



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 23, 2021

Ms. Heather Bjornson-Lam
Regulatory Consultant to Champion USA, LLC
c/o Bjornson Regulatory Consulting LLC
272 Hathaway Lane
Wynnewood, PA 19096

Subject: PRIA Label Amendment – Addition of Efficacy Claims for Horn, Stable and House Flies & Incorporation of Registration Review Mitigation for Diflubenzuron
Product Name: CUS-019-1
EPA Registration Number: 91586-7
Application Dates: March 16, 2020 & March 16, 2021
Decision Numbers: 571982 & 572611

Dear Ms. Bjornson-Lam:

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). This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them. In addition, the Agency, in accordance with FIFRA, as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with the Diflubenzuron Final and/or Interim Decision, and has concluded that your submission is acceptable, subject to the following conditions:

1. You must submit and/or cite all data required for registration/reregistration/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 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://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

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. The next label printing of this product must use this labeling unless subsequent changes have been approved. 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 12 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.

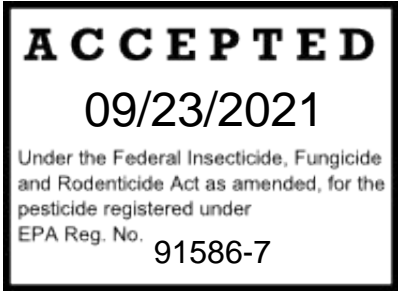
Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). If you have any questions, please contact Mr. Carmen J. Rodia, Jr. by phone at (703) 306-0327, or via email at Rodia.Carmen@epa.gov.

Sincerely,



Tamica Cain, Acting Product Manager 10
Invertebrate & Vertebrate Branch 2
Registration Division (7505P)

Enclosures: *Master Label Stamped "Accepted," dated September 23, 2021*
Efficacy Review, dated July 29, 2021



(Text in braces are notes to the reviewer)
 [Text in brackets alone are optional statements or alternate statements]

(Label for Free Choice Loose Salt)

DIFLUBENZURON	GROUP	15	INSECTICIDE
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CUS-019-1

AN INSECT GROWTH REGULATOR* END-USE PRODUCT TO KILL STABLE FLIES, FACE FLIES, HORN FLIES (AND REDUCE THE EMERGENCE OF HOUSE FLIES) IN THE MANURE OF BEEF AND DAIRY CATTLE.

A NUTRITIONAL SUPPLEMENT CONTAINING DIFLUBENZURON* FOR CONTINUOUS FEEDING TO CATTLE THROUGH THE STABLE, FACE, HORN AND HOUSE FLY SEASON.

*JustiFly® Insect Growth Regulator

ACTIVE INGREDIENT:

Diflubenzuron* (CAS# 35367-38-5)	0.16%
OTHER INGREDIENTS**	<u>99.84%</u>
TOTAL.....	100.00%

*contains 726.4 milligrams of diflubenzuron per pound.

** refers only to ingredients which are not larvicidal

GUARANTEED ANALYSIS

[May vary depending on geographical area or regional feeding requirements]

Salt (NaCl) minimum	88.00%
Salt (NaCl), maximum	99.84%
Calcium (Ca) minimum	0.0%
Calcium (Ca) maximum	5.0%
Phosphorous (P) minimum	0.0%
Magnesium (Mg)	() ppm
Potassium (K), minimum	0%
Sulphur (S) minimum	() ppm
Iron (Fe) minimum	() ppm
Iodine (I) minimum	() ppm
Manganese (Mn) minimum	() ppm
Zinc (Zn), minimum	() ppm
Copper (Cu), minimum	() ppm
Cobalt (Co), minimum	() ppm
Iodine (I), minimum	() ppm
Selenium (Se), minimum	() ppm

FEED INGREDIENTS***

Salt, Calcium, Phosphorous, Magnesium, Potassium, Sulphur, Iron, Iodine, Manganese, Cobalt, Copper, Zinc, Selenium, Mineral Oil.

*** 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.]

[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 in accordance with the directions on the label.] [Used only as directed.]

[This Product contains elemental selenium. Intake of supplemental selenium must not exceed 3 ppm /hd/day on a dry basis. Follow label directions. Feeding added selenium levels in excess of 3 ppm in the total diet is prohibited.]

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE BACK FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Manufactured for
CHAMPION USA LLC
125 N. Congress Avenue #7
Delray Beach, FL 33445

NET CONTENTS: 25 lbs or 40 lbs or 50 lbs

EPA Reg No. 91586-7

EPA Est. No. xxxxx-xxx-xxx

Batch Number or Lot Number

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Wear long-sleeved shirt and long pants, socks, shoes, and gloves.

