) if necessary. (		ut n.)					
Label notification of alterna			d EBA regulations at 40 CEE	2 152 46 and no a	ther ehenges i	have been made to the		
This notification is consiste	int with the provisions of	PR Notice 98-10 an	d EPA regulations at 40 CFF	(152.46, and no o	iner changes	have been made to the		
			stand that it is a violation of 1					
EPA. I further understand t	hat if this notification is i	not consistent with tr	ne terms of PR Notice 98-10	and 40 CFR 152.4	io, this produc	t may be in violation of		
FIFRA and I may be subjec	t to enforcement action	and penalties under	sections 12 and 14 of FIFRA	۱.				
			Section - Ill					
1. Material This Product Will	be Packaged in:	<u></u>		· · · · · · · · · · · · · · · · · · ·	· - · · · · · · · · · · · · · · · · · ·			
Child-Resistant Packaging	Unit Packaging	1	Water Soluble Packagin	2. Type of	Container			
	Yes		Yes		Metal			
Yes	X No		X No	X	Plastic			
∧ No		K:	Non their the		Glass Paper			
* Certification must be	If "Yes Unit Packaging wgt.		Yes Unit No. p ckaging wgt. conta		Other (Specify)			
submitted					··· "			
3. Location of Net Contents Information 4. Size(s) Retail Cont		Itainer	ner 5. Location of Labe					
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X Label X C	omainer	1-2000 lbs.			el Accompanyir	ng Product		
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		Lithograph X Paper glue	sd	On Lab		ng Product		
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6. Manner in Which Label is A	Affixed to Product	Lithograph Paper glue Stenciled identification of indiv Title Seni	Section - IV  ridual to be contacted, if nece or Registration Specialist	Printed on bag	el Accompanyir his application Telephone	:) <u>د د د د د</u> No. (آمذاناتان کاrea Code) 5376 <sub>و</sub> <sup>د</sup> د د		
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EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

Yellow - Applicant copy

Wellmark International

1501 East Woodfield Road, Suite 200 West Schaumburg, Illinois 60173 847 330 5300 www.wellmarkinternational.com

Wellmark

March 15, 2011

Document Processing Desk (NOTIF) Office of Pesticide Programs 7504P U.S. Environmental Protection Agency Room S-4900 One Potomac Yard 2777 South Crystal Drive Arlington, Virginia 22202-4501

ATTENTION: V. Eagle, PM 1

SUBJECT: PER PRN 98-10 NOTIFICATION OF ALTERNATE BRAND NAME FOR WMI 0.04% DIFLUBENZURON CATTLE SUPPLEMENT EPA REG. NO. 2724-795

Dear Ms. Eagle:

Enclosed is a completed EPA Form 8570-1 and 1 copy of revised labeling for the above product. New text is highlighted in red. The label cover sheet details the changes. The alternate brand name is: ClariFly® Larvicide 0.04%.

If you have any questions or if I can provide any further assistance, please, call me directly at 847/330-5376. Thank you for your assistance in this matter.

Yours sincerely, WELLMARK INTERNATIONAL

Mancy Huebl

Nancy Huebl Sr. Registration Specialist <u>nhuebl@central.com</u>

enclosure

cc: C. Elmi



[] and () denote optional language

# WMI 0.04% DIFLUBENZURON CATTLE SUPPLEMENT

Alternate brand name: ClariFly® Larvicide 0.04%

A nutritional supplement containing Diflubenzuron\* Insect Growth Regulator for continuous feeding to cattle through the fly season

A nutritional premix containing (Brand Name) (brand of) Diflubenzuron(\*) Insect Growth Regulator for inclusion in (beef)(and)(dairy)(cattle)(cow)(and)(heifer)(total mixed rations)(TMR's)(rations) that prevents emergence of horn flies, face flies, house flies and stable flies from manure of treated cattle.

#### **ACTIVE INGREDIENT:**

Diflubenzuron (CAS #35367-38-5)	0.04%
OTHER INGREDIENTS:	
TOTAL	100.00%

[\*As the Insect Growth Regulator Dimilin®]

### FEED INGREDIENTS\*\*

Molasses products; Forage products; Grain products; Plant Protein products; Processed Grain by-products; Roughage products; Mineral products; Vitamins; Food Additives Permitted in Animal Feed/Drinking Water; GRAS ingredients; Non-Protein Nitrogen (Urea); Fats/Oils; Animal products; Animal Protein products\*\*\*; Chemical preservatives; Amino Acids and related products; Brewers products; Fermentation products; Distillers products; enzymes; Citrus products; Marine products; Milk products; Oilseed products; Special Purpose products \*\*AAFCO approved feed ingredients may vary depending upon nutritional requirements in

\*AAFCO approved feed ingredients may vary depending upon nutritional require different geographical regions of the country

[\*\*\*Contains no prohibited animal by-product in accordance with FDA regulation 21 CFR 589.2000] [Free from restricted ruminant protein products per Title 21, CFR 589.2000]

[Does not contain any prohibited materials. Does not contain any animal protein]

[This product was manufactured in a facility that does not handle or store animal protein products prohibited in ruminant feed as described in 21 CFR section 589.2000]

[This supplement must be used only in accordance with the directions on the label.][Use as directed] [This product contains supplemental selenium. Intake of supplemental selenium must not exceed X% on a dry basis][Follow label directions(s)]

[Feeding added selenium at levels in excess of XX ppm in the total diet is prohibited.]

