

#### U.S. ENVIRONMENTAL PROTECTION AGENCY

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

75844-10

Date of Issuance:

EPA Reg. Number:

2/1/18

NOTICE OF PESTICIDE:

X Registration Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional, Time-Limited Expires: 02/01/2020

Name of Pesticide Product:

LIBERTY 55 PLUS IGR SPOT-ON FOR CATS

Name and Address of Registrant (include ZIP Code):

Ann M. Tillman Pyxis Regulatory Consulting, Inc. 4110 136<sup>th</sup> 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:

Date:

2/1/18

Elizabeth Fertich, Product Manager 04

Invertebrate-Vertebrate Branch I, Registration Division (7505P)

Page 2 of 4 EPA Reg. No. 75844-10 Decision No. 529733

- 2. This registration is time-limited and expires 02/01/2020.
- 3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
  - EPA Registration Number
  - Product name (brand name)
  - Lot #
  - Where purchased: internet, store, veterinarian
  - Active Ingredient(s)
  - Weight range for product
  - Date on which incident occurred. (mm/dd/yyyy)
  - State in which the incident occurred. (standard 2 letter abbreviation)
  - Registrant case #
  - Species: dog, cat, other (specify)
  - Breed: (as reported by pet owner)
  - Age: months or years
  - Sex: M, F, or neutered
  - Weight: pounds
  - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
  - Body System: neurological, dermatological, GI, respiratory, ocular, other
  - Major signs noted with separate column for each sign, using standard terminology
  - Time to Onset: (hours, days)
  - Treated by veterinarian: yes or no
  - First time product used: yes or no
  - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
  - Any known precondition
  - EPA Severity Code: death, major, moderate, minor
  - Outcome: died, recovered, still treated, unknown
- 4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
  - All incidents should be reported including all minor dermal and ocular irritation reports.
  - Summary table for cats showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

- A similar summary table for dogs (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for cats showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of cat incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for cat weight showing number of incidents for each product weight range. This table should show number of incidents in cats weighing less than that product weight range, number of incidents in cats in lower half of weight range, number of incidents in cats in upper half of weight range, and cats weighing more than the product weight range, as applicable.
- Table showing number of incidents for each cat breed, where provided.
- Table showing number of incidents in cats for each clinical sign.
- Table showing number of incidents in cats for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

- 5. You are required to comply with the data requirements described in the DCI or EDSP Order identified below:
  - a. Etofenprox GDCI-128965-1041

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI or EDSP Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1

- 6. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 75844-10."
- 7. 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

Page 4 of 4 EPA Reg. No. 75844-10 Decision No. 529733

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 05/15/2017

If you have any questions, please contact Helen Hull-Sanders by phone at 703-347-0243, or via email at hull-sanders.helen@epa.gov.

Enclosure

[Note to reviewer: [Text] in brackets designates optional language. {Text} in braces denotes where in the final labeling text will appear, notes to reviewer or directional information.]

### **(FRONT CARTON PANEL TEXT)**

### LIBERTY 55 PLUS IGR SPOT-ON FOR CATS

{Final Label-the word Cat will be at least 75% in height of the largest letter in the primary brand name.} {Final Label will include a large clear picture of a cat in the respective weight range on the front panel of the label}

[Only for [use on][ smaller] cats & kittens 12 weeks and older weighing 3 to 5 lbs.]
[Only for [use on][larger] cats [& kittens] 12 weeks and older weighing 6 lbs. & over]
[For use ONLY on [smaller] cats and kittens 12 weeks or older weighing 6 lbs. & over]
[For use ONLY on [larger] cats [and kittens] 12 weeks or older weighing 6 lbs. & over]
[See Optional Marketing Claims]

### **ACTIVE INGREDIENTS:**

Etofenprox	55.0%
Pyriproxyfen	
OTHER INGREDIENTS:	
TOTAL	100.0%

### ACCEPTED

02/01/2018

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. \_\_\_\_\_\_

75844-10

## KEEP OUT OF REACH OF CHILDREN CAUTION

See back panel for additional Precautionary Statements, Directions for Use and First Aid READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

Manufactured for: Andrew M. Martin Co., NV Inc. 701 S. Carson St., Suite 200-2808 Carson City, NV 89701

