

#### U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460

wasnington, D.C. 20460

#### NOTICE OF PESTICIDE:

X Registration
Reregistration
(under FIFRA, as amended)

| EPA Reg. Number: | Date of Issuance: |
|------------------|-------------------|
|                  |                   |

91586-3 05/05/16

Term of Issuance:
Conditional

Name of Pesticide Product:

JustiFly® 0.16% Diflubenzuron
Milk Replacer Product

Name and Address of Registrant (include ZIP Code):

Mr. Ian Weatherston, Ph.D. Consultant to CHAMPION USA LLC c/o J&T Associates, LLC 4061 North 156<sup>th</sup> Drive Goodyear, AZ 85395

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(B). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

| Signature of Approving Official:   | Date:    |
|------------------------------------|----------|
| Richard Gebken                     | 05/05/16 |
| Product Manager 10                 |          |
| Invertebrate & Vertebrate Branch 2 |          |
| Office of Pesticide Programs       |          |
|                                    |          |

- 1. 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: <a href="http://www.epa.gov/oppsrrd1/contacts\_prd.htm">http://www.epa.gov/oppsrrd1/contacts\_prd.htm</a>

- 2. 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: <a href="http://www.epa.gov/oppsrrd1/contacts\_prd.htm">http://www.epa.gov/oppsrrd1/contacts\_prd.htm</a>
- 3. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
- 4. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 91586-3."
- 5. Submit one copy of the final printed label for the record before you release the product for shipment.

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.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 01/30/2016
- Alternate CSF #1 dated 01/20/2016

Page 3 of 3 EPA Reg. No. 91586-3 Decision No. 513941

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,

Richard Gebken Product Manager 10

Invertebrate & Vertebrate Branch 2 Office of Pesticide Programs

Enclosures: Label Stamped "Accepted," dated 05/05/2016

Acute Toxicity Review, dated 03/01/2016 Product Chemistry Review, dated 04/11/2016

# JustiFly® 0.16% Diflubenzuron Milk Replacer Product

AN INSECT GROWTH REGULATOR END-USE PRODUCT FOR THE CONTROL OF HORN FLY, STABLE FLY, HOUSE FLY AND FACE FLY IN THE MANURE OF BEEF, DAIRY AND VEAL CALVES

For use with whole milk or milk replacer.

Fly control for beef, dairy, veal calves.

Prevents the development and emergence of flies in the manure of treated calves [including veal calves].

Prevents the development and emergence of horn flies, stable flies, house flies and face flies in the manure of beef calves [, dairy calves] and [veal calves].

Prevents the development of horn flies, stable flies, house flies and face flies in the manure of beef calves[and dairy calves] [, including veal calves].

When mixed with whole milk or milk replacers, prevents the development and emergence of horn flies, stable flies, house flies and face flies in the manure of beef calves[, dairy calves] [, including veal calves].

Contains diflubenzuron Insect Growth Regulator [IGR][Chitin Inhibitor].

Breaks the life cycle of the listed insects [horn flies][stable flies][house flies][face flies]. May be used in an integrated pest management [fly control] program.

[ ] optional language

#### **ACTIVE INGREDIENT:**

| Diflubenzuron* (CAS# 35367-38-5) | 0.16%   |
|----------------------------------|---------|
| OTHER INGREDIENTS                |         |
| TOTAL                            | 100.00% |

<sup>\*</sup>contains 726.4 milligrams of diflubenzuron per pound.

KEEP OUT OF REACH OF CHILDREN

#### **CAUTION**

SEE [BACK FOR] ADDITIONAL PRECAUTIONARY STATEMENTS

CHAMPION USA LLC 446 W. Hillsboro Blvd. Deerfield Beach, FL 33441

NET CONTENTS xx lbs [xx g], xx lbs [xx kg]

ACCEPTED

05/05/2016

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 045500

91586-3

EPA Reg No. 91586-G

EPA Est. No. xxxxx-xxx

Batch Number

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

#### **CAUTION**

Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Wash hands 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. Remove and wash contaminated clothing before reuse.

| FIRST AID  |  |   |
|--|--|---|
| <ul> <li>If on skin</li> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for treatment advices.</li> </ul> |  | Rinse skin immediately with plenty of water for 15-20 |

#### HOT LINE NUMBER

Have the product container or label with you when calling a poison control center, doctor, or going for treatment. For emergency information concerning this product, call the National Pesticide Information Center (NPIC) at 1-800-858-7378, Monday through Friday 8 am – 12 pm PST. NPIC Web site (<a href="http://www.npic.orst.edu/">http://www.npic.orst.edu/</a>). After 12 pm PST on weekdays, and weekends, please contact 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 (nitrile rubber, barrier laminate, neoprene rubber or viton). 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.

