

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

NOTIFICATION JUN 1 5 2010

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Laura Doolin Wellmark International 1501 East Woodfield Road, Suite 200 West Schaumburg, Illinois 60173

Subject:

Notification: Updated Storage and Disposal Statement PR Notice 2007-4

WMI 0.04% Diflubenzuron Cattle Supplement

EPA Reg. No. 2724-795

Submission Dated: May 20, 2010

Dear Ms. Doolin:

The Agency is in receipt of your Application for Pesticide Notifications under Pesticide Registration Notice (PRN) 2007-04 dated 5-20-10 for the product EPA Reg. No 2724-795. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 2007-04 and finds that the action(s) requested fall within the scope of PRN 2007-04. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me @ 703-305-5314 or metzger.autumn@epa.gov.

Autumn Metzger

Biologist

Sincerely

Insecticide-Rodenticide Branch Office of Pesticide Programs

Please read instructions on re	verse before completin	n.		Form	ved. O	MB No. 2070	-0060. Approval expires 2-28-95
⇔ EPA	Environme	United States ntal Protection shington, DC 20		X	Registra Amendn Other	tion	OPP Identifier Number
		Applic	ation for Pesticide	- Section I			
Company/Product Number Wellmark International/27	24-795		2. EPA Product K. Bo Davis	Manager	-	3.	Proposed Classification
4. Company/Product (Name) Wellmark International/ Supplement	VMI 0.04% Diflubenz	uron Cattle	PM#				X None Restricted
5. Name and Address of Applic Wellmark International 1501 East Woodfield Roa	•	(IP Code)	1	d Review. In a duct is similar o		compositior	and labeling to:
Schaumburg, Illinois 60°	•		EPA Reg. No NOTIFICATION				
Check if this is a	new address		Product Nan	ne		JUN	1 5 2010
			Section - II				
Amendment - Explain belo	e to Agency letter dated		[[Final printed lat Agency letter da "Me Too" Appli Other - Explain	ated	e to	
Notification of label chang regulations at 40 CFR 156	5.10,156.140, 156.144, t. I understand that it is nsistent with the requir	s notification is 156.146, and a violation of ements of 40 C	consistent with the gui 156.156. No other chan 18 U.S.C. Sec. 1001 to FR 156.10,156.140, 19 s under sections 12 an	iges have been i willfully make ai 56.144, 156.146	made to the I ny false state	abeling or the ment to EP	he Confidential Statement A. I further understand that
			Section - III				
1. Material This Product Will							
Child-Resistant Packaging Yes X No	Unit Packaging Yes X No		Water Soluble Packa Yes No	ging	X P G	etal lastic lass	
* Certification must be submitted	If "Yes Unit Packaging wgt.	No. per container	If "Yes Unit Packaging wgt.	No. per container		aper ther (Specify)	
3. Location of Net Contents In	formation	4. Size(s) Reta		ļ <u> </u>	ation of Label X On Label	Directions	
6. Manner in Which Label is A		Litho	graph er glued	X Other Pri	On Label	Accompanyir	ng Product
			Section - IV				
1. Contact Point (Complete	items directly below for	identification of	individual to be contacte	ed, if necessary, to	process this	application.)	
Name Laura Doolin			Title Regulatory Intern			Telephone No. (Include Area Code) (847) 330-5384	
	any knowingly false or mis		ation ttachments thereto are true ts my be punishable by fine			ι (υ ι () ι () ι ι ι	6. Date Application Received (Stamped)
2. Signature	300lin		3. Title Regulatory Intern		,	(((((((((((((((((((

5. Date

20-May-10

4. Typed Name

Laura Doolin

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



May 20, 2010

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: K. Bo Davis

SUBJECT:

NOTIFICATION PER PRN 2007-4/CONTAINER DISPOSAL FOR

WMI 0.04% DIFLUBENZURON CATTLE SUPPLEMENT/EPA REG. NO. 2724-795

Dear Mr. Davis:

Enclosed is a completed EPA Form 8570-1 and 1 copy of revised highlighted labeling to serve as notification per PRN 2007-4. The added text represents exact wording from the regulations/PR Notice, no other changes were made to the label. This action is not a PRIA action and does not require any fee.

If you have any questions or if I can provide any further assistance, please, call me directly at 847/330-5384. Thank you for your assistance in this matter.

Yours sincerely, WELLMARK INTERNATIONAL

Laura Doolin

Laura Doolin Idoolin@central.com

enclosure

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WMI 0.04% DIFLUBENZURON CATTLE SUPPLEMENT

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 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% of supplemental selenium.

[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

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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	 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 a poison control center or doctor for treatment advice.
If an Clathing or	·+·
If on Clothing or	Take off contaminated clothing.
Skin:	 Rinse skin immediately with plenty of water for 15 – 20 minutes.
	 Call a poison control center or doctor for treatment advice.
Emergency Assista	ance: Have the product container or label with you when calling a poison
control center or do	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.

. . . .

[] and () denote optional language

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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.

- 1. Assure cattle are not starved for nutrients in [(WMI 0.04% Diflubenzuron Cattle Supplement)(BRAND NAME)(this product)] by providing them prior to feeding this product.
- 2. Offer cattle 50 pounds of [(WMI 0.04% Diflubenzuron Cattle Supplement)(BRAND NAME)(this product)] for every 15 head of cattle.
- 3. Remove all other self limiting nutritional supplements.
- 4. Locate [(WMI 0.04% Diffubenzuron Cattle Supplement)(BRAND NAME)(this product)] 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.
- 6. If intake of [(WMI 0.04% Diflubenzuron Cattle Supplement)(BRAND NAME)(this product)] 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 <u>above</u> 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.
- 8. Introduction of this product after adult horn fly infestation is established will require 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)

=
$$\frac{\text{Weight (lbs) X 0.5}}{\text{Daily Dry Matter Consumption (lbs)}}$$

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



[] and () denote optional language



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: Nonrefillable container. Do not reuse or refill this container. Completely empty bag into mixing equipment, then offer for recycling, if available or 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.

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.

For information, call [phone number]
Dimilin® is a registered trademark of Chemtura USA Corporation.

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

