

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-C 0.67% Diflubenzuron Cattle Supplement

EPA Registration Number: 89459-2 Application Date: April 1, 2014 Decision Number: 489560

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

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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 <u>Rodia.Carmen@epa.gov</u>.

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

 $Waiver\ Request\ to\ Register\ a\ Difflubenzuron\ Feed-Through\ Product\ for\ Swine\ Fly$

Control, dated October 27, 2015

RMI-2011-C 0.67% DIFLUBENZURON CATTLE SUPPLEMENT

Alternate brand name: ClariFly® Larvicide Livestock Premix 0.67%

[(Stops)(Prevents the)] [(development)(emergence)] of (Horn flies) (Face flies) (House flies) and (Stable flies) in the manure [(of)(from)] treated (cattle) (lactating and non-lactating beef and dairy cows, slaughter, stocker and feeder cattle and calves including veal calves) (and horses)] Insect Growth Regulator (IGR) for continuous feeding during the fly season (Daily) feed concentrate for (beef and dairy) (cattle) (horses) (swine) containing [(diflubenzuron) (brand name) Insect Growth Regulator (IGR) for continuous feeding during the fly season [(Fly larvicide)(fly control)] for [(beef and dairy cattle) (horses) (and) (swine)] [(Stops)(Prevents the)] development of (Horn fly) (Face fly) (House fly) (Stable fly) (and) (manure breeding fly) larvae in manure [(of)(from)] treated [(beef and dairy cattle) (horses) (and)

[(Stops)(Prevents the)] [(development)(emergence)] of manure breeding flies in the [(manure)(waste)] of treated swine (including nursery, grow-finish and breeding stock). Contains [(diflubenzuron)(brand name)(Insect Growth Regulator)(IGR)(chitin synthesis inhibitor)]

Breaks the [(fly)(flies')] life cycle

Prevents the [(formation)(synthesis)] of (chitin in) fly larvae's exoskeletons (when they molt)(resulting in their death)

(Can be used as) part of [(an integrated)(a total)(a complete)] (fly control)(pest management) program

[(For control of)(Controls) flies [(developing) (growing)] in manure [of treated (cattle)(horses)(and)(swine)]

ACTIVE INGREDIENT (% by weight):

Diflubenzuron* (CAS# 35367-38-5)	
OTHER INGREDIENTS [**]	<u>99.33%</u>
TOTAL	100.00%

^{*}contains 3.04 grams of diffubenzuron per pound.

[** Refers only to ingredients which are not larvicidal.]

KEEP OUT OF REACH OF CHILDREN CAUTION

EPA Reg No. 89459-2

EPA Est. No.

NET WT: xx lbs. (xx kg.)

ACCEPTED

11/24/2015

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

89459-2

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS CAUTION

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID			
 If in eyes Hold eye open and rinse slowly and gently with water for 15 minutes. Remove contact lenses, if present, after the first 5 minutes, 			
	continue rinsing.Call 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.

PERSONAL PROTECTIVE EQUIPMENT: Mixers and other handlers must wear long-sleeved shirt and pants, shoes plus socks, and chemical resistant gloves made of nitrile rubber, barrier laminate, neoprene rubber or viton ≥ 14 mils. 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.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to aquatic invertebrates. Do not contaminate water when disposing of equipment washwaters.

USE INFORMATION

[(RMI-2011-C 0.67% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.67%)(this product)] is intended for blending into feeds or supplements for (beef and dairy) (cattle) (horses) (and) (swine) rations to control manure breeding flies. This product prevents emergence of adult flies from the manure of the treated (cattle) (horse) (swine). Use [(RMI-2011-C 0.67% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.67%)(this product)] only in (beef and dairy) (cattle) (horse) (and) (swine) supplements/rations.

Use [(RMI-2011-C 0.67% Diflubenzuron Cattle Supplement) (ClariFly® Larvicide Livestock Premix 0.67%) (this product)] as part of a(n) [integrated][pest][fly][control] [management] program aimed at reducing fly populations in the treated (cattle's) (horse's) (swine's) environment. Consult your [veterinarian][or][retailer] for program recommendations. In order to achieve optimum fly control, use [(RMI-2011-C 0.67% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.67%)(this product)] in conjunction with [other][brand name] premise and on-animal products as well as good management and sanitation practices.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[(RMI-2011-C 0.67% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.67%)(this product)] contains diflubenzuron, [an][insect growth regulator][IGR] which prevents the development of (horn flies) (face flies) (house flies) (stable flies) (and) (manure breeding flies) in the manure of treated (beef and dairy cattle) (horses) (and) (swine), but is not effective against existing adult flies. Start feeding [(RMI-2011-C 0.67% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.67%)(this product)] early in the spring [(3-4 weeks)(30 days)(1 month) before flies begin to appear, and continue feeding throughout the summer and into the fall until cold weather (restricts)(stops)(ends) fly activity. In some cases, supplemental fly control measures may be needed in and around (pastures) (barns) (feedlots) (and) (facilities) to control adult house and stable flies which can breed in other decaying [(organic)(vegetable)] matter or silage in the area, or that migrate in from other locations.

