



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

February 13, 2008

Kenneth D. Racke, Ph.D.
Regulatory Leader
Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268

Subject: Response to EPA letters of May 4, 2005
Conserve Fly Bait PCO; EPA Reg. No. 62719-506
Conserve Fly Bait RTL; EPA Reg. No. 62719-507
Applications dated June 1, October 26 and December 5, 2005

Dear Dr. Racke:

The labeling for each of the above referenced products, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the following comments:

- On the front panel, and first the bullet under General Use Precautions, revise the statement "Contains the bittering agent, Bitrex" to read "Contains Bitrex"; and delete the last statement of the first sentence ("an intensely bitter by humans."). This statement is considered an "implied safety claim", with no supporting data. Please note that the cited/me-too product's labeling have been revised appropriately.
- Delete the statement "No chemical odor", due to its subjectivity – depending on an individual's senses. Thus, this term is unacceptable, and product labels with this claim should be revised accordingly.
- Under Warranty Disclaimer and Limitation of Remedies, add "*To the extent consistent with applicable law*" to the beginning of the statements "*Dow AgroSciences makes no . . . implied warranty*", "*The exclusive remedy for losses . . .*" and "*AgroSciences shall not be liable . . . loss or damage in writing*" and "*In no case shall AgroSciences . . . damages or losses*". Please refer to the following EPA website for further guidance on warranty statements:
<http://www.epa.gov/pesticides/regulating/labels/projects.html>

Please make the above stated revisions and submit the final printed labels to the Agency. See enclosed copies of the stamped label for your record. If you have any questions, please contact Dr. B.A. Akinlosotu at (703) 605-0653.

Sincerely,



JK

George T. LaRocca,
Product Manager 13
Insecticide Branch
Registration Division (7505P)

Enclosure

(front panel)

Conserve[®] Fly Bait RTL

Granular Fly Control
[Alt. Naturalyte[®] Fly Control]

For control of houseflies outdoors around houses, garbage cans, garbage collection points, outdoor latrines, pet kennels, compost areas, non-commercial animal housing (e.g., on hobby farms) including poultry houses, pig pens, livestock barns, livestock pens, horse stables, stables or other animal handling or feeding facilities.

[Optional marketing claims that may be included on front panel of label.]

- Ready to use
- Use straight from the bag [bottle] [container]
- Contains spinosad
- Flexible application methods
- Broadcast application
- Bait station [device] application
- Hang-board [device] application
- Hang-card [device] application
- Contains the fly attracting pheromone, Z-9 tricosene
- With pheromone attractant, special fly bait and fly killer
- Follow all label directions
- Spinosad is biologically derived from the fermentation of saccharopolyspora spinosa, a naturally occurring soil organism
- Bait formula with Z-9 tricosene
- Kills both sexes of flies
- Contains adult fly sex attractant
- Attracts and kills house flies
- Flies feed and die
- Attracts and kills resistant house flies
- 1 ounce treats 125 sq ft
- X device(s) treats X sq ft
- Yellow color [red color]
- No chemical odor
- With a pheromone fly attractant
- Flies feed on the bait and die
- Flies ingest a lethal dose of bait and die
- Contains the bittering agent, Bitrex[™]

Active Ingredient:

| | |
|---|---------|
| spinosad (a mixture of spinosyn A and spinosyn D) | 0.50% |
| (Z)-9-tricosene (Pheromone) | 0.04% |
| Other Ingredients † | 99.46% |
| Total | 100.00% |

† Contains the bittering agent, Bitrex[™]
U.S. Patent No. 5,362,634 and 5,496,931

**ACCEPTED
with COMMENTS
In EPA Letter Dated:**

FEB 13 2007

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
62719-507**

Keep Out Of Reach Of Children

[Include the following statements only if sold in granule form.]

Precautionary Statements

User Safety Recommendations

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Use of waterproof gloves is recommended when handling this product to avoid staining of skin or clothing.

[Include the following statement if sold as a bait station or hang-board/card device]

4 8 7

Do not tamper with child resistant feature of bait station [device] or hang-board/card bait [device].

Environmental Hazards

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

Notice: Read the entire label. Use only according to label directions. **Before using this product, read Warranty Disclaimer, Inherent Risks of Use, and Limitation of Remedies at end of label. If terms are unacceptable, return at once unopened.**

In case of emergency endangering health or the environment involving this product, call 1-800-992-5994. If you wish to obtain additional product information, visit our web site at www.dowagro.com.

EPA Reg. No. 62719-507

EPA Est. _____

®Trademark of Dow AgroSciences LLC
Dow AgroSciences LLC • Indianapolis, IN 46268 USA

Net Weight __ lb

(back panel)

Directions for Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read entire label before using.

Storage and Disposal

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

Pesticide Storage: Store in original container, tightly closed in a secure place. Keep out of the reach of children and domestic animals.

Pesticide Disposal: [Granular products]If empty: Do not reuse this container. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency or 1-800-992-5994 for disposal instructions. Never place unused product down any indoor or outdoor drain.

Disposal [Bait station device or hang-board/card device]: Dispose of in trash after use.

