2724- 495
Please read instructions on reverse before completing form.

.06/28/2005 Form Approved. OMB No. 2070-0060. Approval expires 2-28-95/5

United States Environmental Protection Agency Washington, DC 20460  United States Environmental Protection Agency Washington, DC 20460  Registration Amendment Other				
	Application for Pesticide - Section	<u>n!</u>		
Company/Product Number     Wellmark International/2724-495	EPA Product Manager     Sheryl Reilly	3. Proposed Classification		
Company/Product (Name)     Wellmark International/RF 2025 Tub	PM# Biopesticides	X None Restricted		
5. Name and Address of Applicant / Registrant (Include ZIP Code Wellmark International 1501 East Woodfield Road, Suite 200W Schaumburg, Illinois 60173  Check if this is a new address		In accordance with FIFRA Section 3(C)(3) milar or identical in composition and labeling to:		
	Section - II			
Amendment - Explain below.  Resubmission in response to Agency letter dated	Final prin	inted labels in response to NOTIFICATION letter dated  Date Reviewed: 28 Jun 05		
Notification - Explain below.	Other - E	Explain below.  Reviewed By: M Duggard		
Notification to include statements required by AAFCO Feed or FDA regulations and provide optional S&D for shrinkwrapped block packaging.  This notification is consistent with the provisions of PR Notice 95-2 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 95-2 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 Unit Packaging Water Soluble Packaging 2. Type of Container				
* Certification must be Packaging wgt. co submitted Packaging wgt. 1	Yes  X No  D. per If "Yes Unit No. per Intainer Packaging wgt.  Container Packaging wgt.			
3 Location of Net Contents Information 4, Size(s) Retail Container 5. Location of Label Directions				
1 🗔	-250 lbs.	X On Label On Label Accompanying Product		
6. Manner in Which Label is Affixed to Product	Lithograph  C Paper glued  X Stenciled	er .		
Section - IV				
Contact Point (Complete items directly below for identification)	cation of individual to be contacted, if necess  Title	sary, to process this application.)  Telephone No. (Include Area Code)		
Name Nancy Huebl	Regulatory Specialist	(847) 330-5376		
Certification  I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. It acknowledge that any knowingly false or misleading statements my be punishable by fine or imprisonment or both under applicable law.  6. Date Application Received  Received  (Stainped)				
2. Signature Mancy Huebl	3. Title Regulatory Specialist			
4. Typed Name Nancy Huebi	5. Date May 3, 2005	,		

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#### Wellmark International

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

### Wellmark

May 3, 2005

Document Processing Desk (NOTIF)
Office of Pesticide Programs 7504C
U.S. Environmental Protection Agency
1801 South Bell Street
Crystal Mall 2 Room 266A
Arlington, Virginia 22202

ATTENTION: S. Reilly

SUBJECT: NOTIFICATION OF LABEL REVISION PER PRN 98-10

RF2025 TUB/EPA REG. NO. 2724-495

Dear Ms. Reilly:

Enclosed is completed EPA Form 8570-1 and one copy of revised labeling (red is new text) for the above product. The revision involves addition of optional feed statements required by AAFCO (Association of American Feed Control Officials) or FDA regulations (for cattle feed products-exposure to prohibited animal protein) and including additional optional Storage & Disposal (per Label Review Manual) for cattle blocks marketed in shrinkwrapped plastic or cardboard. This label revision meets the criteria in PRN 98-10, §II, E, Changes in Packaging & Related Labeling Statements. If you have any questions, please, call me directly at 847/330-5376. Thank you for your assistance in this matter.