The dosage of [(RMI-2011-C 0.67% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.67%)(this product)] is proportional to the animal's body weight and must be offered daily throughout the entire fly season. The following table [(gives dosage information)(provides the feeding rate)] for all approved species.

Species		Daily Feeding Rate of DFB AI	
	mg/kg	mg/cwt	
Cattle - [(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.	0.10	4.55	
Horses - [(Brand name)(This product) may be fed to horses including ponies, burros, and donkeys.	0.15	6.82	
Swine - [(Brand name)(This product) may be fed to swine including nursery, grow-finish, and breeding stock with no withdrawal period. Use the higher inclusion rate for lighter weight pigs.	0.20 - 0.30	9.10 – 13.64	

CATTLE MIXING DIRECTIONS

MIXED WITH FREE-CHOICE MINERALS

Mix [(RMI-2011-C 0.67% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.67%)(this product)] with free-choice-fed minerals to produce a [(RMI-2011-C 0.67% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.67%)(this product)] and mineral mixture as shown in the table below¹.

4 OZ. PER DAY FEEDING RATE

RMI-2011-C 0.67% Diflubenzuron Cattle Supplement		lbs	6.10%		
Free-Choice Minerals	200	lbs	93.90%		
Total	213	lbs	100.00%		
2 OZ. PER DAY FEEDING RATE					
RMI -2011-C 0.67% Diflubenzuron Cattle Supplement	13.5	lbs	11.89%		

Free-Choice Minerals	100.0	lbs	88.11%
Total	113.5	lbs	100.00%

¹These calculations are based on a 1,000 pound animal.

Place the [(RMI-2011-C 0.67% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.67%)(this product)] plus mineral mixture in feeders close to water sources and/or resting areas. Use one feeder for each 15 to 20 head. Fill the feeders with no more than a 5 to 7 day supply of the mixture at one time, and protect the mixture from rain.

MIXED-RATION FEEDING

Use the table below as a guide for mixing [(RMI-2011-C 0.67% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.67%)(this product)] with grain or a feed supplement.

Body Weight	Feed Intake	Feed Intake	RMI -2011-C 0.67% Diflubenzuron Cattle Supplement		
(lbs.)	as a % body wt.	(lbs. /head /day)	[(oz./ton)] [(lbs./ton)]		
100-200	See table bel	ow: "For Formulating Ca	If Starters (and Milk Replacers)		
250	1.50%	3.75	[31.9]	[2.0]	
500	1.50%	7.50	[31.9]	[2.0]	
750	1.50%	11.25	[31.9]	[2.0]	
1000	1.50%	15.00	[31.9]	[2.0]	
1500	1.50%	22.50	[31.9]	[2.0]	
250	2.00%	5.00	[23.9]	[1.5]	
500	2.00%	10.00	[23.9]	[1.5]	
750	2.00%	15.00	[23.9]	[1.5]	
1000	2.00%	20.00	[23.9]	[1.5]	
1250	2.00%	25.00	[23.9]	[1.5]	
250	2.50%	6.25	[19.1]	[1.2]	
500	2.50%	12.50	[19.1]	[1.2]	
750	2.50%	18.75	[19.1]	[1.2]	
1000	2.50%	25.00	[19.1]	[1.2]	
1500	2.50%	37.50	[19.1]	[1.2]	
250	3.00%	7.50	[15.9]	[1.0]	
500	3.00%	15.00	[15.9]	[1.0]	
750	3.00%	22.50	[15.9]	[1.0]	
1000	3.00%	30.00	[15.9]	[1.0]	
1250	3.00%	37.50	[15.9]	[1.0]	

Inclusion of RMI-2011-C = Supplement (lbs/ton)

Body Weight (lbs)

100 X 3

Average Daily
Feed Intake (lb)

Thoroughly mix [(RMI-2011-C 0.67% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.67%)(this product)] with grain or a feed supplement. The mixing and feeding rates in the above table will provide the required daily intake of [(0.10 mg diflubenzuron/kg of body weight)(4.54 mg diflubenzuron/100 lbs. of body weight)] per day.

