



U.S. ENVIRONMENTAL PROTECTION AGENCY

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

EPA Reg. Number:

75844-7

Date of Issuance:

01/8/18

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited
Expires: 01/08/2020

Name of Pesticide Product:

FREEDOM 45 PLUS IGR SPOT
ON FOR DOGS

Name and Address of Registrant (include ZIP Code):

Andrew M. Martin Co., NV Inc.
c/o Ann M. Tillman
Pyxis Regulatory Consulting, Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332

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 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 section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Elizabeth Fertich, Product Manager 4
Invertebrate & Vertebrate Branch 1
Registration Division (7505P)

Date:

1/8/18

2. The Agency has found your company to be in compliance with the terms and conditions for the subject product, and is extending the two-year registration restriction. This registration is time-limited and expires 01/08/2020.
3. Please note that the product is still subject to all other previously required conditions of registration. Your company is required to adhere to the spot-on label mitigation, and to submit quarterly enhanced incident reports and quarterly sales information as stated in an Agency letter dated 6/25/2015.
4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 11/22/2016
- Alternate CSF 1 dated 11/22/2016

If you have any questions, you may contact Julie Breeden-Alemi, DVM at 703-347-0511 or via email at Breeden-Alemi.Julie@epa.gov.

Enclosure

{Note to reviewer: [Text] in brackets denotes optional text}

{Note to reviewer: {Text} in braces denotes notes to reviewer and where in the final label text will appear}

{Front panel - Carton Label}

{Front panel will include picture of dog in the weight range for the product as packaged}

FREEDOM 45 PLUS IGR SPOT ON FOR DOGS

{Font size for word "Dog" in product name will be at least 75% the height of the largest letter in the primary brand name}

FOR USE ONLY ON DOGS [OR] [&] PUPPIES 12 WEEKS OF AGE OR OLDER

For [puppy/toy/miniature] dogs [weighing] 5[-][to]10 lbs.

[OR] For [small] dogs [weighing] 11[-][to]32 lbs.

[OR] For [large] dogs [weighing] 33[-][to]66 lbs.

[OR] For [[extra] [ex-][large][XL]] dogs [weighing] more than 66 lbs. [over 66 lbs.]

[Optional Marketing Claims]

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 the flea life cycle

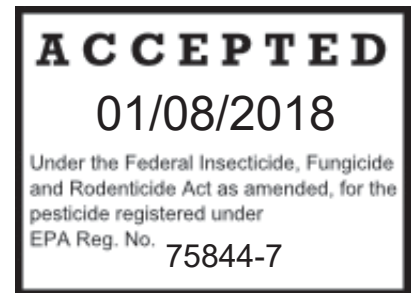
Kills, repels and prevents re-infestation of ticks for up to 6 weeks

Kills, repels and prevents re-infestation of ticks for up to 4 weeks

Kills, repels mosquitoes, lice and mites [on dogs] for up to 4 weeks

Made in USA [includes depiction of American flag]

{Additional marketing claims – see last page for list of options}



ACTIVE INGREDIENTS

Permethrin*45.00%

Pyriproxyfen 1.00%

OTHER INGREDIENTS.....54.00%

TOTAL.....100.00%

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

KEEP OUT OF REACH OF CHILDREN CAUTION

**SEE BACK PANEL FOR FIRST AID AND PRECAUTIONARY STATEMENTS
READ ENTIRE LABEL BEFORE USING THIS PRODUCT**

Andrew M. Martin Co., NV Inc.
707 Spirit 40 Park Drive, Suite 150
St. Louis, MO 63005

EPA Registration No. 75844-7
EPA Establishment No. 75844-CA-02

Package contains a [one] [1] [two] [2]
[three] [3] [four] [4] [six] [6] [eight] [8]
[twelve] [12] month supply
[as applicable]

Net Contents:

0.xx fl. oz. (xx [ml][cc]), [1, 2, 3, 4, 6, 8, 12] x

0.xx fl. oz. (xx [ml][cc]) tubes

DO NOT USE ON CATS



{1.5 cm x 1.5 cm cat prohibition icon and statement will be in the lower right hand corner of the front panel in a box in yellow with black images}

{Back panel - Carton label}

FREEDOM 45 PLUS IGR SPOT ON FOR DOGS

{Optional Marketing claim to appear on back panel:}

[Kills [5][Five] Different Kinds of Pests on Dogs[!][:] fleas, ticks, mosquitoes, lice, [and] mites]

PRECAUTIONARY STATEMENTS HAZARDS TO HUMAN 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. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash hands 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 re-use.