EPA Registration No. 75844-

EPA Establishment No.

```
Net Contents: {for (smaller) cats and kittens 12 weeks or older and 3 to 5 lbs}
[0.024 fl. oz.] [(0.7 mL)] [1] [One] tube
[0.048 fl. oz.] [1.4 mL] [2][Two] tubes, each [0.024 fl. oz.] [(0.7 mL)]
[0.072 fl. oz.] [2.1 mL] [3][Three] tubes, each [0.024 fl. oz. [(0.7 mL)]
[0.096 fl. oz.] [2.8 mL] [Contains [4] [Four] tubes each [0.024 fl. oz. [(0.7 mL)]
[0.12 fl. oz.] [3.5 mL] [Contains [5] [Five] tubes, each [0.024 fl. oz. [(0.7 mL)]
[0.144 fl. oz.] [4.2 mL] [Contains [6] [Six] tubes, each [0.024 fl. oz. [(0.7 mL)]
[0.192 fl. oz.] [5.6 mL] [Contains [8] [Eight] tubes, each [0.024 fl. oz. [(0.7 mL)]
[0.288 fl. oz.] [8.4 mL] [Contains [12] [Twelve] tubes, each [0.024 fl. oz. [(0.7 mL)]
Net Contents: {for (larger) cats 12 weeks or older and 6 lbs. and over}
[0.047 fl. oz.] [(1.4 mL)] [1] [One] tube
[0.094 fl. oz.] [2.8 mL] [2][Two] tubes, each [0.047 fl. oz. [(1.4 mL)]
[0.14 fl. oz.] [4.2 mL] [3] [Three] tubes, each [0.047 fl. oz. [(1.4 mL)]
[0.188 fl. oz.] [5.6 mL] [Contains [4] [Four] tubes, each [0.047 fl. oz. [(1.4 mL)]
[0.235 fl. oz.] [7.0 mL] [Contains [5] [Five] tubes, each [0.047 fl. oz. [(1.4 mL)]
[0.282 fl. oz.] [8.4 mL] [Contains [6] [Six] tubes, each [0.047 fl. oz. [(1.4 mL)]
[0.376 fl. oz.] [11.2 mL] [Contains [8] [Eight] tubes, each [0.047 fl. oz. [(1.4 mL)]
[0.564 fl. oz.] [16.8 mL] [Contains [12] [Twelve] tubes, each [0.047 fl. oz. [(1.4 mL)]
```

[Contains a [one][1] month supply] [two][2] [three][3] [four][4] [five][5] [six][6] [eight][8] [twelve][12] month[s] supply] [Package contains a [one][1] month supply] [two][2], [three][3], [four][4], [five][5], [six][6, [eight][8], [twelve][12] month supply]

[Save Now!] [Value Size] [Club Size] [Bonus Size] [Club Pack] [Great Value] [Better Value] [Bonus Pack] [3 + 1 bonus pack!] [4 + 1 bonus pack!] [5 + 1 bonus pack!] [Buy more and save!] [Buy 3 get 1 free] [Buy 4 get 1 free] [Buy 5 get 1 free] [33% (More) (Free)!] [25% (More) (Free)!] [20% (More) (Free)!] [1 Dose Free!] [1 Month Treatment Free!] [30 Day Treatment- Free!]

{SIDE PANELS 1 and 2} LIBERTY 55 PLUS IGR SPOT-ON FOR CATS [See Optional Marketing Claims]

**{TOP SIDE PANEL 3 (TOP)}**LIBERTY 55 PLUS IGR SPOT-ON FOR CATS
[See Optional Marketing Claims]

**{SIDE PANEL 4 (BOTTOM)}** 

[Bar Code] [®2017 Andrew M. Martin Co., NV Inc. Lot number {only number will appear}

**{BACK CARTON PANEL}** 

### LIBERTY 55 PLUS IGR SPOT-ON FOR CATS

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

**Hazards to Humans:** Causes moderate eye irritation. Avoid contact with eyes and clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Repeated exposure to etofenprox can cause skin irritation.

**Hazards to Domestic Animals:** For external use on cats only. Individual sensitivities, while rare, may occur after using any pesticide product on cats. Certain medications can interact with pesticides. Do not treat your cat with more than one pesticide product at a time. This product is not a substitute for prescribed heartworm preventative. Over dosing your cat can result in serious illness and even death. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant, or nursing cats. Consult a veterinarian before using on cats with known organ dysfunction.