General Information

Conserve® Fly Bait RTL granular [**Naturalyte®**] fly control is intended for control of houseflies outdoors around houses, garbage cans, garbage collection points, outdoor latrines, pet kennels, compost areas, non-commercial animal housing (e.g., on hobby farms) including poultry houses, pig pens, livestock barns, livestock pens, horse stables, stables, or other animal handling or feeding facilities. Conserve Fly Bait RTL can also be used indoors, but only in areas where children, animals or pets cannot come in contact with or ingest the granules. See specific use instructions and precautions below. This product's active ingredient, spinosad, is biologically derived from the fermentation of *Saccharopolyspora spinosa*, a naturally occurring soil organism.

General Use Precautions

- Conserve Fly Bait RTL contains the bittering agent, Bitrex™, an intensely bitter substance intended to prevent inadvertent consumption by humans. Conserve Fly Bait RTL also contains a fluorescent yellow [red] pigment that makes the bait more attractive to flies.

[Include the following four (4) statements only if product is sold in granule form]

- Use of waterproof gloves is recommended when handling Conserve Fly Bait RTL to avoid staining of skin or clothing.
- Keep in original container and store out of direct sunlight in a cool and dry location. To preserve effectiveness, reseal container immediately after measuring and using the product.
- Do not allow Conserve Fly Bait RTL to contact food, feedstuffs, and water. Protect exposed food, feedstuffs, and water, where necessary, to avoid contamination.
- Do not allow pets to feed on garbage treated with Conserve Fly Bait RTL.
- Apply Conserve Fly Bait RTL only in locations inaccessible to children, livestock animals and pets where bait granules cannot be picked up or where animals and pets cannot lick surfaces on which the bait has been placed.

Application Timing

Re-application: Re-apply [Install new bait station device or hang-board/card bait device] when bait [device] is no longer effective in controlling flies.

Bait Application Methods

One or a combination of the following bait presentation methods may be used:

Scatter Bait: Scatter Conserve Fly Bait RTL evenly outdoors around garbage cans, garbage collection points, outdoor latrines, and compost areas where flies are observed to be resting or feeding. Scatter uniformly at the rate of 1 oz per 125 sq ft of area (XX oz of container treats approximately XXX sq ft of area). Do not put into piles. **Note:** Do not use scatter bait application method inside the house, or in areas where children, animals or pets could come in contact with the granules.

Station Bait [Station Delivery Device]: Place a minimum of 1 [station delivery device] per XXX sq ft of open house floor space or other use site in areas where flies are observed to be resting or feeding. Additional stations [delivery devices] may be used in large rooms or areas separated by hallways, doors, or screens.

[Editor's note: Bait to be provided in child-resistant/spill-proof bait station delivery device designed by supplemental distributor. Bait station devices will be designed to deliver in total approximately 1 oz of bait per 125 sq ft of open house floor space or other use site through use of one or multiple station devices]

Hang-Board/Card Bait [Hang-Board/Card Delivery Device]: Place a minimum of 1 [hang-board/card delivery device] per XXX sq ft of open house floor space or other use site in areas where flies are observed to be resting or feeding. Additional [hang-board/card delivery devices] may be used in large rooms or areas separated by hallways, doors, or screens.

[Editor's note: Bait to be provided in child-resistant hang-board/card delivery device designed by supplemental distributor. Hang-board or card devices will be designed to deliver in total approximately 1 oz of bait per 125 sq ft of open house floor space or other use site through use of one or multiple hang-board or card devices]

Terms and Conditions of Use

If terms of the following Warranty Disclaimer, Inherent Risks of Use, and Limitation of Remedies are not acceptable, return unopened package at once to the seller for a full refund of purchase price paid. Otherwise, use by the buyer or any other user constitutes acceptance of the terms under Warranty Disclaimer, Inherent Risks of Use and Limitation of Remedies.

Warranty Disclaimer

Dow AgroSciences warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in strict accordance with the directions, subject to the inherent risks set forth below. Dow AgroSciences MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

Inherent Risks of Use

It is impossible to eliminate all risks associated with use of this product. Lack of performance or other unintended consequences may result because of such factors as use of the product contrary to label instructions (including conditions noted on the label, such as unfavorable temperatures, soil conditions, etc.), abnormal conditions (such as excessive rainfall, drought, tornadoes, hurricanes), presence of other materials, the manner of application, or other factors, all of which are beyond the control of Dow AgroSciences or the seller. All such risks shall be assumed by buyer.

Limitation of Remedies

The exclusive remedy for losses or damages resulting from this product (including claims based on contract, negligence, strict liability, or other legal theories), shall be limited to, at Dow AgroSciences' election, one of the following:

1. Refund of purchase price paid by buyer or user for product bought, or
2. Replacement of product.

Dow AgroSciences shall not be liable for losses or damages resulting from handling or use of this product unless Dow AgroSciences is promptly notified of such loss or damage in writing. In no case shall Dow AgroSciences be liable for consequential or incidental damages or losses.

The terms of the Warranty Disclaimer, Inherent Risks of Use, and this Limitation of Remedies cannot be varied by any written or verbal statements or agreements. No employee or sales agent of Dow AgroSciences or the seller is authorized to vary or exceed the terms of the Warranty Disclaimer or this Limitation of Remedies in any manner.

®Trademark of Dow AgroSciences LLC
Bitrex™ is a trademark of Macfarlin Smith Ltd.

EPA Accepted: 05/04/05