

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 24, 2016

Jan Brill Manager, Registration Bayer CropScience 2 T.W. Alexander Drive Research Triangle Park, NC 27709

Subject: Label Amendment – Addition of claim for Zika virus

Product Name: BES0668 INSECTICIDE EPA Registration Number: 432-1534

Application Date: 05/04/2016 Decision Number: 517048

Dear Mr. Brill:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. 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.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one 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 these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, you may contact Elizabeth Fertich at 703-347-8560 or via email at <a href="mailto:fertich.elizabeth@epa.gov">fertich.elizabeth@epa.gov</a>.

Sincerely,

Kable Bo Davis, Product Manager 3 Invertebrate and Vertebrate Branch 1

Registration Division (7505P)

Office of Pesticide Programs

## **BES0668** Insecticide

Alternate Brand Names: DeltaGard Insecticide; DeltaGard Mosquito Insecticide; Cirrus Insecticide; Nobel Insecticide; Imperium Insecticide

## [Mosquito and/or flies Image]

FOR WIDE AREA MOSQUITO CONTROL USE ONLY BY FEDERAL, STATE, TRIBAL, OR LOCAL GOVERNMENT OFFICIALS RESPONSIBLE FOR PUBLIC HEALTH OR VECTOR CONTROL, OR BY PERSONS CERTIFIED IN THE APPROPRIATE CATEGORY, OR OTHERWISE AUTHORIZED BY THE STATE OR TRIBAL LEAD PESTICIDE REGULATORY AGENCY TO PERFORM ADULT MOSQUITO CONTROL APPLICATIONS, OR BY PERSONS UNDER THEIR DIRECT SUPERVISION, OR AS ALLOWED BY STATE REGULATIONS FOR PERSONS TREATING PRIVATE PROPERTY.

### IFOR THE CONTROL OF FLIES AND MOSQUITOES IN AND AROUND POULTRY AND LIVESTOCK FACILITIES.]

Editorial Note - [Bracketed text] is optional language

[Optional Marketing Claims Section]

ACTIVE INGREDIENT:	
Deltamethrin	2.0 %
OTHER INGREDIENTS :	
TOTAL:	100.0%
Contains 0.17 pounds of Deltamethrin per gallon	
EPA Reg. No. 432-1534	EPA Est. No

PRECAUCION AL CONSUMIDOR: Si usted no lee ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente.

(TO THE USER: If you cannot read English, do not use this product until the label has been fully explained to you.)

# CAUTION

See [Back] [Side] Panel for First Aid Instructions and [Leaflet][Booklet] for Complete Precautionary Statements and Directions for Use. (Note to reviewer: Location of additional precautionary statements, directions for use will vary between those listed, depending on container type/size.)

For <u>MEDICAL</u> and <u>TRANSPORTATION</u> Emergencies <u>ONLY</u> Call 24 Hours A Day 1-800-334-7577

For <u>PRODUCT USE</u> Information, Call 1-800-331-2867

FIRST AID					
If swallowed	<ul> <li>Call a poison control center or doctor for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>Do not give anything to an unconscious person.</li> </ul>				
If in eyes	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li> <li>Call a poison control center or doctor for immediate treatment advice.</li> </ul>				
Have the product container or label with	ou when calling a poison control center or doctor or going for treatment.				

## PRECAUTIONARY STATEMENTS

## HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

ACCEPTED

05/24/2016

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

432-1534

## **Personal Protective Equipment (PPE)**

Mixers, loaders, applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Shoes plus socks

## **User Safety Requirements**

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.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

## **USER SAFETY RECOMMENDATIONS**

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

## **ENVIRONMENTAL HAZARDS**

This product is extremely toxic to fresh water and estuarine fish and invertebrates. Runoff from treated areas into a body of water may be hazardous to fish and aquatic invertebrates.

Do not apply over bodies of water (lakes, rivers, permanent streams, natural ponds, commercial fish ponds, swamps, marshes, or estuaries), except when necessary to target areas where adult mosquitoes are present, and weather conditions will facilitate movement of applied material away from the water in order to minimize incidental deposition into the water body. Do not contaminate water when disposing of equipment rinsate or wash waters.

