

2724-801

29-28-2910

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SEP 28 2010

Nancy Huebl
Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, IL 60173

Subject: Label Notification for RF2128 Dry Concentrate MUP (EPA Reg.# 2724-801)

Dear Ms. Huebl:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated September 3, 2010, for the product RF2128 Dry Concentrate MUP (EPA Reg. # 2724-801). The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The Confidential Statement of Formula (CSF) and/or label submitted with the application has (have) been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-347-0156 or urbanski.jennifer@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Urbanski".

Jennifer Urbanski
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/2724-801	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 MUP	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

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

SEP 28 2010

Notification to clarify use statement

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
 Label Container

4. Size(s) Retail Container
40 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 _____

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.

2. Signature
Nancy Huebl

3. Title
Senior Registration Specialist

4. Typed Name
Nancy Huebl

5. Date
03-Sep-10

6. Date Application Received (Stamped)

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

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September 3, 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 TO CLARIFY USE STATEMENT
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 change. The only revision is the restatement of the use statement to clarify that this Manufacturing Use Product is only for manufacturing/formulating EPA registered end-use cattle or horse supplements. This clarification is being made to allow feed facilities who purchase/use this product to more easily differentiate the MUP from the similar product used to "custom blend" cattle supplements, RF2128 Dry Concentrate, 2724-798.

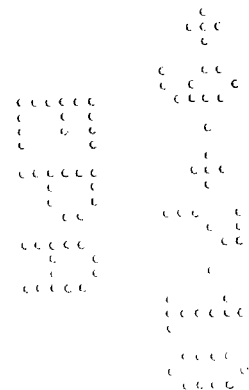
If you have any questions or if I can provide any further assistance, please, call me directly at 847/330-5384. Thank you for your assistance in this matter.

Yours sincerely,
WELLMARK INTERNATIONAL

A handwritten signature in cursive script that reads "Nancy Huebl".

Nancy Huebl
Senior Registration Specialist
nhuebl@central.com

enclosure



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NOTIFICATION

SEP 28 2010

[] & () denote optional language

RF2128 DRY CONCENTRATE MUP
FOR MANUFACTURING OR FORMULATING EPA-REGISTERED [CATTLE][HORSE]
SUPPLEMENTS 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.....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. 2724-801

EPA Est. No.

Lot Number:

Lot Number: [Faint barcode/lot number markings]

**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

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 end-use products intended to be used in animal food processing or manufactured products, and animal food or feed containers or dispensers.

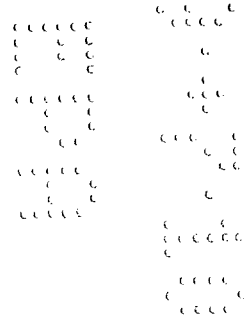
Products formulated with [(Brand name)(This product)] may be fed to beef and dairy cattle, including breeding cattle, lactating dairy cattle, growing and finishing cattle and calves, either in dry lot or on pasture up to slaughter and to lactating dairy cows without withholding milk from market during 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) containig 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 Manufactured	Diflubenzuron		
	%	Amount of [(RF2128 Dry Concentrate MUP)(Brand Name)]/Ton of Product	
		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.]



(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.

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

(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.

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

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

