

2724-798

12-15-2009

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DEC 15 2009

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

Subject: Application for Pesticide Notification (PRN 98-10)
RF2128 Dry Concentrate
EPA Reg. No. 2724-798
Application Dated November 6, 2009

Dear Ms. Oliver;

The Agency is in receipt of your filing of a revised Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested fall 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 call me directly at 703-305-6736 or electronically at Edwards.joanne@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Joanne S. Edwards".

Joanne S. Edwards
Insecticide-Rodenticide Branch
Registration Division (7505P)
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/2724-798	2. EPA Product Manager J. Hebert	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/RF2128 Dry Concentrate	PM # 07	
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 15 2009

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

Notification of alternate brand name: ClariFly Larvicide 8% Concentrate

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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input 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 <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 40 lbs	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" 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 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	6. Date Application Received (Stamped)
4. Typed Name Nancy Huebl	5. Date 06-Nov-09	

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Wellmark International
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Schaumburg, Illinois 60173
847 330 5300
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November 6, 2009

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: J. Hebert, PM 7

SUBJECT: LABEL NOTIFICATION OF ALTERNATE BRAND NAME
FOR RF2128 DRY CONCENTRATE/EPA REG. NO. 2724-798

Dear Mr. Hebert:

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 main revision is the addition of ClariFly® Larvicide 8% Concentrate as the alternate brand name.

I have enclosed a self-addressed postcard for notification confirmation. 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

Nancy Huebl
Sr. Registration Specialist
nhuebl@central.com

enclosure

cc: C. Elmi

cc: C. Elmi

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NOTIFICATION

DEC 15 2009

[] & () denote optional language

RF2128 DRY CONCENTRATE

Alternate brand name: ClariFly® Larvicide 8% Concentrate
(Diflubenzuron) (Dimilin®)[8.0%][(Oral Larvicide)(Granules)(Premix)(Concentrate)
An (Insect Growth Regulator)(IGR)(Larvicide)(Insecticide)

For Use in (Cattle)(Horse)(Feeds)(Supplements)(Rations)

For use in cattle feeds and supplements as part of an integrated pest management program to control flies developing in manure

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

[(Fly larvicide)(fly control)] for [(cattle)(horses)]

Controls flies [(developing) (growing)] in manure [of treated (cattle)(horses)(listed animals)]

[(Stops)(Prevents the)] development of House fly, Stable fly, Face fly and Horn fly larvae in manure [(of)(from)] treated [(cattle)(horses)(listed animals)]

[(Stops)(Prevents the)] emergence of adult House flies, Stable flies, Face flies and Horn flies from manure [(of)(from)] treated [(cattle)(horses)(listed animals)]

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

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

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

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

(Patent pending)

ACTIVE INGREDIENT:

Diflubenzuron [CAS# 35367-38-5] 8%

OTHER INGREDIENTS: 92%

Total 100%

Contains 1.28 ounces (36 grams) of diflubenzuron per pound.

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See [side][back] panel(s) for additional Precautionary Statements

Net Weight: _____ lbs

EPA Reg. No. 2724-798XXX

EPA Est. No.

Lot Number:

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION**

Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Wear long-sleeved shirt and long pants, shoes plus socks, and chemical resistant gloves. Remove and wash contaminated clothing before reuse.

FIRST AID	
Call a poison control center or doctor immediately for treatment advice.	
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.
If Swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
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.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-347-8272 for emergency medical treatment information.	

PERSONAL PROTECTIVE EQUIPMENT

Mixers and other handlers must wear long-sleeved shirt and pants, shoes plus socks and chemical resistant gloves. 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.

USER RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

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

DIRECTIONS FOR USE

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

[(Brand Name)(This product)] [(prevents)(inhibits)(controls)] the [(development of fly larvae in)(fly emergence from)] the manure of treated [(cattle)(horses)(listed animals)]. When fed to [(cattle)(horses)(listed animals)] according to label directions, [(Brand Name)(This product)(Dimilin)(Diflubenzuron)] prevents the [(development)(emergence)] of [(horn flies), (face flies), (house flies) and (stable flies) (fecal flies)] [(in)(from)] the manure of treated [(cattle)(horses)(listed animals)]. Start feeding [(Brand Name)(This product)] early in the spring before flies begin to appear and continue feeding throughout the summer and into the fall until cold weather restricts fly activity.

[(Brand Name)(This product)(Dimilin)(Diflubenzuron)] prevents the [(development) (emergence)] of [(horn flies), (face flies), (house flies) and (stable flies)(fecal flies)] [(in)(from)] the manure of treated [(cattle)(horses)(listed animals)], but is not effective against existing adult flies. When starting a feeding program during the fly season, it is desirable to use other control measures to reduce the population of existing adult flies.

In some cases, supplemental fly control measures may be needed in and around [(cattle)(horses)(animals)] [(lots)(buildings)(stalls)(barns)(paddocks)(facilities)(sheds)(houses)] to control adult house flies and stable flies, which can breed not only in [(cattle)(horse)(listed animal)] manure, but in decaying vegetable matter or silage on the premises. In order to achieve optimum fly control, use [(Brand Name)(This product)(Dimilin)(Diflubenzuron)] in conjunction with other good management and sanitation practices.

The dosage of [(Brand Name)(This product)] is proportional to the animal's body weight and must be offered daily throughout the entire fly season. The following table [(gives dosage information)(provides the feeding rate)] for all approved species.

Species	Daily Feeding Rate of DFB AI	
	mg/kg	mg/cwt
Cattle - [(Brand name)(This product)] may be fed to beef and dairy cattle, including breeding cattle, lactating dairy cattle, growing and finishing cattle and calves, either in dry lot or on pasture up to slaughter and to lactating dairy cows without withholding milk from market during or after treatment.	0.10	4.55
Horses - [(Brand name)(This product)] may be fed to horses including ponies, burros, and donkeys. This product is not approved for use in pregnant mares.	0.15	6.82

[(Brand Name)(This product)] is a specially formulated granular material for use in [(cattle)(horse)] feeds. It is approved for use in [(supplements)(complete feeds)(concentrates)(premixes)(hand feeds)(mineral supplements)(blocks)(tubs)]. It may also be used in [(liquid feeds)(dry milk replacer)] when suspension agents are used to maximize the positional stability of the other feed ingredients.

(Cattle) Feed Mixing Directions - 0.10 mg/kg/day
The following formula can be used when mixing cattle rations, including complete feeds, liquid feeds, (milk replacers,) supplements, premixes, supplements for hand feeding and mineral mixes.
$\left(\frac{\text{CWT}}{\text{Consumption (lbs)}} \right) \times 0.25 = \frac{\text{lbs of [(RF2128) (Brand Name)]}}{\text{product being manufactured}} \text{ per Ton of}$

(Horse) Feed Mixing Directions - 0.15 mg/kg/day
The following formula can be used when mixing horse rations, including complete feeds, tubs and blocks.
$\left(\frac{\text{CWT}}{\text{Consumption (lbs)}} \right) \times 0.375 = \frac{\text{lbs of [(RF2128)(Brand Name)]}}{\text{product being manufactured}} \text{ per Ton of}$

STORAGE AND DISPOSAL

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

PESTICIDE 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 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.

f/d

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. To the extent consistent with applicable law, Seller's liability for any breach of warranty shall not exceed the purchase price of the material as to which claim is made.

For information or in case of emergency, contact 1-800-347-8272.

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

ClariFly is a registered trademark of Wellmark International.
Dimilin is a registered trademark of Chemtura Corporation.
Contains Dimilin® (diflubenzuron) manufactured by Chemtura Corporation and/or its affiliates

