

75844-7

04/01/2008

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U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (H7505C)  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

EPA Reg. Number:  
75844-7

Date of Issuance:  
APR 1 2008

Term of Issuance:  
Conditional

Name of Pesticide Product:  
  
Freedom 45 Plus IGR Spot-On for  
Dogs

# NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration

(Under FIFRA as amended)

Name and Address of Registrant (include ZIP Code):

Andrew M. Martin Co., NV Inc.  
1802 N. Carson Street, Suite 212-2808  
Carson City, NV 89701

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/reregistered 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:

1. You will submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. You will make the following label changes before you release the product for shipment:
  - a) Revise the EPA Registration Number to read "EPA Reg. No. 75844-7."
  - b) Modify the following claim as noted: *Kills, repels mosquitoes, lice and mites on dogs for up to 4 weeks.*
  - c) Remove the following claims from the product label or revise the formulation by increasing the pyriproxyfen concentration to 1.9 % (Please note that if you choose to revise the formulation by increasing the amount of pyriproxyfen, you will need to submit a revised CSF). The database does not support claims for pyriproxyfen as a spot-on at the label application rate. Therefore, you must submit data supporting these claims at the lower concentration (refer to the enclosed Product Performance/Efficacy Review Memorandum for details):
    - 1) Kills flea eggs and larvae for up to 8 weeks
    - 2) Kills flea eggs and larvae for up to 6 weeks
    - 3) Kills flea eggs and larvae for up to 4 weeks
    - 4) BREAKS FLEA LIFE CYCLE!

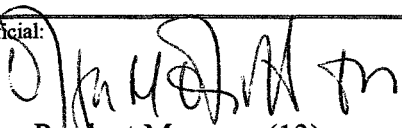
- d) Remove the following claims from the product label. Claims relating to product effectiveness may not be false or misleading, and heightened efficacy/comparative claims are not acceptable: *7 WAY PROTECTION; PROTECT 7 WAYS; AMRx.*
  - e) Since the product is in Acute Toxicity Category IV for all routes of exposure, the Signal Word, Hazards to Humans and First Aid statements are not required. You may delete these statements. Note that the Child Hazard Warning is still required.
  - f) Revise the 2<sup>nd</sup> sentence of the Environmental hazards to read: *Do not allow treated dogs to go swimming for 12 hours following treatment.*
  - g) Under Hazards to Domestic Animals add the typical symptoms of sensitivity as listed on the cited me-too product i.e. add, *"Signs of sensitivity include skin sensitivity, increased itchiness, redness, rash, hair discoloration or hair loss at the application site, lethargy".*
  - h) Following the heading Hazards to Domestic Animals add in bold type *"For external Use on Dogs only: Do not Use on Cats or animals other than dogs. Consult a veterinarian...."*
  - i) Add *"pregnant, or nursing pups"* to the statement beginning, *"Consult a veterinarian before using this product...."*
  - j) Under the Warranty Statement add *"To the extent consistent with applicable law"* in front of:
    - 1) *"Andrew M. Martin Co., NZ Inc.'s maximum liability..."*
    - 2) *"Buyer and user acknowledge and assume all risks..."*
  - k) The EPA registration number must also appear on the tube label.
  - l) The container disposal statements for pesticides have been revised. Refer to PR Notice 2007-4 and modify your label accordingly.
  - m) Revise the data matrix by citing the appropriate companion animal safety data.
3. The confidential statement of formula (CSF) dated 12-11-2007 is acceptable.
4. The product chemistry data requirements for guidelines 830 Series subgroup A and Subgroup B are satisfied with the exception of storage stability (830.6317) and corrosion characteristics data (830.6320). These data are outstanding and must be submitted to the Agency. It is required that observations be made at 0, 3, 6, 9, and 12 month intervals. Please refer to the Product Chemistry Review Memorandum for details.

5. Submit two (2) copies of your final printed labeling before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing amended labeling constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that a notice of availability of EPA's reregistration eligibility document (RED) for products containing permethrin was published in the FR on June 28, 2006 (Vol. 71 No. 124 pg. 36788). Additional data and/or labeling changes may be required for products containing permethrin.

If you have any questions regarding this action, please contact Olga Odiott of my team at (703) 308-9369.

Signature of Approving Official:



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

Date:

APR 1 2008

Enclosures

Front panel

# FREEDOM 45 PLUS SPOT-ON FOR DOGS

[Cat/slash icon]

For use on dogs and puppies over twelve weeks of age

## DO NOT USE ON CATS

[Kills, repels and prevents re-infestation of fleas for up to 5 weeks]  
[Kills, repels and prevents re-infestation of fleas for up to 4 weeks]  
[Kills flea eggs and larvae for up to 8 weeks]  
[Kills flea eggs and larvae for up to 6 weeks]  
[Kills flea eggs and larvae for up to 4 weeks]

### BREAKS FLEA LIFE CYCLE!

[Kills, repels and prevents re-infestation of ticks for up to 6 weeks]  
[Kills, repels and prevents re-infestation of ticks for up to 4 weeks]  
[Kills, repels mosquitoes, lice and mites on dogs for up to 4 weeks]

### 7 WAY PROTECTION

### PROTECT 7 WAYS

### AMRX

#### ACTIVE INGREDIENT

Permethrin\*[CAS# 52645-53-1] ..... 45.00%

Pyriproxyfen [CAS# 95737-68-1]..... 1.00%

OTHER INGREDIENTS ..... 54.00%

TOTAL 100.00%

\* Cis/trans ration: max 55% [ $\pm$ ] cis and min 45% [ $\pm$ ] trans

## KEEP OUT OF REACH OF CHILDREN

## CAUTION

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS  
READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

Andrew M. Martin Co., NV Inc.  
1802 Carson Street, Suite 212-2808  
Carson City, NV 89701