GUARANTEED ANALYSIS (Will vary depending on geographic area and regional feeding )

# KEEP OUT OF REACH OF CHILDREN CAUTION

# See additional Precautionary Statements

EPA Reg. No. 2724-795 EPA Est. No.

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NET WEIGHT: \_\_\_\_\_ lbs

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# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash clothing before reuse.

Personal Protective Equipment (PPE): Applicators and other handlers of this product must wear:

- Long sleeve shirt and long pants
- Chemical Resistant gloves
- Shoes
- Socks

	FIRST AID
If in Eyes	<ul> <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.</li> </ul>
	Call a poison control center or doctor for treatment advice.
If on Clothing or Skin:	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.
<b>Emergency Assist</b>	ance: Have the product container or label with you when calling a poison
control center or d	octor, or going for treatment.

#### **ENVIRONMENTAL HAZARDS**

This pesticide is toxic to aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark.

#### DIRECTIONS FOR USE

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

#### FEEDING AND MANAGEMENT INSTRUCTIONS

When used as directed, [(WMI 0.04% Diflubenzuron Cattle Supplement)(Brand Name)(this product)] provides sufficient diflubenzuron insect growth regulator to prevent the emergence of adult House flies [*Musca domestica*], Stable flies [*Stomoxys calcitrans*], Horn flies [*Haematobia irritans*], and Face flies [*Musca autumnalis*] from manure of treated cattle. Existing adult flies will not be affected. Start feeding before flies appear and continue use until cold weather marks the end of the fly season. Use [(WMI 0.04% 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)(cow's)] environment. House and stable flies can [(breed)(develop)] in decaying vegetable matter or spilled silage on premises. Good sanitation [practices], [such as cleaning up spilled feed and preventing manure (build-up)(accumulation)] around barns and fences or under feed bunks, will eliminate additional breeding sites for these flies.

## **Feeding Directions for Cattle on Pasture**

Allow free choice to cattle. Cattle should consume an average of 0.4 ounces of [(WMI 0.04% Diflubenzuron Cattle Supplement)(BRAND NAME)(this product)] per 100 lbs. of body weight per day, which is equivalent to 4 ounces per day for a 1,000 pound animal.

- Assure cattle are not starved for nutrients in [(WMI 0.04% Diflubenzuron Cattle -1-Supplement)(BRAND NAME)(this product)] by providing them prior to feeding this product.
- Offer cattle 50 pounds of [(WMI 0.04% Diflubenzuron Cattle Supplement)(BRAND 2. NAME)(this product)] for every 15 head of cattle.
- Remove all other self limiting nutritional supplements. 3.
- Locate [(WMI 0.04% Diffubenzuron Cattle Supplement)(BRAND NAME)(this product)] 4. where cattle congregate (watering, loafing, shade areas).
- 5. Replenish [(WMI 0.04% Diflubenzuron Cattle Supplement)(BRAND NAME)(this product)] on a regular basis as needed.
- If intake of [(WMI 0.04% Diflubenzuron Cattle Supplement)(BRAND NAME)(this product)] 6. is below 0.4 ounces per 100 lbs. animal body weight per day, increase the number of feeding locations and/or change location(s) to areas more frequented by cattle.
- 7. If intake of [(WMI 0.04% Diflubenzuron Cattle Supplement)(BRAND NAME)(this product)] is above 0.4 ounces per 100 lbs. animal body weight per day, reduce the number of feeding locations and/or change location(s) to areas less frequented by cattle.
- Introduction of this product after adult horn fly infestation is established will require 8. treatment of cattle with adulticides if elimination of the adult fly population is desired.

## Feeding Directions for Confined (Beef)(and)(Dairy)(Cattle)(Cows)(and)(Heifers)

Mix (WMI 0.04% Diflubenzuron Cattle Supplement) (BRAND NAME) (this product) with (a TMR) (the ration) to provide 0.1 mg Diflubenzuron/kg of body weight. Use the following equation to determine the exact amount of (WMI 0.04% Diflubenzuron Cattle Supplement)(BRAND NAME)(this product) needed per ton of (TMR)(ration).

Pounds of (WMI 0.04% **Diflubenzuron Cattle** Supplement)(BRAND NAME)(this product) required per ton of (TMR) (ration)

Weight (lbs) X 0.5

Daily Dry Matter Consumption (lbs)

- Assure (cattle) (cows) (and) (heifers) are provided [(WMI 0.04% Diflubenzuron Cattle 1. Supplement)(BRAND NAME)(this product)] on a daily basis.
- Introduction of this product after an adult fly infestation is established will require 2. (treatment of cattle with adulticides) (and)(or)(use of insecticidal baits and traps) if elimination of the adult fly population is desired.

# STORAGE AND DISPOSAL

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

Storage: Store pesticide in original container in a dry place.

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

Container Disposal: Completely empty bag, then dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

[] and () denote optional language

# 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. To the extent consistent with applicable law, 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.

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For information, call [phone number] Dimilin<sup>®</sup> is a registered trademark of Chemtura USA Corporation. ClariFly is a registered trademark of Wellmark International

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