## When used for mosquito adulticiding;

This pesticide is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow drift when bees are foraging the treatment area, except when applications are made to prevent or control a threat to public and / or animal health determined by a state, tribal, or local health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes, or the occurrence of mosquito-borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort.

## When applied outdoors for fly control;

This pesticide is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow drift when bees are foraging the treatment area.

## DIRECTIONS FOR USE

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

Do not apply by aircraft.

Before making the first application in a season, it is advisable to consult with the state or tribal agency with primary responsibility for pesticide regulation to determine if other regulatory requirements exist.

**SHAKE OR AGITATE THOROUGHLY BEFORE USE:** Product (either diluted or undiluted) must be thoroughly agitated before use. Avoid prolonged storage of excess formulation in application equipment.

**NOTICE:** This concentrate is for dilution with water only; it cannot be diluted in oil.

## APPLICATION INSTRUCTIONS

Apply this product with hand-held, backpack, portable, and truck mounted Ultra-Low Volume (ULV) sprayers and portable and vehicle mounted mist-blowers for wide area applications, to control adult mosquitoes, black flies, gnats, non-biting midges, stable flies, horse flies, deer flies, sheep flies, horn flies, and nuisance flying insects such as houseflies or blow flies.

## WIDE AREA AND SPACE SPRAY APPLICATION FOR MOSQUITO CONTROL OVER NON CROP AREAS

Do not exceed 0.036 pounds of AI per acre per year to any site. During any three day period do not apply more than 0.00134 lb a.i./A. Do not make more than 25 applications per site per year at the high rate of 0.00134 lb ai/A. More frequent applications and more than 25 applications per site may be made to prevent or control a threat to public and/or animal health determined by a state, tribal or local

health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes or the occurrence of mosquito-borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort.

BES0668 INSECTICIDE is approved for application as an Ultra-Low Volume (ULV) aerosol to control flying or resting adult mosquitoes (including mosquitoes that may transmit Zika, Dengue, Chikungunya, and West Nile virus) in residential, industrial, urban, recreational, and municipal areas where adult mosquitoes are found. This product is used for control of mosquitoes in areas such as residential areas, industrial areas, urban areas (such as utility tunnels, sewers, storm drains and catch basins, pipe chases, basements, underground passages, parking decks, crawl spaces, or uninhabited buildings), parks, campsites, woodlands, athletic fields, golf courses, playgrounds, recreational and overgrown waste areas, roadsides, swamps, marshes, tidal areas, corrals, feed lots, swine lots, poultry ranges, zoos, animal quarters, barns, dumps, junkyards, tire dumps, and other areas where adult mosquitoes may be found.

For best results, apply when insects are most active and meteorological conditions are conducive to keeping the spray cloud in the air column close to the ground. An inversion of air temperatures and a light breeze is preferable. Application during the cooler hours of the night or early morning is recommended. Apply when wind speed is equal to or greater than 1 mph.

### APPLICATIONS OVER CROPS OR TO AREAS FAVORING DRIFT OVER CROPS

This product may be applied over any and all crops or agricultural areas, (including row, tree, fruit, citrus, pasture, rangeland, and other areas where agricultural enterprises take place) for the control of adult mosquitoes within or adjacent to the treatment areas, or to areas where drift over cropland could occur. Use label rates and follow directions for use as directed in this label. Applications over crops or where drift may occur over crops are limited to 0.0134 lb ai per acre per year, with no more than one application in any three day interval. Maximum number of applications per year depends on the application rate used; 10 applications at 0.00134 lb ai/A, 15 applications at 0.00089 lb ai/A, or 30 applications at 0.00045 lb ai/A. More frequent applications and more than 0.0134 lb. ai per acre per year per site may be made to prevent or control a threat to public and/or animal health determined by a state, tribal or local health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes or the occurrence of mosquito-borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort.

