

70787-4

03/25/2008

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs

Biopesticides and Pollution Prevention Division (7511P)

1200 Pennsylvania Ave., NW

Washington, D.C. 20460

NOTICE OF PESTICIDE: ☒ Registration
☐ Reregistration
 (under FIFRA, as amended)

EPA Reg. Number:

70787-4

Date of Issuance:

3/25/08

Term of Issuance:

Conditional

Name of Pesticide Product:

balEnce™ HF23 5ES
 biological insecticide Fly Bait

Name and Address of Registrant (include ZIP Code):

JABB of the Carolinas
 P.O. Box 310
 456 E. Main Street
 Pine Level, NC 27568

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention 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 sec. 3(c)(7)(A) provided that you do the following:

1. Submit two (2) copies of the revised final printed label before you release the product for shipment. Refer to attached Type Size Requirements for final printed labeling.
2. Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.
3. Submit by December 31, 2008, efficacy data to show the effectiveness of the product against the target pest, house fly, at the lower TGA1 concentration and to demonstrate that the product is stable for the period tested.
4. Provide, by June 21, 2008, analyses of five (5) batches of the Technical Grade Active

Signature of Approving Official:

Janet L. Andersen
 Janet L. Andersen, Ph.D., Director
 Biopesticides and Pollution Prevention Division (7511P)

Date:

3/25/08

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Ingredient (TGAI, EPA Reg. No. 70787-1; registered December 27, 2006) which is used for production of this and other End-use Products (EPs) intended for control of house fly. The data for the TGAI must include:

- (a) detection and regulatory limits of beauvericin and any other fungal metabolites of toxicological concern associated with *Beauveria bassiana* strain HF23.
- (b) detection, identification, enumeration and rejection limits of potential human pathogens (bacterial and fungal) in the analysis of production batches. All batches containing human pathogens above regulatory levels must be destroyed. *Bacilli* contamination must not exceed 10^4 colony forming units per gram Technical Grade Active Ingredient.


The monitoring period for Quality Assurance and Quality Control of the pesticide products containing *Beauveria bassiana* HF23 may be longer depending on the evaluation of these data submissions.

The registrations of the TGAI and this EP (balEnce™ Fly Bait) will automatically expire on midnight June 30, 2009, which allows time for review of data submissions concurrent with the terms and conditions specified for the registration of the TGAI and EPs. Any requests for time extensions to provide the data listed above must be submitted in writing prior to the appropriate deadline. If the data, or a request for an extension, are not received by the appropriate deadline, these products are subject to cancellation. Successful conversion of the status of *Beauveria bassiana* HF23 products from conditional to unconditional registration is contingent upon Agency review and acceptance of these data.

If EPA determines, at any time, that additional data are required to maintain in effect an existing conditional registration, the Agency will require submission of such data under Section 3(c)2(B) of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended. If you do not comply with these conditions, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the approved label in connection with this conditional registration is enclosed for your records. If you have any other questions regarding this registration, do not hesitate to email Shanaz Bacchus at bacchus.shanaz@epa.gov or call her on 703-308-8097.

Sincerely,



Janet L. Andersen, Ph.D., Director
Biopesticides and Pollution Prevention Division (7511P)

cc: file 70787-1, 70787-2, 70787-4
Encl: approved label

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balEnce™ HF23 5ES biological insecticide Fly Bait

For control of flies in Poultry Facilities.

Active Ingredient:

Beauveria bassiana HF23 conidia	0.095%
5 x 10 ¹¹ conidia per 1 kg substrate (5.0 x 10 ⁸ cfu/g of product)	
Other Ingredients	99.905%
Total:	100%

EPA Registration Number: 70787-4

Manufactured By:
Jabb of the Carolinas, Inc
456 East Main Street
Pine Level, NC 27568
USA

ACCEPTED

3/25/08

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 70787-4

Net Contents: 5 lbs (2.27 kg)

Lot Number:

Expiration Date:

KEEP OUT OF REACH OF CHILDREN

CAUTION:

Avoid contact with skin, eyes or clothing. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

USER PRECAUTIONARY STATEMENTS

May cause eye irritation. May cause skin irritation. Do not get in eyes, on skin, or on clothing. Wear goggles, face shield or safety glasses when handling. May be harmful if swallowed or inhaled. Avoid breathing spray mist. Wear dust/filtering respirator meeting NIOSH standards of at least N-95, R-95 or P-95. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Keep in original container and store out of direct sunlight in a cool dry location. Do not allow balEnce fly bait to contact food, feedstuffs or water. Apply bait in locations inaccessible to children, poultry, other animals and pets where bait cannot be picked up or where animals and pets cannot contact or eat. Use bait stations or trays that are a minimum of 4 feet above ground.

USER SAFETY RECOMMENDATIONS

User should: Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Use of waterproof glove is recommended when handling this product.

STATEMENT OF PRACTICAL TREATMENT

FIRST AID	
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
If on skin or clothing	<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.
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 eye. • 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.	

ENVIRONMENTAL HAZARDS

This product is potentially pathogenic to honey bees. Avoid applying to areas where honeybees are actively foraging or around hives. Do not apply directly to water, to areas where surface water is present or to intertidal areas below mean water mark. Do not contaminate surface water by disposal of equipment wash waters.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling. For specific requirements to your state or tribe, consult the agency responsible for pesticide regulations.

GENERAL INFORMATION

Failure to follow directions and precautions on this label may result in poor insect control.

APPLICATION PROCEDURES

balEnce Fly Bait is a fly bait formula containing a fungal pathogen of flies. balEnce Fly Bait should **NOT** be used inside homes.

Methods of Application

Do not apply fungicides prior to the use of this product.

Bait Use: Do not use inside homes. Pour balEnce Fly Bait granules onto desired

location. Bait stations should be a minimum of 4 feet above ground. Use the product at 1/4 pound per 500 square feet of area. Do not spread granules within reach of children or animals. Use balEnce Fly Bait in poultry production facilities where flies are present.

Bait Stations: Use balEnce Fly Bait by scattering bait in bait pan or tray hung above head level where poultry cannot contact. Bait should be replaced every 5 to 7 days. Empty bait stations before refilling with bait.

STORAGE AND DISPOSAL

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

STORAGE: Store in a cool, dry place. Do not store at temperatures exceeding 80° F (27° C). Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then 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.

Limited Warranty/Disclaimer

Manufacturer warrants that this product is suited for the labeled use when applied according to label directions. Manufacturer makes no warranty of merchantability. To the extent required by state law, there are no warranties that extend beyond the description on this label and in no event shall manufacturer be liable for any consequential damages.