Hazards to Domestic Animals: For external use on dogs only. Do not use on cats or animals other than dogs. Do not treat (use on) dogs or puppies less than 12 weeks of age, weighing less than *[insert the lowest weight range of product as packaged]*. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing dogs. Consult a veterinarian before using on dogs with known organ dysfunction. Sensitivities can occur after ANY pesticide product on dogs. If signs of sensitivity occur, discontinue use, bathe your dog 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. This product is not a substitute for prescribed heartworm preventative.

DO NOT USE ON CATS: May be toxic or potentially fatal if applied to or ingested by cats. Accidental application to cats and/or grooming a recently treated dog may result in tremors and/or uncoordinated muscle movements. If this occurs, immediate veterinary care should be provided.

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none">• 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 by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
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 after the first 5 minutes, then continue rinsing.• Call a poison control center or doctor for treatment advice.
HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies, or pesticide concerns), you may call the Poison Control Center 1-800-222-1222 twenty four [24] hours per day, seven [7] days per week.	

ENVIRONMENTAL HAZARDS

This product is extremely toxic to aquatic organisms, including fish and invertebrates. To protect the environment, do not allow pesticide to enter or run-off into storm drains, drainage ditches, gutters or surface waters. 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.

DIRECTIONS FOR USE

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

For external use only. Do not allow children to apply product. Read entire label before use.

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USE RESTRICTIONS

- **DO NOT USE ON CATS OR KITTENS. Do not treat cats or their bedding. This product may be toxic or potentially fatal if applied to or ingested by cats or kittens.**
- Do not apply this product to puppies less than 12 weeks of age, or to dogs weighing less than *[insert the lowest weight in range of product as packaged]*.
- Do not apply this product more than once *[a month][every 30 days][every 4 weeks]*.
- Do not apply more than the specified amount of tubes per dog per treatment.
- Do not allow your dog to ingest this product.
- Do not allow adults, children or pets to touch treated area until dry.

{Photos or photos similar to the ones below for opening tubes will be shown.}

Ready to use, no dilution necessary. Apply this product only as specified on this label. Do not contaminate food or feedstuff.



- Dog must be dry at the time of application.
- Hold tube in upright position pointing away from user's and dog's face and body. Break off tip or cut with scissors. *[optional graphic/photograph/image to illustrate on right]* Apply FREEDOM 45 PLUS IGR SPOT ON FOR DOGS *[this product]* as follows by gently squeezing the tube.
- Part dog's hair between shoulder blades.

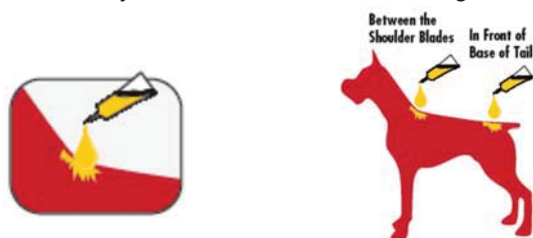
{The following text and a representative pictogram(s) will appear on individual product packages for the following weight ranges: 5-10 lbs., 11-32 lbs}

- Apply specified amount of solution to the skin on the dog's back between the shoulder blades as illustrated in the pictogram. SEE DOSE INFORMATION BELOW.



{The following text and a representative pictogram(s) will appear on individual product packages for the following weight ranges: 33-66 lbs., over 66 lbs}

- Apply specified amount of solution to the skin on the dog's back between the shoulder blades and to the skin directly in front of the base of the dog's tail as illustrated in the pictogram. SEE DOSE INFORMATION BELOW.



