

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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

February 6, 2017

Steven Spaulding Senior Director of Regulatory Affairs Wellmark International 1501 East Woodfield Road Suite 200 West Schaumburg, IL 60173

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling and Formulation Label

Amendment – To revise labeling language to declare, clarify or remove specific feed ingredients; to add an Agency statement clarifying the responsibilities of EPA, FDA, the manufacturer and the user of feed-through pesticides in cattle feed mixtures to the labeling; and to add an alternate source of active ingredient to the product via alternate CSF #2

Product Name: RF2025 TUB

EPA Registration Number: 2724-495 Application Date: February 5, 2015 OPP Decision Number: 499907

Dear Mr. Spaulding:

The amended labeling and Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable.

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.

Please note that the record for this product currently contains the following acceptable CSFs:

- Basic CSF dated 03/05/2005
- Alternate CSF #1 dated 03/05/2005
- Alternate CSF #2 dated 02/03/2017

Any CSFs other than those listed above are superseded/no longer valid.

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

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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 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 by phone at (703) 308-0352 or via email at greene.cheryl@epa.gov.

Sincerely,

Andrew Bryceland, Team Leader Biochemical Pesticides Branch Biopesticides and Pollution Prevention Division (7511P)

andrew C. Engelow

Office of Pesticide Programs

Enclosure

ACCEPTED

02/06/2017

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 2724-495

[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%

^{*}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. [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][Follow label directions.][Use as directed.][This supplement should be used only inaccordance with the directions on the label.][This product contains supplemental selenium. Selenium can be fed at levels up to 120 ppm in a mixture for free-choice 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.

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.: 602-NE-001, 1990-NE-001, 7138-KY-003, 7138-KY-007, 7627-KS-1, 7698-MN-003, 7698-TX-001, 7698-SD-003, 7698-CA-001, 7698-KY-001, 7698-KY-002, 65901-NE-1, 65901-IA-001, 70081-ND-001, 70081-TX-003, 70933-MO-01, 70933-TX-01, 70933-ND-01, 73600-TX-001, 73600-IN-001, 74634-IA-001, 74885-TX-001, 75319-TX-001, 81058-ND-001, 82109-KS-01, 82109-ND-01, 82545-OK-001, 82545-SD-001, 82545-NV-001, 84311-MO-001, 84315-TX-001, 88921-TX-1, 88921-IA-001 NET WEIGHT: 15 to 250 lbs.

Lot Number

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 pesticide 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 Administration (FDA) for cattle feed use when mixed with this pesticide product. 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, 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 cattle body weight per day, which is equivalent to 8 ounces per day for a 1,000-pound cow.

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. [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 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.).
- 4. Remove all other self-limiting nutritional supplements while the cattle are consuming this product.
- 5. Locate RF2025 TUB/block where cattle congregate (watering, loafing, shade areas).
- 6. Replenish RF2025 TUB/block on a regular basis as needed.
- 7. If intake of RF2025 TUB/block is <u>below</u> 0.8 ounces per 100 pounds 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 RF2025 TUB/block is <u>above</u> 0.8 ounces per 100 pounds cattle 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.
- 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 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 Handling (for plastic tubs, 125-250 lbs.): Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, 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.

Container Handling when sold in refillable steel drums (250 lbs.): Refillable container. Refill this container with this product only. Do not reuse this container for any other purpose. Return empty tubs to [company] for cleaning and recycling. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. If the container is not returned, completely empty container by tapping sides and bottom to loosen material. Then offer for recycling if available or dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

Container Handling 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 the National Poison Control Center at [1-800-222-1222], (24 hrs./day, 7 days/wk.)

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

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

Made in USA