



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 24, 2015

Mr. Steven R. Spaulding
Senior Director, Regulatory Affairs
Farnam Companies, Inc.
1501 E. Woodfield Road, Suite 200W
Schaumburg, IL 60173

Subject: PRIA Label Amendment – Addition of Swine Feed-Through New Use
Product Name: RMI-2011-D 0.04% Diflubenzuron Cattle Supplement
EPA Registration Number: 89459-3
Application Date: April 1, 2014
Decision Number: 489561

Dear Mr. Spaulding:

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable under FIFRA Section 3(C)(7)(B), and is subject to the following conditions:

1. You must submit and/or cite all data required for registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
2. You are required to comply with the data requirements described in the DCI identified below:
 - a. Diflubenzuron GDCI-108201-1286

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

http://www.epa.gov/oppsrrd1/contacts_prd.htm

3. Be aware that proposed data requirements have been identified in a Work Plan. For more information on these proposed data requirements, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:
http://www.epa.gov/oppsrrd1/contacts_prd.htm

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 the 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 the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements 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 Agency 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.

Your release for shipment of the product constitutes acceptance of these conditions. If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). If you have any questions, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or Rodia.Carmen@epa.gov.

Sincerely,



Richard Gebken
Product Manager 10
Invertebrate & Vertebrate Branch 2
Office of Pesticide Programs

*Enclosures: Label Stamped "Accepted," dated November 24, 2015
EFED Risk Assessment, dated September 30, 2015
HED Risk Assessment, dated October 27, 2015
Waiver Request to Register a Diflubenzuron Feed-Through Product for Swine Fly Control, dated October 27, 2015*

RMI -2011-D

0.04% DIFLUBENZURON CATTLE SUPPLEMENT

Alternate brand name: ClariFly® Larvicide Livestock Premix 0.04%

A nutritional supplement containing Diflubenzuron Insect Growth Regulator for continuous feeding to (cattle), (horses) (and/or) (swine) through the fly season.

A [nutritional] premix containing [Diflubenzuron Insect Growth Regulator] for inclusion in [(beef) (and) (dairy) (cow) (heifer) (swine) (nursery) (grow-finish) (breeding stock) (Total mixed rations)(TMR's)(rations)] [to] [that] prevent(s) the emergence of (horn flies) (face flies) (house flies) (stable flies) (manure breeding flies) from (manure)(waste) of treated (cattle) (horses) (and) (swine)
(Can be used as) part of [(an integrated)(a total)(a complete)] (fly control)(pest management) program

ACTIVE INGREDIENT:

Diflubenzuron* (CAS #35367-38-5).....0.04%

OTHER INGREDIENTS:.....99.96%

TOTAL.....100.00%

*Contains 181.6 mg diflubenzuron/lb.

FEED INGREDIENTS**

Molasses products; Forage products; Grain products; Plant Protein products; Processed Grain by-products; Roughage products; Mineral products; 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 and 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 on nutritional requirements in different geographical areas of the country

[Contains no prohibited animal by-products in accordance with FDA regulation 21 CFR 589.2000]

[Free from restricted ruminant protein product per Title 21 CFR 589.200]

[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 nutrient feed as described in 21 CFR 589.2000]

[This supplement must be used only in accordance with the directions on the label] [Use only as directed]

[This product contains elemental selenium. Intake of supplemental selenium must not exceed x% on a dry basis] [Follow label directions] [Feeding added selenium levels in excess of xx ppm in the total diet is prohibited].

GUARANTEED ANALYSIS

(Will vary depending on geographic area and regional feeding)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See additional Precautionary Statements

EPA Reg. No. 89459-3

EPA Est. No.

Lot Number:

NET WEIGHT: 50 lbs

ACCEPTED

11/24/2015

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

EPA Reg. No. 89459-3

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION

Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash clothing before reuse.