FIRST AID	
IF IN EYES:	<ul> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>Remove contact lenses after the first 5 minutes, then continue rinsing.</li> <li>Call a poison control center or doctor for treatment advice.</li> </ul>
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 Rocky Mountain Poison Center at 1-303-389-1883 twenty-four [24] hours per day, seven [7] days per week.

**PHYSICAL OR CHEMICAL HAZARDS:** Combustible. Do not use or store near heat or open flame. Do not mix or allow contact with oxidizing agents. Hazardous chemical reaction may occur.

### **DIRECTIONS FOR USE**

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

DO NOT ALLOW CHILDREN TO APPLY PRODUCT. TO PREVENT HARM TO YOU AND YOUR CAT READ ENTIRE LABEL BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY.

### Restrictions

Do not use on animals other than cats. Do not allow your cat to ingest this product. Do not use on kittens under 12 weeks of age. Do not apply to cats weighing less than [3][6] lbs. Do not apply more than one tube per treatment for one cat regardless of cat's weight. Do not get this product in your cat's eyes or mouth. Do not apply more often than once every 30 days. Do not bathe cat within the first 24 hours after this product has been applied. Households with more than one cat should not allow cats to groom each other until solution has dried.

{The following text in a box will be placed in the lower right hand corner of back panel.}

**Side Effects:** Monitor your cat after application. [Some cats may experience temporary startle effects when any product is applied.] Cats may experience some temporary irritation at the site of product application such as redness, scratching, rash, hair discoloration or hair loss or other signs of discomfort. If signs of sensitivity occur, bathe your cat with a mild soap and rinse with large amounts of water. If these or other side effects occur, consult your veterinarian or call 1-303-389-1883. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating application. The most common signs of incidental ingestion are excessive salivation and foaming at the mouth. If these symptoms occur, immediately feed your cat as it may reduce symptoms and continue to monitor your cat for the next 24 hours.

### **HOW TO APPLY:**

{Package for cats weighing 3 to 5 lbs. and 12 weeks or older}

**Do not apply this product to cats weighing less than 3 lbs or under 12 weeks of age.** Apply 0.7 mL of Liberty 55 Plus IGR Spot-On for Cats to a spot high on the back of the cat's neck behind its head.

Hold tube in upright position pointing away from user's and cats's face and body. Break off tip or cut with scissors. Part cat's hair on the neck behind its head. Apply [Liberty 55 Plus IGR Spot-On for Cats] [this product] by gently squeezing the tube. Apply the entire contents of the tube to the skin on the cats's neck behind its head. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

{Package for cats weighing 6 lbs. and over and 12 weeks or older}

Do not apply this product to cats weighing less than 6 lbs or under 12 weeks of age.

Apply 1.4 mL of Liberty 55 Plus IGR Spot-On for Cats as a spot or stripe, starting high on the back of the cat's neck to in front of the shoulder blades.

Hold tube in upright position pointing away from user's and cats's face and body. Break off tip or cut with scissors. Part cat's hair on the neck behind its head. Apply [Liberty 55 Plus IGR Spot-On for Cats] [this product] by gently squeezing the tube. Apply the entire contents of the tube to the skin on the cats's neck behind its head. Hold the cat for a few seconds to give the solution time to be absorbed into the cat's coat.

[Optional pictogram for opening tube]

[Optional pictogram for applying product to cat]

### STORAGE AND DISPOSAL

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

**PESTICIDE STORAGE:** Store in a cool (below 25°C), dry place, away from heat or open flame, in an area that is inaccessible to children and animals. Do not refrigerate. Protect from direct sunlight.

**PESTICIDE DISPOSAL AND CONTAINER HANDLING:** Nonrefillable container. Do not reuse or refill this container. **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 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.]

©2018 Andrew M. Martin Co., NV Inc.

**{TEXT FOR TUBE}** 

{Tube panel text}

LIBERTY 55 PLUS IGR SPOT-ON FOR CATS [3-5 lbs] [6 lbs & over] and over 12 wks Etofenprox 55%
Pyriproxyfen 2.2%

EPA Reg. No. 75844-

[0.024 fl. oz. (0.7 mL)] [0.047 fl. oz. (1.4 mL)]

KEEP OUT OF REACH OF CHILDREN

CAUTION. Read accompanying label before use.