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 poison control center or doctor for treatment advice.
HOT LINE NUMBER Have the product container or label with you when calling a poison control center, doctor, or going for treatment. For non-emergency general information on this pesticide product (including health concerns or pesticide incidents), call the National Pesticide Information Center (NPIC) at 1-800-858-7378, Monday through Friday, 8:00 AM to 12:00 PM Pacific Time (NPIC Web site: www.npic.orst.edu). After 12:00 PM Pacific Time Weekdays and during the weekend, call your poison control center at 1-800-222-1222.	

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 \geq 14 mils. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, 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 washwater.

DIRECTIONS FOR USE

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

PRODUCT INFORMATION: There is no withdrawal period for CUS-019-1. Start feeding CUS-019-1 in the spring before Stable, Horn, Face, and House flies begin to emerge and continue use until cold weather marks the end of Stable, Horn, Face, and House fly season. In some cases, supplemental Stable, Horn, Face control and reduced adult House Fly emergence measures may be needed in and around pastures, barns, and feedlots to kill adult stable flies which can breed in other decaying matter or silage in the area, or that migrate in from other locations.

FEEDING AND MANAGEMENT INSTRUCTIONS: Feed this product to cattle only. When used as directed CUS-019-1 will provide sufficient diflubenzuron insect growth regulator to prevent the emergence of adult Stable, Horn, Face and House Flies from manure of treated cattle. Existing adult Stable, Horn, Face, and House flies will not be affected. Start feeding before (Stable, Horn, Face, and House) flies appear, and continue feeding until cold weather marks the end of the (Stable, Horn, Face and House) fly season. Allow free choice to cattle. Cattle should consume an average of 0.1 oz of CUS-019-1 per 100 lbs of body weight/day, which is equivalent to 1 oz per day per 1,000 lb animal.

1. Assure cattle are not starved for nutrients in this product prior to feeding this product.
2. Offer 50 lbs of CUS-019-1 for every 20-30 head of cattle.
3. Remove all other self-limiting nutritional supplements while the cattle are being fed CUS-019-1

4. Replenish CUS-019-1 on a regular basis as needed.
5. If intake of this product is below 0.1 oz/100 lbs animal body weight/day, increase the number of feeding locations and/or change locations(s) to areas more frequented by cattle
6. If intake of this product is above 0.1 oz/100 lbs animal body weight/day, reduce the number of feeding locations and/or change locations(s) to areas less frequented by cattle.
7. Introduction of this product after (Stable, Horn, Face and, House) fly, infestations are established may require treatment of the cattle with an adulticide, if elimination of the adult stable fly populations are required.

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 away from other pesticides, fertilizer, food or feed that is inaccessible to children and animals.

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 empty bag in a sanitary landfill or by other procedures approved by state and local authorities.

WARRANTY AND LIMITATION OF DAMAGES

Seller warrants that this material conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use and Buyer assumes the risk of any use contrary to such directions. To the extent consistent with applicable law, Seller makes no other express or implied warranty of Fitness or of Merchantability, and no agent of Seller is authorized to do so except in writing and with specific reference to this warranty. In no event shall Seller's liability for any breach of warranty exceed the purchase price of the material as to which claim is made.

For additional information about this product, call 1-877-726-1778.

JustiFly® is the registered trademark of Champion Farmoquimoco Ltda.

Made in the USA

[Label iteration 7-03162021]

Optional Label Claims

- Controls Stable, Horn and Face Flies
- Prevents the Emergence of Stable, Horn and Face Flies
- Reduces the Emergence of Adult House Flies
- Prevents the Development of Stable, Horn, and Face Fly Larvae in the Manure of Treated Cattle
- Reduces the Development of House Fly Larvae in the Manure of Treated Cattle
- A nutritional (protein) (mineral) (vitamin) supplement for cattle during fly season
- A nutritional (protein) (mineral) (vitamin) supplement containing diflubenzuron for continuous feeding to cattle during fly season
- Stable Fly, Horn Fly, Face Fly and House Fly larvicide for cattle
- Controls Stable Fly, Horn Fly and Face Fly developing in the manure of cattle
- Contains diflubenzuron a chitin synthesis inhibitor
- Can be used as a part of an integrated pest management program
- Solid feed supplement for all classes of (beef) and (dairy) cattle
- Breaks the Stable Fly, Horn Fly, Face Fly and House Fly life cycle in cattle