### DROPLET SIZE DETERMINATION FOR GROUND APPLICATION EQUIPMENT

This proprietary FFAST (Film Forming Aqueous Spray Technology) formulation greatly reduces the evaporation rate of water from the sprayed droplets and allows the water-based spray cloud to behave as that produced by a typical oil-based formulation. This enables the spray droplets to maintain optimum size and stability while drifting through the target area.

Spray equipment must be adjusted so that the volume median diameter (VMD) is between 8 - 30 microns ( $8\mu \le D_{v0.5} \le 30\mu$ ) and that 90% of the spray is contained in droplets smaller than 50 microns ( $D_{v\,0.9} < 50\mu m$ ). Directions from the equipment manufacturer or vendor or a test facility using a laser-based measurement instrument must be used to adjust equipment to produce acceptable droplet size spectra. Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rate(s) are properly calibrated.

## **ULV NON-THERMAL AEROSOL (COLD FOG):**

Apply through any non-thermal ULV application equipment capable of producing the required droplet spectrum. Base acreage calculations on the equipment manufacturer's recommended swath width. Apply at a rate not to exceed 0.00134 pounds of deltamethrin per acre in any given 3 day interval. An optimum swath is created when this product is applied from a truck that is being driven perpendicular to the wind direction. Direct the spray head of equipment to ensure even distribution of the spray cloud throughout the area.

This product may be applied through ULV Cold Aerosol Generators, or other equipment designed for non-thermal ULV aerosol applications. The desired application rate may be obtained under different conditions by altering the dilution rate of this product, the flow rate of the insecticide from the application equipment, and the vehicle speed. Examples are given in the following table:

Flow Rate based on a 300 foot swath width (Fluid Ounces Per Minute)

Application Rate (lb deltamethrin/ Acre)	Vehicle Speed (MPH)	Undiluted	Diluted 1 + 1	Diluted 1 + 2	Diluted 1 + 3	Diluted 1 + 4
0.00045	5	1.01	2.02	3.03	4.04	5.05
	10	2.02	4.04	6.06	8.08	10.11
	15	3.03	6.06	9.10	12.13	15.16
	20	4.04	8.08	12.13	16.17	20.21
0.00089	5	2.02	4.04	6.06	8.08	10.11
	10	4.04	8.08	12.13	16.17	20.21
	15	6.06	12.13	18.19	24.25	30.32
	20	8.08	16.17	24.25	32.34	40.42
0.00134	5	3.04	6.09	9.13	12.17	15.22
	10	6.09	12.17	18.26	24.34	30.43
	15	9.13	18.26	27.39	36.52	45.65
	20	12.17	24.34	36.52	48.69	60.86

Where dense vegetation or a public health emergency is present, the use of the highest label rate is recommended.

When targeting organophosphate resistant or other difficult to control species of mosquitoes or flies use of the high label rate is recommended.

**PORTABLE, BACKPACK OR HAND CARRIED ULV APPLICATION**: Apply through non-thermal ULV application equipment and base acreage calculations on a 50 foot swath. At a pace of 2 MPH (2.9 ft/sec) apply 1 ounce per minute of BES0668 INSECTICIDE diluted as follows: for an application rate of 0.00045 pounds of Deltamethrin per acre dilute 1 to 14, for an application rate of 0.00089 pounds of deltamethrin per acre dilute 1 to 6.5, for an application rate of 0.00134 pounds of deltamethrin per acre dilute 1 to 4. Based on the above dilution and application rates apply 5 ounces of diluted product while walking 870 feet (290 yards).

#### APPLICATION FOR FLY CONTROL

BES0668 INSECTICIDE is approved for application as an Ultra-Low Volume (ULV) aerosol to control flying or resting adult flies in residential, industrial, urban, recreational, and municipal areas where flies are found. This product is used for control of flies in areas such as residential areas, industrial areas, urban areas (such as utility tunnels, sewers, storm drains and catch basins, pipe chases, basements, underground passages, parking decks, crawl spaces, or uninhabited buildings), parks, campsites, woodlands, athletic fields, golf courses, playgrounds, recreational and overgrown waste areas, roadsides, swamps, marshes, tidal areas, corrals, feed lots, swine lots, poultry ranges, zoos, animal quarters, barns, dumps, junkyards, tire dumps, and other areas where adult mosquitoes and flies may be found.