#### **USER SAFETY RECOMMENDATIONS**

#### Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

### **ENVIRONMENTAL HAZARDS**

This pesticide is toxic to aquatic invertebrates. Do not apply directly to water, or to areas where standing water is present or to intertidal areas below the high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

#### **USE INFORMATION**

JustiFly® 0.16% Diflubenzuron Milk Replacer Product is intended for daily dosing by mixing with [adding to] whole milk or reconstitued milk replacers to prevent [control] the development and emergence of infestations of horn fly, stable fly, house fly and face fly in the manure of treated of beef calves, [dairy calves], [including veal calves].

When mixed with whole milk or milk replacer products, diflubenzuron, the active ingredient in JustiFly® 0.16% Diflubenzuron Milk Replacer Product, passes through the digestive tract and into the feces in sufficient concentration to kill fly larvae. JustiFly® 0.16% Diflubenzuron Milk Replacer Product controls the infestation by inhibiting the development of horn fly, stable fly, house fly and face fly larvae in the manure and feces of treated animals but is not effective against existing adult flies.

This product can be used as part of a(n) [integrated][pest][fly][control][management] program aimed at reducing fly populations in the cattle's environment. Consult your [veterinarian][or][retailer] for program recommendations. In order to achieve optimum fly control, use JustiFly® 0.16% Diflubenzuron Milk Replacer 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.

There is no withdrawal period for JustiFly® 0.16% Diflubenzuron Milk Replacer Product. Start feeding JustiFly® 0.16% Diflubenzuron Milk Replacer Product in the spring before flies begin to emerge and continue use until cold weather marks the end of fly season. In some cases, supplemental fly control measures may be needed in and around pastures, barns, and feedlots to control adult flies which can breed in other decaying matter or silage in the area, or that migrate in from other locations.

To ensure that each animal receives 0.1 oz per 100 lb of body weight; the dose of Justifly® 0.16% Diflubenzuron Milk Replacer Product needs to be proportional to the calf's body weight. Calves should NOT receive in excess of 0.1 mg/kg/day (4.55 mg diflubenzuron/100 lbs body weight/day).

#### **MIXING INSTRUCTIONS** (Multiple calves)

| Dose of JustiFly 0.16%             | Average weight of calves in lbs |     |     |     |
|------------------------------------|---------------------------------|-----|-----|-----|
| Diflubenzuron Milk Replace Product | 75                              | 100 | 150 | 200 |

| 10 Calves                               | 2 TBS          | 8 tsp          | 0.25 C (4 TBS) | 0.33 C (5 TBS) |
|---|----------------|----------------|----------------|----------------|
| 20 Calves                               | 0.25 C (4 TBS) | 0.33 C (5 TBS) | 0.5 C (8 TBS)  | 0.67 C (11TBS) |
| 40 Calves                               | 0.5 C (8 TBS)  | 0.67 C (11TBS) | 1.0 C (16 TBS) | 1.33 C (21TBS) |
| 80 Calves                               | 1.0 C (16 TBS) | 1.33 C (21TBS) | 2.0 C (32 TBS) | 2.67 C (43TBS) |
| 100 calves                              | 1.25 C (20TSP) | 1.67 C (27TBS) | 2.5 C (40TBS)  | 3.33 C (53TBS) |
| tsp = teaspoon TBS = Tablespoon C = Cup |                |                |                |                |

IMPORTANT: Mix the material to be fed to the calves according to the table above. Feed each calf an equal portion of the total milk treated out of individual containers. It is important to thoroughly mix the Justifly® 0.16% Diflubenzuron Milk Replacer Product immediately before feeding. Improper mixing or settling out may result in underdosing of the animals.

## **MIXING INSTRUCTIONS** (Individual calves)

Daily, prepare individual portions of whole milk or milk replacer for each calf. To achieve the 0.1 mg/kg dose of diflubenzuron, add the Justifly® 0.16% Diflubenzuron Milk Replacer Product at the rate of 0.25 tsp/30 lbs body weight. Mix thoroughly and feed the complete portion immediately.

#### 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 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 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.

Draft label iteration B-2 (050416)