

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 13, 2017

Nancy Hubel Regulatory Affairs Specialist Wellmark International 1501 E. Woodfield Rd. Suite 200W Schaumburg, IL 60173

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment to

add FDA Compliance Language to Version of Label Approved on April 14, 2016

Product Name: RF 9904 Granules EPA Registration Number: 2724-494 Application Date: December 9, 2016 OPP Decision Number: 528345

Dear Ms. Hubel:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

With this letter, the Agency accepts the label revision under OPP Decision Number 528345 to add the following language: "All feed ingredients listed on this product label must adhere to the specifications and limits (if applicable) ascribed by the Food and Drug Administration (FDA) for the use of pesticides in cattle feed." This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be

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considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Cheryl Greene of my team by phone at (703) 308-0352 or via email at Greene.cheryl@epa.gov.

Sincerely,

Andrew Bryceland, Team Leader Biochemical Pesticides Branch

for 2-12

Biopesticides and Pollution

Prevention Division (7511P)

Enclosure

04/13/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

2724-494

[optional text dependent on copper concentration]

RF9904 Granules

PREVENTS ADULT HORN FLY EMERGENCE FROM MANURE OF TREATED CATTLE

A [mineral] nutritional supplement containing S-Methoprene* Insect Growth Regulator for continuous feeding to cattle through the horn fly season

ACTIVE INGREDIENT:

S-Methoprene (CAS	#65733-16-6)	0.01%
OTHER INGREDIENTS: 99.99%		
TOTAL100.00%		100.00%

^{*}As the Insect Growth Regulator ALTOSID®

FEED INGREDIENTS

Dicalcium Phosphate, Calcium Carbonate, Sodium Chloride, Magnesium Oxide, Grain By-Products, Plant Protein Products, Grain Products, Vitamin A Supplement, D-Activated Animal Sterol (source of Vitamin D₃), Vitamin E Supplement, Manganous Oxide, Zinc Oxide, Zinc Sulfate, Ferrous Carbonate, Ferrous Sulfate Monohydrate, Copper Chloride, Copper Sulfate, Ethylenediamine Dihydriodide, Cobalt Chloride, Potassium Chloride, Sodium Selenite, Iron Oxide, Molasses, Yeast, Soybean Oil, Ethoxyquin, Mineral Oil, Petrolatum

[GUARANTEED ANALYSIS		
Calcium (Ca), minimum	0-24.00%	
Calcium (Ca), maximum	1-25.00%	
Phosphorous (P),		
Salt (NaCl), minimum		
Salt (NaCl), maximum		
Sodium, minimum	0-49.00%	
Sodium, maximum	1-50.00%	
Potassium (K),	0-2.50%	
Magnesium,		
Additional vitamins and trace minerals may be included at formulator's discretion in Guaranteed		
Analysis (based on formulation) unless required by feed regulation Components listed in () are variable depending on formular		

This product was made in a feed manufacturing facility that does not handle or store products containing animal proteins prohibited in ruminant feed.] [Free from restricted ruminant protein products per Title 21, CFR 589.2000] [Followlabel directions.] [This product contains supplemental selenium. Selenium can be fed at levels up to 120 ppm in a mixture for freechoice feeding at a rate not to exceed an intake of 3 mg per head per day.][CFR Title 21 Sec. 573.920 (c)(3)(ii)]

This product contains ethoxyquin, a preservative.

KEEP OUT OF REACH OF CHILDREN WARNING See additional Precautionary Statements

EPA Reg. No. 2724-494

EPA Est No.: will vary dependent on subregistrant, examples: 084056-NM-001, 40770-KS-01, 040741-MO-001, 1352-IA-003, 48013-ND-051, 88091-TN-001, 26171-TX-001, 6552-IA-01, 74672-VT-001, 2011-NE-01, 602-IN-001, 9374-MO-01,

7698-KS-001, 7138-NC-021 NET WEIGHT: 5 - 75 lb

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS WARNING

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

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 eye. Call a poison control center or doctor for treatment advice.
doctor, or g	oduct container or label with you when calling a poison control center or oing for treatment. You may also contact 1-800-222-1222 24 hrs/day, 7 emergency medical treatment information.

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.

GENERAL INFORMATION

This product is to be used as a cattle feed-through pesticide for the control of horn flies. All feed ingredients listed on this product label must adhere to the specifications and limits (if applicable) ascribed by the Food and Drug Adminsitration (FDA) for the use of pesticides in cattle feed. This product contains ethoxyquin, a preservative. The amount of ethoxyquin may vary according to the individual manufacturer's formulation and will not exceed the 150 ppm maximum limit established for ethoxyquin by FDA, per 21 CFR 573.380.

FEEDING AND MANAGEMENT INSTRUCTIONS

Feed this product to cattle only. When used as directed, RF9904 Granules 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 0.4 ounces of RF9904 Granules per 100 lbs. of cattle body weight per day, which is equivalent to 4 ounces per day for a 1,000 pound cow.

- 1. Assure cattle are not starved for nutrients in RF9904 Granules by providing them prior to feeding RF9904 Granules.
- 2. [This product contains added copper. Do not feed to cattle in close proximity to sheep or other species that have a low tolerance to supplemental copper.] (statement required dependent on copper concentration)
- 3. Offer cattle 50 pounds of RF9904 Granules for every 15 head of cattle.
- 4. Remove all other self limiting nutritional supplements while the cattle are consuming this product.
- 5. Locate RF9904 Granules where cattle congregate (watering, loafing, shade areas).
- 6. Replenish RF9904 Granules on a regular basis as needed.

- 7. If intake of RF9904 Granules is <u>below</u> 0.4 ounces per 100 lbs. cattle body weight per day, increase the number of feeding locations and/or change location(s) to areas more frequented by cattle.
- 8. If intake of RF9904 Granules is <u>above 0.4</u> ounces per 100 lbs. cattle body weight per day, reduce the number of feeding locations and/or change location(s) to areas less frequented by cattle.
- 9. 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 in a cool 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 Handling: Nonrefillable container. Do not reuse or refill this container. Completely empty bag, 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.

For information, call [1-800-222-1222] 24 hours per day, 7 days per week ALTOSID® Insect Growth Regulator is a registered trademark of Wellmark International.

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

Made in USA