{The following directions are for use on puppies/toy/miniature dogs 5-10 lbs. with cartons containing 1, 2, 3, 4, 6, 8, or 12 x 0.75 cc tube(s)}

Do not apply to dogs weighing less than 5 *[lbs.][pounds]* or to puppies less than 12 weeks of age. Apply 0.75 *[ml][cc]* of FREEDOM 45 PLUS IGR SPOT ON FOR DOGS to the skin of the dog's back between the shoulder blades.

{The following directions are for small dogs 11-32 lbs. with cartons containing 1, 2, 3, 4, 6, 8, or 12 x 1.5 cc tube(s)}
Apply 1.50 *[ml][cc]* of FREEDOM 45 PLUS IGR SPOT ON FOR DOGS to the skin of the dog's back between the shoulder blades.

{The following directions are for large dogs 33-66 lbs. with cartons containing 1, 2, 3, 4, 6, 8, or 12 x 3.0 cc tube(s)}
Apply 1.50 *[ml][cc]* of FREEDOM 45 PLUS IGR SPOT ON FOR DOGS to the skin of the dog's back between the

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shoulder blades and 1.50 [ml][cc] to the skin directly in front of the base on the dog's tail.

{The following directions are for extra-large dogs over 66 lbs. with cartons containing 1, 2, 3, 4, 6, 8, or 12 x 6.0 cc tube(s)}

Apply 3.0 [ml][cc] of FREEDOM 45 PLUS IGR SPOT ON FOR DOGS to the skin of the dog's back between the shoulder blades and 3.0 [ml][cc] to the skin directly in front of the base on the dog's tail. Do not apply more than one [1] tube per treatment per dog regardless of the dog's weight.

{Additional packaging option –The below packaging option contains 2, 4, 6, 8, or 12 x 0.75 cc tubes and will be used for small, large, and extra-large dogs}

{The following directions are for small dogs 11-32 lbs.}

Apply 1.50 [ml][cc] of FREEDOM 45 PLUS IGR SPOT ON FOR DOGS (2 tubes) to the skin of the dog's back between the shoulder blades.

{The following directions are for large dogs 33-66 lbs.}

Apply 1.50 [ml][cc] of FREEDOM 45 PLUS IGR SPOT ON FOR DOGS (2 tubes) to the skin of the dog's back between the shoulder blades and 1.50 [ml][cc] (another 2 tubes) to the skin directly in front of the base on the dog's tail

{The following directions are for extra-large dogs over 66 lbs.}

Apply 3.0 [ml][cc] of FREEDOM 45 PLUS IGR SPOT ON FOR DOGS (4 tubes) to the skin of the dog's back between the shoulder blades and 3.0 [ml][cc] (another 4 tubes) to the skin directly in front of the base on the dog's tail. Do not apply more than eight [8] tubes per treatment per dog regardless of the dog's weight.

Side Effects: Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or the Poison Control Center 1-800-222-1222.

{Side effects box will be located immediately above the cat warning box}



DO NOT USE ON CATS – MAY BE FATAL. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately.

{1.5 x 1.5 cm cat prohibition icon and above warning text will be placed on the lower right hand corner of the back panel in a box with yellow and black images}

FOR USE ONLY ON DOGS [OR] [&] PUPPIES 12 WEEKS OF AGE OR OLDER {The previous statement will appear if any of the statements below also appear on the back panel of the label}

[5-] to 10 lbs.] [For [Puppies][Toy][Miniature] Dogs 5-] to 10 lbs.]

[11-] to 32 lbs.] [For Small Dogs 11-] to 32 lbs.]

[33-] to 66 lbs.] [For Large Dogs 33-] to 66 lbs.]

[More than 66 lbs.] [For XL Dogs over 66 lbs.]

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry (preferable locked) place, away from heat or open flame, in an area that is inaccessible to children and animals.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling (tubes): Nonrefillable container. Do not reuse or refill the tube. If empty: 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.

