



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

IIIN 2 3 2010

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Ms. Laura Doolin Wellmark International 1501 East Woodfield Road Suite 200 West Schaumburg, IL 60173

Subject: Alternate Brand Name Change

Dear Ms. Doolin:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated June 7, 2010 for:

**EPA Registration 2724-801** 

**RF2128 Dry Concentrate MUP** (Alternate Brand Name: Clarifly Lavicide 8% Manufacturing Use Product)

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 (7505P) Insecticide/Rodenticide Branch

CATION Form Appl. .. OMB No. 2070-0060. Approval expires 2-28-95 Please read instructions on reverse before completing for. OPP Identifier Number Registration **United States** Environmental Protection Agentin 2 3 2010 **⇔** EPA **Amendment** Washington, DC 20460 Other Application for Pesticide - Section I 2. EPA Product Manager 1. Company/Product Number 3. Proposed Classification J. Hebert Wellmark International/2724-801 4. Company/Product (Name) PM # Restricted Wellmark International/RF2128 Dry Concentrate MUP 5. Name and Address of Applicant / Registrant (Include ZIP Code) 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 Schaumburg, Illinois 60173 Product Name Check if this is a new address Section - II Final printed labels in response to Amendment - Explain below. Agency letter dated 'Me Too" Application Resubmission in response to Agency letter dated Other - Explain below. Notification - Explain below. Explanation: Use additional page(s) if necessary. (For section I and section II.) Notification of alternate brand name: ClariFly Larvicide 8% Manufacturing Use Product 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: Unit Packaging Water Soluble Packaging 2. Type of Container Child-Resistant Packaging Yes Yes Metal Yes  $\overline{\mathbf{x}}$ Х Plastic Nο Nο Nο Glass Paper If "Yes If "Yes No. per No. per Other (Specify) Packaging wgt. container Packaging wgt. container \* Certification must be submitted 3. Location of Net Contents Information 4. Size(s) Retail Container 5. Location of Label Directions X On Label X Label Container 40 lbs On Label Accompanying Product Lithograph 6. Manner in Which Label is Affixed to Product Other Paper glued Stenciled Section - IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Title Name Telephone No. (Include Area Code) Laura Doolin Regulatory Intern (847)-330-5384 Certification 6. Date Application Receiveo 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 my be punishable by fine or imprisonment or both (Staniped) under applicable law. 2. Signature aura poolin Regulatory Intern

5 Date

07-Jun-10

Laura Doolin

Wellmark In ational

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June 7, 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: J. Hebert, PM 7

SUBJECT:

LABEL NOTIFICATION OF ALTERNATE BRAND NAME

FOR RF2128 DRY CONCENTRATE MUP/EPA REG. NO. 2724-801

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% Manufacturing Product Use as the alternate brand name.

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

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Laura Doolin Regulatory Intern

Idoolin@central.com

enclosure

## NOTIFICATION

[ ] & ( ) denote optional language

JUN 2 3 2010

### **RF2128 DRY CONCENTRATE MUP**

FOR MANUFACTURING OR FORMULATING USE ONLY

Alternate brand name: ClariFly® Larvicide 8% Manufacturing Use Product [(Diflubenzuron) (Dimilin®)][8.0%][(Oral Larvicide)(Granules)(Premix)(Concentrate)]

An (Insect Growth Regulator)(IGR)(Larvicide)(Insecticide)

Manufacturing Use Product

For use in the manufacturing of EPA-Registered (Cattle)(Horse)(Feeds)(Supplements)

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

(Patent pending)

ACTIVE INGREDIENT:	
Diflubenzuron [CAS# 35367-38-5]	8%
OTHER INGREDIENTS:	92%
Total	

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 EPA Est. No.	I-801 <del>xxx</del>	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 cont	trol center or doctor immediately for treatment advice.
If on Skin or	Take off contaminated clothing.
Clothing	Rinse skin immediately with plenty of water for 15-20 minutes.
If Swallowed	<ul> <li>Call a poison control center or doctor immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> </ul>
	Do not give anything by mouth to an unconscious person.
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 eye.</li> </ul>

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

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**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

#### **DIRECTIONS FOR USE**

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

Products formulated with this product must be registered by the EPA. For formulation into enduse products intended to be used in animal food processing or manufactured products, and animal food or feed containers or dispensers.

Products formulated with [(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.

[Products formulated with [(Brand name)(This product) may also be fed to horses including ponies, burros, and donkeys. Products formulated with this product are not approved for use in pregnant mares.

[(Brand Name)(This product)] is used as a starting material for manufacturing of EPA-registered [(supplements)(concentrates)(premixes)(mineral supplements) (blocks) (tubs)] (ClariFly® Larvicide)] containing diflubenzuron, such as (WMI 0.67% diflubenzuron cattle supplement)(2724-794)(Brand name)] and [(0.04% diflubenzuron)([WMI 0.04% diflubenzuron cattle supplement)(2724-795)(Brand name)] supplements.

Product Mixing Directions					
Product being	Diflubenzuron	Amount of [(RF2128 Dry Concentrate MUP)(Brand Name)]/Ton of Product			
Manufactured	%	grams	pounds		
[(ClariFly® Larvicide) (WMI 0.67% diflubenzuron cattle supplement)(2724- 794)(Brand Name)]	0.67%	76045	167.50		
[(0.04% Diflubenzuron) (WMI 0.04% diflubenzuron cattle supplement)(2724-					
795)(Brand Name)]	0.04%	4540	10.00		

[(Brand Name)(This product)] is a specially formulated granular material for use in [(cattle)(horse)] feeds. It is approved for use in EPA-registered [(supplements)(concentrates)(premixes)(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.]

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#### (Cattle) Feed Mixing Directions - 0.10 mg/kg/day

The following formula can be used when mixing cattle products, including premixes, supplements, (liquid feeds,)(milk replacers,) (tubs,)(blocks,) and mineral mixes.

$$\left(\frac{\text{CWT}}{\text{Consumption (lbs)}}\right) \times 0.25 = \frac{\text{lbs of [(RF2128) (Brand Name)] per Ton of}}{\text{product being manufactured}}$$

#### (Horse) Feed Mixing Directions - 0.15 mg/kg/day

The following formula can be used when mixing horse products, including premixes, supplements, tubs, blocks, and mineral mixes.

$$\left(\frac{\text{CWT}}{\text{Consumption (lbs)}}\right) \times 0.375 = \frac{\text{lbs of [(RF2128)(Brand Name)] per Ton of product being manufactured}}{\text{product being manufactured}}$$

#### 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.

#### **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