Personal Protective Equipment (PPE): Applicators and other handlers of this product must wear:

- Long sleeve shirt and long pants
- Chemical Resistant gloves
- Shoes
- Socks

| FIRST AID | |
|---|---|
| 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.• Call a poison control center or doctor for treatment advice. |
| If on Skin: | <ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 – 20 minutes.• Call a poison control center or doctor for treatment advice. |
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents, call 1-800-347-8272, 24 hours per day, 7 days per week. | |

ENVIRONMENTAL HAZARDS

This pesticide is toxic to aquatic invertebrates. 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, (RMI-2011-D 0.04% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.04%)(this product) provides sufficient diflubenzuron insect growth regulator to prevent the emergence of (adult) (House flies) (*Musca domestica*) (Stable flies) (*Stomoxys calcitrans*), (Face flies) (*Musca autumnalis*), (and) (Horn flies) (*Haematobia irritans*), (manure breeding flies) from manure of treated (cattle) (horses) (and) (swine). Existing adult flies will not be affected. Start feeding before flies appear and continue use until cold weather marks the end of the fly season. Use (RMI-2011-D 0.04% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.04%)(this product) as part of a(n) [integrated][pest][fly] [control] [management] program aimed at reducing fly populations. House and stable flies can [(breed)(and)(develop)] in decaying vegetable matter or spilled silage on premises in the (cow's) (cattle's) (horse's) (swine's) (hog's) environment. Good sanitation practices, such as cleaning up spilled feed and preventing manure build-up around barns and fences or under feed bunks, will eliminate additional breeding sites for these flies.

Feeding Directions for Confined Beef and Dairy Cattle

Mix (RMI-2011-D 0.04% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.04%)(this product) with the ration to provide 0.1 mg Diflubenzuron/kg of body weight. Use the following equation to determine the exact amount of this product needed per ton of ration.

$$\text{Pounds of RMI-2011-D required per ton of ration} = \frac{\text{Weight (lbs)} \times 0.5}{\text{Consumption (lbs/day)}}$$

1. Assure (cattle)(cows)(and)(heifers) are provided (RMI-2011-D 0.04% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.04%)(this product) on a daily basis.
2. Introduction of this product after an adult fly infestation is established will require treatment of cattle with adulticides or use of insecticidal baits and traps if elimination of the adult fly population is desired.

Feeding Directions for Pastured Beef and Dairy Cattle

Place [(RMI-2011-D 0.04% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.04%)(this product)] in feeders close to water sources and/or resting areas. Allow free choice to cattle. Cattle should consume an average of 0.4 ounces of [(RMI-2011-D 0.04% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.04%)(this product)] per 100 lbs. of animal body weight per day, which is equivalent to 4 ounces per day for a 1,000 pound animal.

1. Assure cattle are not starved for nutrients by providing them prior to feeding [(RMI-2011-D 0.04% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.04%)(this product)].
2. [This product contains added copper. Do not feed 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 [(RMI-2011-D 0.04% diflubenzuron cattle supplement)(ClariFly® Larvicide Livestock Premix 0.04%)(this product)] for every 15 head of cattle.
4. Remove all other self limiting nutritional supplements.
5. Locate [(RMI-2011-D 0.04% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.04%)(this product)] where cattle congregate (watering, loafing, shade areas).
6. Replenish [(RMI-2011-D 0.04% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.04%)(this product)] on a regular basis as needed.
7. If intake of [(RMI-2011-D 0.04% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.04%)(this product)] is below 0.4 ounces per 100 lbs. animal 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 [(RMI-2011-D 0.04% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.04%)(this product)] is above 0.4 ounces per 100 lbs. animal 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.

Feeding Directions for Equine

Mix (RMI-2011-D 0.04% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.04%)(this product) with the ration to provide 0.15 mg Diflubenzuron/kg of animal body weight. Use the following equation to determine the exact amount of this product needed per ton of ration.

$$\text{Pounds of RMI-2011-D required per ton of ration} = \frac{\text{Weight (lbs)} \times 0.75}{\text{Consumption (lbs/day)}}$$

Feeding Directions for Swine

Mix (RMI-2011-D 0.04% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.04%)(this product)with the ration to provide 0.2 mg Diflubenzuron/kg of animal body weight to 0.3 mg Diflubenzuron/kg of body weight. Use the higher inclusion rate for lighter weight pigs.