Apply this product with hand-held, backpack, portable, and truck mounted ULV sprayers and portable and vehicle mounted mist-blowers for area applications, to control, black flies, gnats, non-biting midges, stable flies, horse flies, deer flies, sheep flies, horn flies, and nuisance pests such as face flies or blow flies. Spray equipment must be adjusted so that the volume median diameter (VMD) is between 8 - 30 microns ( $8\mu \le Dv0.5 \le 30\mu$ ) and that 90% of the spray is contained in droplets smaller than 50 microns ( $Dv 0.9 < 50\mu m$ ).

For the treatment of livestock and poultry facilities (e.g., cattle, dairy and livestock barns, goat houses, horse stables/barns, loafing sheds, poultry houses, shade houses, stables, swine houses, feedlots, manure piles, swine yards, corrals, stockyards, holding pens, and other animal facilities) where flies become pests and quick knockdown is needed.

This product may be applied undiluted, but to maximize efficacy against larger fly species (e.g., blow flies, filth flies) it is recommended to dilute in water (1 + 1) before application, increasing the droplet density in the ULV cloud.

Indoors, reduce air movement as much as possible before applying by closing doors, windows and other openings; if animals are present, ventilate the treated area immediately following application. When treating indoors, cover any exposed drinking water, drinking fountains, and animal feed before application. Outdoors, apply when insects are most active, usually in late afternoon when there is little wind. Pay particular attention to areas where flies congregate, such as around feed bunks, fences, and on the exterior walls of buildings. Animals may be present during treatment.

## STORAGE AND DISPOSAL

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

**PESTICIDE STORAGE:** Store upright at room temperature. Avoid exposure to extreme temperatures. In case of spill or leakage, soak up with an absorbent material such as sand, sawdust, earth, fuller's earth, etc. Dispose of with chemical waste.

**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:**

Rigid, Non-refillable containers small enough to shake (i.e., with capacities equal to or less than 5 gallons)

Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning 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.

Rigid Non-refillable containers that are too large to shake (i.e., with capacities greater than 5 gallons or 50 pounds)

Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse or pressure rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning 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.

Refillable container: Refill this container with pesticide only. Do not reuse this container for any other purpose. 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. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by State and Local authorities, by burning. If burned, stay out of smoke.

## IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer 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. Crop injury, 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 Bayer CropScience LP. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP 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 Bayer CropScience LP is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE LP 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 BAYER CROPSCIENCE LP'S ELECTION, THE REPLACEMENT OF PRODUCT.

DeltaGard is a registered trademark and FFAST is a trademark of the Bayer Group

Net Contents:

## PRODUCED FOR



Bayer Environmental Science A Division of Bayer CropScience LP PO BOX 12014, 2 T. W. Alexander Drive Research Triangle Park, NC 27709

BES0668 INSECTICIDE (PENDING) 03/04/2016, 03/08/2016, 05/20/2016

## Marketing Claims:

- For Effective Control of Adult Mosquitoes (Including organophosphate resistant species), Midges (non-biting), and Flies
- For use as a Space Spray by [Ground] Application to Control Adult Mosquitoes and Flies
- Formulation Allows Dilution with Water Rather Than Oil
- [Contains] no [synergist] [piperonyl butoxide] [PBO]
- Contains no [Volatile Organic Compounds] [VOCs]
- Low odor
- Uses Water as a Diluent
- Fast and Effective Control of Adult Mosquitoes and Flies
- Low use rates
- · Provides Quick Knockdown and Effective Control of Mosquitoes, Flies, Gnats, and Non-Biting Midges
- For Ground Application
- A FFAST™ Formulation
- May be Applied Undiluted or Diluted in Water
- ULV application provides control at Rates Up to 0.00134 Pounds Deltamethrin per Acre
- ULV application provides control at Rates As low as 0.00045 Pounds Deltamethrin per Acre
- Provides quick, knockdown of Adult Mosquitoes and Flies