

U.S. ENVIRONMENTAL PROTECTION AGENCY

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

NOTICE OF PESTICIDE:

X Registration ___ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:

Date of Issuance:

75257-1

9/30/21

Term of Issuance:

Conditional, Time-Limited Expires: 02/02/2022

Name of Pesticide Product:

FREEDOM 45 SPOT ON FOR **DOGS**

Name and Address of Registrant (include ZIP Code):

Ann Tillman Agent for Manna Pro Products, LLC c/o 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/registration/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:
Elberal Falul	9/30/21
Elizabeth Fertich, Product Manager 04	
Invertebrate & Vertebrate Branch 1	
Registration Division (7505P)	
Office of Pesticide Programs	

- 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 02/02/2022.
- 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 in the agency letter dated 06/25/2015.
- 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 03/10/2016
- Alternate CSF 1 dated 03/10/2016

If you have any questions, please contact Kaitlin Saunders by phone at 703-347-8454, or via email at Saunders.Kaitlin@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}

{Picture of dog that is appropriate for each weight range}

FREEDOM 45 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, WEIGHING [5-10 LBS.] [11-32 LBS.] [33-66 LBS.] [MORE THAN 66 LBS.] [5 to 10 LBS.] [11 to 32 LBS.] [33 to 66 LBS.] [OVER 66 LBS.]

ACCEPTED

09/30/2021

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

75257-1

ACTIVE INGREDIENT

Permethrin*	45.00%
OTHER INGREDIENTS	55.00%
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 ADDITIONAL PRECAUTIONARY STATEMENTS
READ ENTIRE LABEL AND ALL DIRECTIONS BEFORE USING THIS PRODUCT

EPA Registration No. 75257-1 EPA Establishment No.

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

Net Contents

{Puppies/Toy/Miniature Dogs:} 0.025 fl. oz. (0.75 mL) [1 tube containing 0.025 fl. oz. (0.75 mL)] 0.050 fl. oz. (1.5 mL) [2 tubes each containing 0.025 fl. oz. (0.75 mL)] 0.075 fl. oz. (2.25 mL) [3 tubes each containing 0.025 fl. oz. (0.75 mL)] 0.10 fl. oz. (3.0 mL) [4 tubes each containing 0.025 fl. oz. (0.75 mL)] 0.15 fl. oz. (4.5 mL) [6 tubes each containing 0.025 fl. oz. (0.75 mL)] 0.20 fl. oz. (6.0 mL) [8 tubes each containing 0.025 fl. oz. (0.75 mL)] 0.30 fl. oz. (9.0 mL) [12 tubes each containing 0.025 fl. oz. (0.75 mL)] {Small Dogs} 0.050 fl. oz. (1.5 mL) [1 tube containing 0.05 fl. oz. (1.5 mL)] 0.10 fl. oz. (3.0 mL) [2 tubes each containing 0.05 fl. oz. (1.5 mL)] 0.15 fl. oz. (4.5 mL) [3 tubes each containing 0.05 fl. oz. (1.5 mL)] 0.20 fl. oz. (6.0 mL) [4 tubes each containing 0.05 fl. oz. (1.5 mL)] 0.30 fl. oz. (9.0 mL) [6 tubes each containing 0.05 fl. oz. (1.5 mL)] 0.40 fl. oz. (12.0 mL) [8 tubes each containing 0.05 fl. oz. (1.5 mL)] 0.60 fl. oz. (18.0 mL) [12 tubes each containing 0.05 fl. oz. (1.5 mL)] {Large Dogs} 0.10 fl. oz. (3.0 mL) [1 tube containing 0.10 fl. oz. (3.0 mL)]

FREEDOM 45 SPOT ON FOR DOGS

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Label Version dated Sept. 28, 2021 [EPA APPROVAL DATE]

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0.20 fl. oz. (6.0 mL) [2 tubes each containing 0.10 fl. oz. (3.0 mL)] 0.30 fl. oz. (9.0 mL) [3 tubes each containing 0.10 fl. oz. (3.0 mL)] 0.40 fl. oz. (12.0 mL) [4 tubes each containing 0.10 fl. oz. (3.0 mL)] 0.60 fl. oz. (18.0 mL) [6 tubes each containing 0.10 fl. oz. (3.0 mL)] 0.80 fl. oz. (24.0 mL) [8 tubes each containing 0.10 fl. oz. (3.0 mL)] 1.2 fl. oz. (36.0 mL) [12 tubes each containing 0.10 fl. oz. (3.0 mL)] [Extra Large Dogs] 0.20 fl. oz. (6.0 mL) [1 tube containing 0.20 fl. oz. (6.0 mL)] 0.40 fl. oz. (12.0 mL) [2 tubes each containing 0.20 fl. oz. (6.0 mL)] 0.80 fl. oz. (24.0 mL) [4 tubes each containing 0.20 fl. oz. (6.0 mL)] 1.20 fl. oz. (36.0 mL) [6 tubes each containing 0.20 fl. oz. (6.0 mL)] 1.20 fl. oz. (36.0 mL) [8 tubes each containing 0.20 fl. oz. (6.0 mL)] 1.60 fl. oz. (48.0 mL) [8 tubes each containing 0.20 fl. oz. (6.0 mL)] 2.4 fl. oz. (72.0 mL) [12 tubes each containing 0.20 fl. oz. (6.0 mL)]
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{A 1.5 x 1.5 cm cat prohibition icon will be in a box in the lower right hand corner of the front panel in yellow and black images}