Yours sincerely,

WELLMARK INTERNATIONAL

nancy Huell

Nancy Huebl

Regulatory Specialist

nancy.huebl@wellmarkint.com

enclosure

cc: C. Elmi/J. Richardson

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Date Reviewed: 28 Jun 05

Reviewed By: M. Duggard

[optional text]

#### **RF2025 TUB**

PREVENTS ADULT HORN FLY EMERGENCE FROM MANURE OF TREATED CATTLE

A [Nutritional] [Mineral and Vitamin] Supplement [for beef calves and cattle] Containing S-Methoprene\* Insect Growth Regulator for Continuous Feeding to [beef] Cattle [on pasture] through the Horn Fly Season

Contains Altosid® IGR

Mineral Supplement for Beef and Dairy Cattle on pasture [Solid feed supplement] [for all classes of [Beef] and [Dairy] [Lactating and Non-Lactating] Cattle][Only]

#### **ACTIVE INGREDIENT:**

(S)-Methoprene (CAS #65733-16-6)	0.005%
OTHER INGREDIENTS:	<u>99.995%</u>
TOTAL	100.000%

<sup>\*</sup>As the Insect Growth Regulator ALTOSID®

#### FEED INGREDIENTS\*\*

Molasses products, Forage products, Grain products, Plant Protein products, Processed Grain By-products, Roughage products, Mineral products (except calcium iodate, calcium periodate, potassium iodate, sodium iodate), 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 & 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-products 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 should be used only in accordance with the directions on the label.][Use as directed.][This product contains supplemental selenium. Intake of supplemental selenium should not exceed X% on a dry basis][Follow label direction(s).][Feeding added selenium at levels in excess of XXppm in the total diet is prohibited.]

#### **GUARANTEED ANALYSIS**

Will vary depending on geographic area and regional feeding requirements

## KEEP OUT OF REACH OF CHILDREN CAUTION

EPA Reg. No. 2724-495

EPA Est No.

NET WEIGHT: 15 to 250 lbs.

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

[This product contains high levels of copper. Consumption of this product by sheep or goats may result in copper toxicity.] (statement required dependent on copper concentration)

#### **ENVIRONMENTAL HAZARDS**

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, RF2025 TUB/block will provide sufficient (S)-methoprene insect growth regulator to prevent the emergence of adult horn flies from manure of treated cattle. Existing adult horn flies will not be affected. Start feeding before horn flies appear and continue use until cold weather marks the end of the horn fly season. Allow free choice to cattle. Cattle should consume an average of 0.8 ounces of RF2025 TUB/block per 100 lbs. of animal body weight per day, which is equivalent to 8 ounces per day for a 1,000 pound animal.

To Open: Remove top [cardboard and] [plastic cover] [protective] sheet.

- 1. Assure cattle are not starved for nutrients prior to feeding RF2025 TUB/block.
- 2. [Offer cattle 1 RF2025 TUB/block for every 15 to 25 head of cattle.] [Offer cattle 1 RF2025 TUB/block for every (range of 15 to 25) head of cattle. (for tubs/blocks of 33-50 lbs) [Offer cattle 1 RF2025 TUB/block for every (range of 15 to 25) head of cattle (for tubs/blocks of 120-250 lbs).
- 3. Remove all other self limiting nutritional supplements.
- 4. Locate RF2025 TUB/block where cattle congregate (watering, loafing, shade areas).
- 5. Replenish RF2025 TUB/block on a regular basis as needed.
- 6. If intake of RF2025 TUB/block is <u>below</u> 0.8 ounces per 100 pounds 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 RF2025 TUB/block is <u>above 0.8</u> ounces per 100 pounds animal body weight per day, [reverse the above procedure] 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.

**STORAGE AND DISPOSAL:** Do not contaminate water, food, or feed by storage or disposal.

**Storage:** Store RF2025 TUB/block in a cool, dry place.

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

**Container Disposal:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill or by incineration or if allowed by state and local authorities by burning. If burned, stay out of smoke. [Return empty tubs to [company] for cleaning and recycling.] Optional for shrink wrapped blocks: [Completely empty [wrapper][container]]. [Dispose of [wrapper][container][packaging material] in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.]

[For information or in an emergency call [phone number] or visit our Web site (URL)]

ALTOSID® Insect Growth Regulator is a registered trademark of Wellmark International.

Wellmark International Schaumburg, IL 60173

Made in USA