Lot number {only number will appear}

### **{OPTIONAL MARKETING CLAIMS}**

- 1. Fleas Ticks Mosquitoes
- 2. Kills [three][3] different kinds of pests on cats [:][-] Fleas, Ticks, & Mosquitoes
- 3. Kills [three][3] different feline pests[:][-] Fleas, Ticks, & Mosquitoes
- 4. Improved formula
- 5. IGR Insect Growth Regulator
- 6. Provides Monthly [4 Weeks][28 Days] Protection
- 7. Reapply Once a Month
- 8. Repels mosquitoes [for up to 28 days]
- 9. Breaks the Flea Life Cycle For Up To [3 Months][12 Weeks][90 Days]
- 10. Kills Adult Fleas For Up To [28 Days][4 Weeks][1 Month] [Per Application]
- 11. Kills Flea Eggs and Flea Larvae For Up To [3 Months] [90 Days] [12 Weeks] [Per Application]
- 12. Kills Fleas, [Deer][Or][Black Legged] Ticks, Flea Eggs and Larvae
- 13. [Kills Fleas, [Deer][Or][Black Legged] Ticks For Up To [4 Weeks] [1 Month] [28 Days] [Per Application]
- 14. Kills [Deer][Or][Black Legged] Ticks For Up To [28 Days] [4 Weeks] [1 Month] [Per Application]
- 15. Monthly Protection from Flea, [Deer][Or][Black Legged] Tick, Mosquito, And Flea Egg And Larvae Infestations
- 16. Protects 5 Ways[:][-] Kills fleas, [Deer][or][Black Legged] Ticks, Flea Eggs & Larvae, and repels mosquitoes
- 17. Prevents Flea Eggs From Developing Into Biting Adults For Up To [90 Days][3 Months] [Per Application]
- 18. Kills [Deer][Or][Black Legged] Ticks That May Transmit Lyme Disease, For Up To [4 Weeks][1 Month] [Per Application]
- 19. Prevents Mosquitoes [That May Transmit West Nile Virus] From Feeding On Cats For Up To One Month [per application]
- 20. A squeeze-on that leaves no oily residue
- 21. Cats can't rub off on furniture leaving oily residue behind.
- 22. No oily residue [on your cat's coat]
- 23. Quick drying
- 24. [Dries quickly] [Quick-drying formula] [Quick-Drying]
- 25. Squeeze-On. Stays on and doesn't rub off
- 26. Spreads using the cats natural skin oils
- 27. Kills [and repels] mosquitoes that may transmit heartworm
- 28. Kills fleas that may cause flea allergy dermatitis, flea bite anemia, and tapeworm infestation
- 29. Monthly Flea, Tick and Mosquito Treatment
- 30. Easy to Use tube
- 31. No-mess tube
- 32. ONLY for [smaller] cats & kittens 3 to 5 lbs & 12 weeks or older
- 33. ONLY for [larger] cats [and kittens] 6 lbs. [and] [&)] over & 12 weeks or older
- 34. Kills, repels and prevents re-infestation of fleas for up to [28 days] [4 weeks] [1 month]
- 35. Kills flea eggs and larvae for up to [90 days] [3 months] [12 weeks]
- 36. Breaks the flea life cycle for up to [3 months] [90 days] [12 weeks]
- 37. Kills, repels and prevents re-infestation of [Deer][or][Black legged] ticks for up to [28 days] [4 weeks] [1 month]
- 38. Kills or repels mosquitoes on cats [for up to 28 days] [4 weeks][1 month]
- 39. Protects 5 ways Kills fleas, [Deer][or][Black Legged] ticks, Flea Eggs & Larvae, and repels mosquitoes
- 40. Kills [five][5] different kinds of pests on cats[:][-] fleas ticks Flea Eggs Larvae mosquitoes
- 41. 5 ways Protection from pests[:][-] fleas ticks Flea Eggs Larvae mosquitoes
- 42. fleas ticks Flea Eggs Larvae mosquitoes
- 43. Kills 3 Different Kinds of Pests on Cats! Fleas, Ticks, & Mosquitoes
- 44. Prevents Reinfestation! Fleas Ticks Mosquitoes
- 45. Improved Technology

- 46. [Odorless] [unscented] [fragrance free]
- 47. Optional pictogram for pests48. Optional pictogram for opening tube
- 49. Optional pictogram for applying product to cat
- 50. Optional pictogram of flea, flea eggs, flea larvae, ticks, mosquitoes
- 51. Optional pictogram of tube



































