

## U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs Registration Division (7505P) 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460

MOTTCE	೧೫	PESTICIDE:

X Registration
 Reregistration

	Reg.				
Number:					
758/	14-8				

Date of Issuance: SEP - 4 2008

Term of Issuance: Conditional

Name of Pesticide Product: Freedom 50 Plus IGR Spot On For Dogs

(Under FIFRA as amended)

Carson City, Nevada 89701

Name and Address of Registrant (include ZIP Code): Andrew M. Martin Company, NV Inc. 1802 N. Carson Street, #212-2808

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 you:

- 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 Registration Number 75844-8.".
- b. Delete "Contains  $AMR_x^{**}$ , [Seven in One Protection], [7 in 1 Protection], [Six in One Protection], [6 in One Protection], [Five in One Protection], and [5 in One Protection]. Claims relating to product effectiveness may not be false or misleading, and heightened efficacy/ comparative claims are not acceptable.

Si	gnature	of	Approving	Offici	.al:

Date:

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- c. Revise the pet precautions within the box to read as follows: "DO NOT USE ON CATS. Accidental application to cats and/or grooming a recently treated dog may result in tremors and/or unconditional muscle movements. If this occurs, immediate veterinary care should be provided.". The coloring of the box and text must provide "contrasting color" to other label text as to be clearly legible and readily identified by the consumer.
- d. Under Storage and Disposal Statements change "Do not reuse this container." to "Do not reuse or refill this container." for tubes. Also add "Place in trash or offer for recycling" for the bottle container disposal.
- 3. Under Environmental Hazards we note the precaution, "Do not allow treated dogs to go swimming for 12 hours following treatment.". Is this an efficacy related claim? Or does it pertain to residues in water? Is this statement based on data and has it been submitted to the Agency?
- 4. You must generate studies corresponding to guidelines 830.6317 (one year storage stability) and 830.6320 (corrosion characteristics). The results must be submitted to the Agency along with and electronic format also.
- 5. Please note that a notice of availability of EPA's registration eligibility document (RED) for product containing Permethrin was published in the FR on June 28, 2006 (Vol71 No. 124 page 36788). Additional data and/or labeling changes may be required for products containing Permethrin.
- 6. Please 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.

If you have any questions regarding this action, please contact Linda A. DeLuise of my team at (703) 305-5428.

Front panel

# FREEDOM 50 PLUS IGR 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 for 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 the flea life cycle]

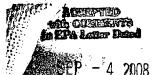
[Kills, repels and prevents re-infestation of ticks for up to 6 weeks] [Kills, repels and prevents re-infestation of ticks for up to 4 weeks] [Kills or repels mosquitoes, lice and mites on dogs for up to 4 weeks] [Contains AMR<sub>x</sub> \*\*]

**ACTIVE INGREDIENT** 

Permethrin\*[CAS# 52645-53-1] ..... 50.00% Pyriproxyfen [CAS# 95737-68-1].... 1.20% OTHER INGREDIENTS ...... 48.80%

TOTAL 100.00%

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



## KEEP OUT OF REACH OF CHILDREN

## CAUTION

BOOK STATEMENTS Constitution and Redemistion AGREAD ALL DIRECTIONS BEFORE USING THIS PRODUCT CONTROL FOR THE PRODUCT CONTROL FOR THE PRODUCT CONTROL FOR THE PARENTS NO.

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

EPA Registration No. 75844-1 EPA Establishment No. 75844-CA-02 Package contains a two [2], three [3], six [6], twelve [12] months supply. (as applicable)

#### **Net Contents**

3 x 1.35 cc applicators; 3 x 2.70 cc applicators; 2 x 5.4 cc applicators; 12 x 1.35 cc applicators 240 cc bottle with dosing gun; 480 cc bottle with dosing gun.

[\*\* AMRx is a proprietary solvent/spreader mixture.] [\*\* AMR<sub>x</sub> is a proprietary solvent/spreading agent.]

alternative or optional verbiage

#### 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: For external use on dogs only. Do not use on cats or animals other than dogs. Consult a veterinarian before using this product on debilitated, aged or medicated animals, pregnant or nursing pups. 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. Signs of sensitivity include skin sensitivity, increased itchiness, redness, rash, hair discoloration or hair loss at the application site and lethargy.

#### 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

#### **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 or 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 for medical treatment advice.

#### **ENVIRONMENTAL HAZARDS**

This product is extremely toxic to fish and other aquatic organisms. Do not allow treated dogs to go swimming for 12 hours following treatment...

#### **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 (tubes): 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.

CONTAINER DISPOSAL (bottle): Nonrefillable container. Do not reuse or refill this container.

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. Apply FREEDOM 50 Plus IGR 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 1.35cc of FREEDOM 50 Plus IGR Spot On For Dogs to the skin of the dog's back between the shoulder blades.

#### Package for dogs weighing 33 - 66 lbs

Apply 1.35cc of FREEDOM 50 Plus IGR Spot On For Dogs to the skin of the dog's back between the shoulder blades and 1.35cc to the skin directly in front of the base of the dog's tail.

#### Package for dogs weighing more than 66 lbs

Apply 2.70 cc of FREEDOM 50 Plus IGR Spot On For Dogs to the skin of the dog's back between the shoulder blades and 2.70 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 1.35 cc of FREEDOM 50 Plus IGR 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 1.35 cc of FREEDOM 50 Plus IGR Spot On For Dogs (1 tube) to the skin of the dog's back between the shoulder blades and 1.355 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 2.70 cc of FREEDOM 50 Plus IGR Spot On For Dogs (2 tubes) to the skin of the dog's back between the shoulder blades and 2.70 cc (another 2 tubes) to the skin directly in front of the base of the dog's tail.

Dosing Gun (For use only with the 240 and 480 cc bottles in kennels, shelters and boarding and grooming establishments)

Use the FREEDOM PRE-FIXED 1.35 cc dosing gun in the same manner as the individual tubes. To mount the bottle on to the gun hold the gun upside down, slide bottle collar onto the bottle, insert puncture barb into bottle and then tighten the collar to the gun. Dose animals as described above for individual tubes.

#### WARRANTY

Andrew M. Martin Co., NV Inc., warrants that this product conforms to the chemical description on the label. Andrew M. Martin Co., NV Inc., neither makes nor authorizes any agent or representative to make any other warranty or fitness or merchantability, guarantee or representation, express of implied, concerning this material. To the extent consistent with applicable law Andrew M. Martin Co., NV Inc.'s maximum liability for breach of this warranty shall not exceed the purchase price of this product. To the extent consistent with applicable law 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 50% PLUS IGR SPOT ON FOR DOGS

PERMETHRIN INSECTICIDE 50% PYRIPROXYFEN INSECTICIDE 1.2%

Back tube panel text:

KEEP OUT OF REACH OF CHILDREN

DO NOT USE ON CATS or CAT/SLASH ICON

EPA Reg # 75844-I

Read entire label before each use.

#### ALTERNATIVE MARKETING CLAIMS

[Kills five different kinds of pests on dogs]
[Kills 5 different kinds of pests on dogs]
[Kills five different canine pests]
[Kills 5 different canine pests]
[Kills 5 different canine pests]
[Kills canine pests belonging to five different orders]
[Kills canine pests belonging to 5 different orders]
[Seven in One Protection]
[7 in 1 Protection]
[Six in One Protection]
[6 in 1 Protection]
[Five in One Protection]
[5 in 1 Protection]

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