{Back panel - Carton label}

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 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 in 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, contact your veterinarian immediately.

{the First Aid may be in paragraph form if bullet points not used}

FIRST AID		
IF SWALLOWED:	 Call a poison control center or doctor immediately for treatment advice. Have a 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:	 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. 	

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 1-303-389-1883 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.

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.

Application of product on pets must only be done indoors.

{the Use Restrictions may be in paragraph form if bullet points not used}

USE RESTRICTIONS

- For indoor use only.
- DO NOT USE ON CATS OR KITTENS. <u>Do not treat cats or their bedding. This product may be toxic or potentially fatal if applied to or ingested by cats or kittens.</u>
- Do not apply this product to puppies less than 12 weeks of age, weighing less than [5][11][33][66] lbs.
- Do not allow your dog to ingest this product.
- Weigh your dog to be sure you are applying the correct product for the weight of your dog.
- Do not apply more than one tube regardless of the dog's weight.
- Your dog must be dry before application. Keep your dog dry for 24 hours after application. Separate the treated dog from all other dogs and cats for 24 hours after treatment has been applied.
- Do not apply more frequently than once every [4 weeks][1 month][30 days].
- Do not allow children/adults to touch dog until dry.

{Back or inside printed card}

Ready to use, no dilution necessary. Apply this product every [4 weeks][1 month][30 days].

{optional graphic /photographs/images or similar to the one below to illustrate how to open package] {application directions may be in paragraph form if bullet points not used}



- Hold tube in upright position pointing away from user's and dog's face and body. Break off tip or cut with scissors.
- Apply [FREEDOM 45 SPOT ON FOR DOGS] [this product] by gently squeezing the tube. Part dog's hair between shoulder blades {this additional text only applies to large and extra-large dogs' packages:} and in front of the base of the dog's tail.
- Apply specified amount of solution to the skin on the dog's back between the shoulder blades {this additional text only applies to large and extra-large dogs' packages:} and in front of the base of the dog's tail.

{pictogram of appropriate sized dog with arrow or arrows pointing where application(s) should be made}









{tubes for puppy/toy/miniature dogs contain 0.025 fl oz (0.75 mL); tubes for small dogs contain 0.05 fl oz (1.5 mL); tubes for large dogs contain 0.10 fl oz (3.0 mL) and tubes for extra large dogs contain 0.2 fl oz (6.0 mL); Only the text appropriate for the weight range of dog will be on the package}

[puppy/toy/miniature dogs] dogs [weighing] [5-10 lbs.][5 to 10 lbs.] and 12 weeks or older

Do not apply to dogs weighing less than 5 [lbs.] [pounds]. Apply 1 tube (0.75 ml) of FREEDOM 45 SPOT ON

FOR DOGS to the skin of the dog's back between the shoulder blades. Do not apply more than 1 tube.

[small dogs] dogs and puppies [weighing] [11-32 lbs.][11 to 32 lbs.] and 12 weeks or older Apply 1 tube (1.50 ml) of FREEDOM 45 SPOT ON FOR DOGS to the skin of the dog's back between the shoulder blades. Do not apply more than 1 tube.

[large dogs] dogs and puppies [weighing] [33-66 lbs.][33 to 66 lbs.] and 12 weeks or older Apply 1/2 tube (1.50 ml) of FREEDOM 45 SPOT ON FOR DOGS to the skin of the dog's back between the shoulder blades and 1/2 tube (1.50 ml) to the skin directly in front of the base of the dog's tail. Do not apply more than 1 tube.

[extra large][XL dogs] dogs and puppies [weighing] [more than 66 lbs.][over 66 lbs.] and 12 weeks or older Apply 1/2 tubes (3.0 ml) of FREEDOM 45 SPOT ON FOR DOGS to the skin of the dog's back between the shoulder blades and 1/2 tubes (3.0 ml) to the skin directly in front of the base of the dog's tail. Do not apply more than 1 tube.

