

## 10/24/2006

#### **UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

WASHINGTON, D.C. 20460

OCT 24 2006

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Allergy Technologies, LLC c/o Mr. John Wright Product & Regulatory Associates, LLC P.O. Box. 1683 Voorhees, NJ 08043-9998

Dear Mr. Wright:

Subject: Amendment - Add Bed Bug control claim ActiveGuard Mattress Liner EPA Registration Number 82123-1 Your submission dated May 19, 2006

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(a), is conditionally acceptable provided that you:

- 1. Submit and/or cite all data or other material required for registration/reregistration of your product under FIFRA section 3(c)(5) or FIFRA section 4 when the Agency requires all registrants of similar products to submit such data.
- 2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling.
  - a. While the general claim "Kills dust mites and bed bugs in mattresses" is acceptable, certain specific claims are not acceptable and by virtue of the nature of the product are unable to be supported; therefore, the following must be deleted from the label:
    - i. "For dust mite and bed bug control"
    - ii. "Controls dust mites"
    - iii. "Dust mite allergens are a major cause of asthma, allergic rhinitis and eczema"
    - iv. "Kills bed bugs"
    - v. "Controls bed bugs"
    - vi. "Helps prevent bites and allergic reactions caused by bed bugs"

- b. The following label claims must be modified, as indicated by italicized text (the added text will not be italicized on your label):
  - i. "Kills dust mites in mattresses"
  - ii. "Kills dust mites in mattresses, which may be a source of home allergens"
  - iii. "Kills dust mites in mattresses for up to 2 years"
  - iv. "Kills bed bugs in mattresses"
- 3. Confirmatory data are needed as a condition of registration demonstrating that the product is efficacious against bed bugs for a minimum of 2 years under normal use conditions. The aforementioned 2 years of normal use is in addition to one year as a stored product. A copy of the Agency's product performance/efficacy review is enclosed for your records.

A stamped copy of the label is enclosed for your records. Please submit five copies of the amended labeling bearing the above revisions before you release the amended label for shipment.

Sincerely,

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

ACCEPTED with COMMENTS

In EPA Letter Dated: OCT 24 2006

Under the Federal Insecticióe,

Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA, Reg. N

#### Front panel:

### ActiveGuard™

**Mattress Liner** 

For dust mite and beg bug control. Kills dust mites and bed bugs in mattresses! Kills dust mites.

Controls dust mites.

Kills dust mites which maybe a source of home allergens.

ActiveGuard™ is fatal to dust mites.





(Format pictures with line through them – implying that we stop the pests)

Kills dust mites for 2 years.

Dust mites in the home live in mattresses.

Dust mite allergens may cause allergies in humans.

Kills dust mites in mattresses for up to 2 years.

Dust mite allergens are a major cause of asthma, allergic rhinitis and eczema.

Dust mites live and breed in mattresses.

Kills bed bugs.

Controls bed bugs.

Bed bug bites can be itchy and painful and may cause allergic reactions.

Helps prevent bites and allergic reactions caused by bed bugs.

Impregnated Liner:

- Soft and Comfortable
- Completely Odorless
- Easy to use

ACTIVE INGREDIENT: Permethrin 1.64% OTHER INGREDIENTS:

98.36%

100.00%

#### **CAUTION**

Do Not Allow Children to Play with Mattress Liner.
READ THE DIRECTIONS AND PRECAUTIONS FOR USE ON BACK PANEL.

Retain This Package Label for Future Reference on Proper Handling of This Mattress Liner.

**EPA Registration No. 82123-1 NET CONTENTS: 6.1 ounces** 

Size:

#### Back panel:

# ActiveGuard TM Mattress Liner

#### Kills dust mites and bed bugs in mattresses





(Format pictures with line through them – implying that we stop the pests)

ActiveGuard™ Mattress Liners, manufactured with patented ActiveGuard™ technology, are soft, comfortable, completely odorless and easy to use.

#### **DIRECTIONS FOR USE**

It is a Violation of Federal Law to Use This Product in a Manner Inconsistent with its Labeling.

#### **IMPORTANT**

Do Not Use This Product on Bedding (Mattresses) of Children Five (5) Years Old or Under.

Do Not Lie Directly on the Mattress Liner.

Do Not Use for Purposes Other Than a Mattress Liner.

Always Place the Mattress Pad and Barrier Encasement or Bottom Sheet over Mattress Liner Before Use.

- Fit the ActiveGuard™ liner over the mattress. Place the mattress pad and barrier encasement or bottom sheet over the mattress liner.
- After eight (8) weeks remove the ActiveGuard™ liner and vacuum your mattress thoroughly while ventilating the room to remove any remaining allergens. For best results, we would recommend using new filters and fresh bags in your vacuum cleaner. If you suffer from dust mite induced allergies, have someone else vacuum your mattress.
- 3. Re-apply the *ActiveGuard*™ mattress liner on your mattress immediately, and then leave the mattress liner undisturbed for two (2) years. No need for further removal or vacuuming.

Note: Washing the *ActiveGuard*™ mattress liner removes the active ingredient and reduces the effectiveness of the product against dust mites and bed bugs.

- 4. Follow the above directions for re-applying or fitting a new mattress liner.
- 5. For best results, replace with a new ActiveGuard ™ Mattress Liner every 18 months.

Note: Wash hands immediately after applying or fitting the ActiveGuard™ mattress liner.

#### PRODUCT RANGE

ActiveGuard<sup>™</sup> mattress liners come in a range of sizes to accommodate most standard mattress sizes - (Single, Full, Queen and King).

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Storage: Prior to installation, store in a cool, dry place away from direct sunlight. Disposal: Discard used mattress liner in trash.

**NOTICE:** Buyer assumes all risks of use, storage or handling of this product not in accordance with directions.

Contact InfoTrac at 1-800-535-5053 for emergency medical treatment information.

For general information online at www.allergytechnologies.com

U.S. Patents 5,916,580, 6,214,365, 6,440,438 and pending patents

ActiveGuard and logos are trade marks of Allergy Technologies, LLC, © 2005 Allergy Technologies, LLC

EPA Establishment No. 083228-GBR-001

Allergy Technologies, LLC.
124 South Maple Street
Ambler, PA 19002
www.allergytechnologies.com

**UPC Code** 

Size:

7057

#### This label is to be attached to the ActiveGuard<sup>TM</sup> Mattress Liner.

ActiveGuard™ Mattress Liner

Active Ingredient: Permethrin 1.64% w/w

#### **CAUTION**

Do Not Allow Children to Play with Mattress Liner

EPA Reg. No. 82123-1 EPA Est. No. 083228-GBR-001

See package label for complete directions and precautions for use. Kills dust mites in mattress for up to two (2) years.

Date first fitted to bed ----/---

Discard used mattress liner in trash.