FOR FORMULATING CALF STARTERS (AND MILK REPLACERS)

For formulating calf starters and milk replacers to be fed to calves weighing between 50 and 200 pounds, use the following table:

		INCLUSION RATE	
CALF WEIGHT	FEED INTAKE Ibs/head/day	lbs of (Brand name)/ton	g of Diflubenzuron/ton
50 - 99 lbs	1.0 – 1.4	3.0	9.1
100 – 150 lbs	1.0 – 1.4	4.5	13.6
100 – 170 lbs	1.5 – 1.7	3.6	10.9
100 – 200 lbs	≥1.8	3.0	9.1

EQUINE MIXING DIRECTIONS MIXED-RATION FEEDING

Use the formula below to calculate the inclusion level of [(RMI-2011-C 0.67% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.67%)(this product)] with grain or a feed supplement.

Thoroughly mix [(RMI-2011-C 0.67% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.67%)(this product)] with grain or a feed supplement.

SWINE MIXING DIRECTIONS MIXED-RATION FEEDING

Use the formulas below to calculate the inclusion level of [(RMI-2011-C 0.67% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.67%)(this product)] with grain or a feed supplement based on the target dosage. 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**:

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

Thoroughly mix [(RMI-2011-C 0.67% Diflubenzuron Cattle Supplement)(ClariFly® Larvicide Livestock Premix 0.67%)(this product)] with grain or a feed supplement.

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. Do not contaminate with pesticides or fertilizer.

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 by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into mixing equipment. Then offer for recycling, if available, or dispose of 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.

Central Garden & Pet Comapny 1501 E. Woodfield Road, Suite 200W Schaumburg, IL 60173 Made in USA.



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-Insecticidall 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 cildren.

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



Supplemental Labeling

FOR BLENDING INTO FEEDS OR SUPPLEMENTS FOR CONTROL OF FLIES DEVELOPING/GROWING IN MANURE OF TREATED SWINE

EPA Reg. No. 89459-2

This supplemental label expires November 24, 2018 and must not be used or distributed after this date.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Read the label affixed to the container for CLARIFLY® LARVICIDE LIVESTOCK PREMIX 0.67% before using.

IMPORTANT: Use of **CLARIFLY® LARVICIDE LIVESTOCK PREMIX 0.67%** according to this labeling is subject to the use precautions and limitations imposed by the label affixed to the container for **CLARIFLY® LARVICIDE LIVESTOCK PREMIX 0.67%**.

For blending into feeds or supplements for control of flies developing/growing in manure of treated swine.

CLARIFLY® LARVICIDE LIVESTOCK PREMIX 0.67% is intended for blending into feeds or supplements for swine rations to control manure breeding flies. Use **CLARIFLY® LARVICIDE LIVESTOCK PREMIX 0.67%** as part of an integrated pest management program aimed at reducing fly populations in the treated animal's environment. Consult your veterinarian or retailer for program recommendations. In order to achieve optimum fly control, use **CLARIFLY® LARVICIDE LIVESTOCK PREMIX 0.67%** in conjunction with other premise and on-animal products as well as good management and sanitation practices.

CLARIFLY® LARVICIDE LIVESTOCK PREMIX 0.67% contains diflubenzuron, which prevents the development of manure breeding flies in the manure of treated swine, but is not effective against existing adult flies. In some cases, supplemental fly control measures may be needed in and around facilities to control adult house and stable flies which can breed in other decaying organic matter or silage in the area, or that migrate in from other locations.

The dosage of **CLARIFLY® LARVICIDE LIVESTOCK PREMIX 0.67%** is proportional to the animal's body weight and must be offered daily throughout the entire fly season. The following table gives dosage information.

Species	Daily Feeding Rate of Diflubenzuron Al		
·	mg/kg	mg/cwt	
Swine - CLARIFLY® LARVICIDE LIVESTOCK PREMIX 0.67% may be fed to swine including nursery, grow-finish, and breeding stock with no withdrawal period. Use the higher inclusion rate for lighter weight pigs.	0.20 - 0.30	9.10 – 13.64	



SWINE MIXING DIRECTIONS MIXED-RATION FEEDING

Use the formulas below to calculate the inclusion level of **CLARIFLY® LARVICIDE LIVESTOCK PREMIX 0.67%** with grain or a feed supplement based on the target dosage. 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**:

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

Thoroughly mix **CLARIFLY® LARVICIDE LIVESTOCK PREMIX 0.67%** with grain or a feed supplement.

This labeling must be in the possession of the user at the time of application.

Registrant:

Central Garden & Pet Company 1501 East Woodfield Road 200W Schaumburg, Illinois 60173