EPA Registration No. 75844-?  
EPA Establishment No. 75844-CA-02

Package contains a two [2], three [3],

#### Net Contents

3 x 1 ½ cc applicators  
3 x 3 cc applicators  
2 x 6 cc applicators

ACCEPTED  
with COMMENTS  
In EPA Letter Dated  
APR 1 2008  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
75844-7

12 x 1 ½ cc applicators  
240ML BOTTLE  
4-240 ML BOTTLE W/GUN

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

### CAUTION

**Hazards to Humans:** Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove and wash contaminated clothing before re-use. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

**Hazards to Domestic Animals:** Consult a veterinarian before using this product on debilitated, aged or medicated animals. Consult a veterinarian before using on dogs with known organ dysfunction. Sensitivities can occur after ANY pesticide product for animals. If signs of sensitivity occur, discontinue use, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

#### **DO NOT USE ON CATS.**

May be toxic and potentially fatal if applied to, or ingested by cats. **Cats which actively groom or engage in close physical contact with recently treated dogs may be at risk of serious harmful effects.**

### FIRST AID

#### IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.

#### IF ON SKIN OR CLOTHING

- 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

- Hold eye open and rinse slowly and gently with water for 15 - 20 minutes.
- Remove contact lenses after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice

**HOT LINE NUMBER:** Have the product container to label with you when calling a poison control center or doctor, or going for treatment. You may also contact the Rocky Mountain Poison Control at 1-303-595-4869.

### ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish and other aquatic organisms. Do not apply directly to water.

### CHEMICAL HAZARDS

Do not use or store near heat or open flame.

### STORAGE AND DISPOSAL STATEMENTS

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

**PESTICIDE STORAGE:** Store on a cool, dry place. Protect from freezing.

**PESTICIDE DISPOSAL:** Call your local solid waste agency or 1-800-CLEANUP or equivalent organization for disposal instructions. Unless otherwise instructed place in trash. Never pour unused product down the drain or on the ground.

**CONTAINER DISPOSAL:** 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 for disposal instructions. Never place unused product down any indoor or outdoor drain.

### DIRECTIONS FOR USE

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

#### DO NOT USE ON CATS

Ready to use, no dilution necessary.

- Hold tube in upright position pointing away from user's face and body. Break off tip or cut with scissors. Using the cc marks on the body of the applicator as a guide apply FREEDOM 45 Plus Spot On For Dogs as follows by gently squeezing the applicator.
- Part dog's hair between shoulder blades.
- Apply recommended amount of solution to the skin on the dog's back between the shoulder blades. For large and extra-large dogs, application of the solution to the skin directly in front of the base of the dog's tail is also required. SEE RECOMMENDED DOSING GUIDELINES BELOW.

Package for dogs weighing 33 lbs or less

Apply 1.5 cc of FREEDOM 45 Plus Spot-On For Dogs to the skin of the dog's back between the shoulder blades.

Package for dogs weighing 33 - 66 lbs

Apply 1.5 cc of FREEDOM 45 Plus Spot-On For Dogs to the skin of the dog's back between the shoulder blades and 1.5 cc to the skin directly in front of the base of the dog's tail.

Package for dogs weighing more than 66 lbs

Apply 3.0 cc of FREEDOM 45 Plus Spot-On For Dogs to the skin of the dog's back between the shoulder blades and 3.0 cc to the skin directly in front of the base of the dog's tail.

Multi package

For dogs weighing 33 lbs or less

Apply 1.5 cc of FREEDOM 45 Plus Spot-On For Dogs (1 tube) to the skin of the dog's back between the shoulder blades.

For dogs weighing 33 - 66 lbs

Apply 1.5 cc of FREEDOM 45 Plus Spot-On For Dogs (1 tube) to the skin of the dog's back between the shoulder blades and 1.5 cc (a second tube) to the skin directly in front of the base of the dog's tail.

For dogs weighing more than 66 lbs

Apply 3.0 cc of FREEDOM 45 Plus Spot-On For Dogs (2 tubes) to the skin of the dog's back between the shoulder blades and 3.0 cc (another 2 tubes) to the skin directly in front of the base of the dog's tail.

#### DOSING GUN

FOR KENNELS USE ONLY

MUST USE FREEDOM PRE-FIXED 1.5CC DOSING GUN. USE IN THE SAME WAY OF DOSING AS COSTCO TUBES.

MOUNT 240ML BOTTLE ON TO GUN

1. HOLD GUN UP-SIDE DOWN.
2. SLIDE BOTTLE COLLAR ONTO BOTTLE.
3. INSERT PUNCTURE BARB INTO BOTTLE.
4. TIGHTEN COLLAR TO GUN.
5. FLIP GUN OVER AND PRIME GUN FOR USE.

#### WARRANTY

Andrew M. Martin Co., NZ Inc., warrants that this product conforms to the chemical description on the label. Andrew M. Martin Co., NZ Inc., neither makes nor authorizes any agent or representative to make any other warranty or fitness or merchantability, guarantee or representation, express or implied, concerning this material. Andrew M. Martin Co., NZ Inc.'s maximum liability for breach of this warranty shall not exceed the purchase price of this product. Buyer and user acknowledge and assume all risks and liabilities resulting from the handling, storage and use of this product which extend beyond the use of the product under normal conditions and in accord with statements made on the label.

#### APPLICATOR TUBE

Front tube panel text: FREEDOM 45 PLUS SPOT-ON FOR DOGS

PERMETHRIN INSECTICIDE 45%

PYRIPROXYFEN INSECTICIDE 1%

DO NOT USE ON CATS or CAT/SLASH ICON

Back tube panel text: KEEP OUT OF REACH OF CHILDREN

Read entire label before each use.