Use the following equation when calculating inclusion level based on a **0.20 mg/kg dosage**:

$$\text{Pounds of RMI-2011-D required per ton of ration} = \frac{\text{Weight (lbs)} \times 1}{\text{Consumption (lbs/day)}}$$

Use the following equation when calculating inclusion level based on a **0.30 mg/kg dosage**:

$$\text{Pounds of RMI-2011-D required per ton of ration} = \frac{\text{Weight (lbs)} \times 1.5}{\text{Consumption (lbs/day)}}$$

1. Assure (swine) (nursery) (grow-finish) (breeding stock) are provided (RMI-2011-D 0.04% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.04%)(this product) on a daily basis.
2. Introduction of this product after an adult fly infestation is established will require treatment of swine with adulticides or use of insecticidal baits and traps if elimination of the adult fly population is desired.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: Keep this product in its tightly closed original container. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

Pesticide Disposal: Wastes resulting from the use of this pesticide 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 into mixing equipment, then offer for recycling, if available or dispose of empty bag in a sanitary landfill or by other procedures approved by state and local authorities

CONDITIONS OF WARRANTY AND LIMITATION OF LIABILITY

Read the entire Directions for Use, Conditions of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once. By using this product, user or buyer accepts the following Conditions, Disclaimer of Warranties and Limitations of Liability.

CONDITIONS: The Directions for Use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Central Garden & Pet Company. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: To the extent consistent with applicable law, Central Garden & Pet Company makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. No agent of Central Garden & Pet Company is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent consistent with applicable law, Central Garden & Pet Company disclaims any liability whatsoever for special, incidental or consequential damages resulting from the use or handling of this product.

LIMITATIONS OF LIABILITY: To the extent consistent with applicable law, the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, shall not exceed the purchase price paid or at Central Garden & Pet Company's election, the replacement of product.

For more information, call 1-800-xxx-xxxx

Central Garden & Pet Company
1501 E. Woodfield Road, Suite 200W
Schaumburg, IL 60173

Made in USA

(OPTIONAL LANGUAGE)



IMPLEMENT THE OPTIMUM IPM

House flies, stable flies, face flies and horn flies are pervasive and resilient pests. Make the most of your control efforts by incorporating an integrated pest management program (IPM) with (Brand name)(this product). The ideal program will hit flies where they breed, and can help reduce populations to manageable levels.

IPM PROGRAM OVERVIEW

PLANNING

- Assess your operation and find the fly hot spots.
- Establish a plan to minimize pest damage by the most economical means, utilizing various control measures.
- Set an action threshold, a point at which pest populations or environmental conditions indicate that pest control action must be taken.
- Train other employees on the plan.

IMPLEMENTATION

Sanitation Control

- Keep buildings in good repair and your grounds free of debris where flies can breed.
- Keep animal areas as clean and dry as possible. Flies lay their eggs in manure, decaying silage, spilled feed, and soiled bedding.
- Calf hutches and other temporary housing that are clean, well ventilated, and relocated with regularity will address a major breeding area for flies.
- Keep feed storage areas, bunks, and water troughs in good repair, clean, and as dry as possible.
- Keep grass and weeds around barns, feeders, hutches, and manure piles cut low. Overgrown areas provide an ideal resting and breeding ground for flies.

Non-Insecticidal Controls

- The Starbar® line of sticky/jug traps can be used for controlling adult flies and are ideal for keeping track of control efforts.
- Traps are good for areas where conventional chemical control is out of the question such as milking parlors and feeding areas.

Traditional Chemical Controls

- Scatter baits from Starbar® such as QuikStrike® and Golden Malrin® Scatter Baits are a form of chemical control that can be used in rotation to fight fly resistance. Scatter baits can be used in a variety of locations (consult labels) around the operation. However, keep away from animals and children.

IGR Larvicide Controls

- Incorporate an IGR larvicide into all (cattle)(horse)(swine)(animal) feed.

EVALUATION

- Keep track of fly populations with speck cards as well as non-insecticidal jug and sticky traps.
- Document your progress with a concise record of locations, conditions, and action taken.
- Rotate traditional chemical control products to fight fly resistance.

No one aspect of an IPM will eliminate flies. Incorporation of all these steps into one program is key. (Brand name)(this product) is an important component to help control fly populations in a successful IPM program on your operation. For more information about (brand name)(this product), call 1-800-XXX-XXXX or visit [URL]. For more information about Starbar® products, visit starbarproducts.com