{A box labeled Side Effects will be immediately placed above the cat warning box on the back panel.}

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.



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

{A 1.5 x 1.5 cm icon and statements in a box in yellow with black images will be placed on the lower right-hand corner of back panel}

{Back or side panel}

FREEDOM 45 SPOT ON FOR DOGS EPA Reg. No. 75257-1 Label Version dated Sept. 28, 2021 [EPA APPROVAL DATE]

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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): <u>If empty</u>: Do not reuse or refill the tube. Place in trash or offer for recycling if available. <u>If partly filled</u>: Call your local solid waste Agency for local disposal options. Do not pour or dispose down-the-drain or sewer.

WARRANTY

Manna Pro Products, LLC warrants that this product confirms to the chemical description on the label. Manna Pro Products, LLC neither makes nor authorized any agent or representative to make any other warranty or fitness or merchantability, guarantee or representation, express or implied concerning this material. To the extent consistent with applicable law Manna Pro Products, LLC'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 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.

MANNA PRO PRODUCTS, LLC
707 Spirit 40 Park Dr., Suite 150
St. Louis, MO 63005

{Text for Tubes}

FREEDOM 45% SPOT ON FOR DOGS PERMETHRIN INSECTICIDE 45% KEEP OUT OF REACH OF CHILDREN

DO NOT USE ON CATS – MAY BE FATAL or Cat/Slash Icon/Graphic {representative graphic shown} EPA Reg. NO. 75257-1



Read entire label before each use.

{One of the following statements will be placed on tubes depending on the weight range of dog}

Only for [puppy/toy/miniature] dogs > 12 weeks old [weighing] 5-10 lbs. [5 to 10 lbs.]

Only for [small] dogs and puppies > 12 weeks old [weighing] 11-32 lbs. [11 to 32 lbs.]

Only for [large] dogs and puppies > 12 weeks old [weighing] 33-66 lbs. [33 to 66 lbs.]

Only for [extra [ex-] [large] [XL] dogs and puppies > 12 weeks old [weighing] more than 66 lbs. [over 66 lbs.] Lot #

{ALTERNATIVE MARKETING CLAIMS}

- 1. Kills fleas, ticks, mosquitoes, lice, and mites [on dogs]
- 2. Kills [five][5] pests: fleas, ticks, mosquitoes, lice, and mites on dogs
- 3. Kills [five][5] different canine pests: fleas, ticks, mosquitoes, lice, and mites
- 4. Kills [five][5] different kinds of canine pests: fleas, ticks, mosquitoes, lice, and mites
- 5. Kills [five][5] different kinds of pests on dogs: fleas, ticks, mosquitoes, lice, and mites
- 6. Kills and repels mosquitoes
- 7. Kills, repels [and prevents re-infestation of] fleas for up to 5 weeks
- 8. Kills, repels [and prevents re-infestation of] fleas for up to [4 weeks][1 month][30 days] on dogs
- 9. Kills, repels [and prevents re-infestation of] ticks for up to 6 weeks
- 10. Kills, repels [and prevents re-infestation of] ticks for up to 4 weeks[1 month][30 days] on dogs
- 11. Kills, repels mosquitoes, lice and mites on dogs for up to [4 weeks][1 month][30 days]

FREEDOM 45 SPOT ON FOR DOGS

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- 12. Prevents re-infestation of fleas on dogs for up to [4 weeks][1 month] [30 days]
- 13. Prevents re-infestation of ticks on dogs for up to [4 weeks][1 month] [30 days]
- 14. Prevents re-infestation of fleas on dogs for up to [5 weeks][35 days]
- 15. Prevents re-infestation of ticks on dogs for up to [6 weeks][42 days]
- 16. Puppy/toy/miniature Dogs > 12 weeks old and [5-10 lbs.][5 to 10 lbs.]]
- 17. Puppy/toy/miniature Dogs [5 to 10 lbs.][5-10 lbs.] and > 12 weeks old
- 18. Small Dogs and puppies [11 to 32 lbs][11-32 lbs] and > 12 weeks old
- 19. Large Dogs and puppies [33-66 lbs.][33 to 66 lbs.] and > 12 weeks old
- 20. XL Dogs and puppies over 66 lbs. and > 12 weeks old
- 21. Water resistant 24 hours after application
- 22. Topical
- 23. 4 for the price of 3
- 24. Bonus pack {bonus pack will not include more than the amount allowed in the net contents}
- 25. Value Pack {value pack will not include more than the amount allowed in the net contents}
- 26. Filled & assembled in USA (US flag icon)

{Optional Graphics}

{any graphics provided below may appear anywhere on the label}



