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 authorized any agent or representative to make any other

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warranty or fitness or merchantability, guarantee or representation, express or 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 an user acknowledge and assume all risk and liabilities resulting from 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.

{Side panel #1 & #2 – Carton label}

FREEDOM 45 PLUS IGR SPOT ON FOR DOGS

{One of the following 4 statements will be used on the side panel as appropriate for the weight range of the product as packaged:}

[For] [puppy/toy/minature] dogs 12 weeks of age or older [weighing] 5-10 lbs. [5 to 10 lbs.]

[For] [small] dogs 12 weeks of age or older [weighing] 11-32 lbs. [11 to 32 lbs.]

[For] [large] dogs 12 weeks of age or older [weighing] 33-66 lbs. [33 to 66 lbs.]

[For] [[extra] [ex-] [large] [XL]] dogs 12 weeks of age or older [weighing] more than 66 lbs. [over 66 lbs.]

{any claims listed on the front panel or under “Additional Optional Marketing Claims” may appear on side panel:}

{Side panel #3 – Carton label}

FREEDOM 45 PLUS IGR SPOT ON FOR DOGS

{any claims listed on the front panel or under “Additional Optional Marketing Claims” may appear on side panel:}

{Side panel #4 – Carton label}

Andrew M. Martin Co., NV Inc.

707 Spirit 40 Park Drive, Suite 150

St. Louis, MO 63005 [Barcode]

[Lot][Batch] # _____

{Tube}

FREEDOM 45 PLUS IGR SPOT ON FOR DOGS

[Puppy][Toy][Small][Large][Ex-Large]

PERMETHRIN 45%

PYRIPROXYFEN 1.0%

EPA Reg. No. 75844-7

Xx [ml][cc] (0.xx fl. oz.)



DO NOT USE ON CATS – MAY BE FATAL

For dogs [5-][to] 10 lbs.][11-][to] 32 lbs.][33-][to] 66 lbs.][more than 66 lbs.][over 66 lbs.]

For dogs 12 weeks or older.

For external use only. *{The previous statement will only appear if space on the tube permits}*

Read accompanying label before each use.

KEEP OUT OF REACH OF CHILDREN

[Lot][Batch] # _____ *{Note to reviewer: Lot # embossed on tube seal}*

[Additional OPTIONAL MARKETING CLAIMS]

{any claims listed on the front panel and below may appear anywhere on the label}

- Kills fleas, ticks, mosquitoes, lice, and mites [on dogs]
- Kills five [5] [different] canine pests: fleas, ticks, mosquitoes, lice, and mites
- Kills five [5] pests: fleas, ticks, mosquitoes, lice, and mites on dogs

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- Kills five [5] different kinds of canine pests[!][:] fleas, ticks, mosquitoes, lice, [and] mites
- Kills five [5] different kinds of pests on dogs[!][:] fleas, ticks, mosquitoes, lice, [and] mites
- Kills and repels mosquitoes
- Nylar® (IGR) kills flea eggs/larvae/pupae
- Nylar® is a registered trademark of McLaughlin, Gormley, King Company
- IGR – Insect Growth Regulator
- Prevents re-infestation of fleas [on dogs] for up to 4 weeks [1 month] [30 days]
- Prevents re-infestation of ticks [on dogs] for up to 4 weeks [1 month] [30 days]
- Prevents re-infestation of fleas [on dogs] for up to 5 weeks [35 days]
- Prevents re-infestation of ticks [on dogs] for up to 6 weeks [42 days]
- Kills & repels mites, lice, & mosquitoes for up to 4 weeks
- Puppies/Toy Dogs [For Dogs] 5[-][lbs][to]10 lbs 12 weeks of age or older
- Small Dogs [For Dogs] 11[-][lbs][to]32 lbs 12 weeks of age or older
- Large Dogs [For Dogs] 33[-][lbs][to]66 lbs 12 weeks of age or older
- Ex-Large Dogs [For Dogs] [over] 66 lbs [[&][and] over] 12 weeks of age or older