

75257-1

3/15/2004

1/6



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St. S.W.
Washington, D.C. 20460

EPA Reg. Number:

75257-1

Date of Issuance:

MAR 15 2004

Term of Issuance: Conditional

Name of Pesticide Product:

FREEDOM® 45 FOR DOGS

NOTICE OF PESTICIDE:

Registration

Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Star Business Products, Inc.
262 W. Washington Street
Ridgeland, MS 39157

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. 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. **Make the following labeling changes:**
 - a) Revise the EPA Registration Number to read "EPA Reg. No. 75257-1".
 - b) Under Precautionary statements separate the hazards to humans from the hazards to domestic animals. Revise the hazards to humans to read as follows:

Hazards to Humans: Harmful if absorbed through 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, or using tobacco. Remove and wash contaminated clothing before reuse.

Hazards to Domestic Animals: Consult a veterinarian before using this product on debilitated... consult a veterinarian immediately.

- c) Move all cat information to a box under Precautionary statements to help draw the consumer's attention to this information. The following precautionary statements should appear on the label: "*May be toxic and potentially fatal if applied to or ingested by cats. Cats which actively groom or engage in close physical contact with treated dogs may be at risk of serious harmful effects*". This last statement must be highlighted.
- d) In addition to the above referred box, an icon of a cat in a circle with a slash through it should be added to the label's front panel. Circle and slash should be red in color. The statement "Do not use on cats" and/or the icon must also appear on the small tubes.
- e) Since this product is placed in acute toxicity category IV for the oral, inhalation, and dermal irritation routes, only the "If on skin and clothing" and the "If in eyes" first aid statements are required. If you choose to keep the "If Swallowed" statements, they should be listed last.
- f) Under Environmental Hazards add: "*and other aquatic organisms*" to the end of the first sentence. Also, delete the last sentence.
- g) Revise the Pesticide and Container Disposal statements to read: "*If empty: Do not reuse this container. Place in trash or offer for recycling if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain*".
- h) Delete "*Each tube provides 1 month protection*" since this conflicts with your claims for 5/6 weeks.

3. Please submit two (2) copies of your final printed label before you release 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 Olga Odiott of my team at (703) 308-9369.

Signature of Approving Official: George T. LaRocca Product Manager (13) Insecticide Branch/Registration Division (7505C)	Date: MAR 15 2004
---	----------------------

3/6

FRONT PANEL

FREEDOM® 45 FOR DOGS

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 ticks for up to 6 weeks
Kills mosquitoes, lice and mites on dogs for up to 4 weeks

ACTIVE INGREDIENT	
Permethrin* [CAS# 52645-53-1]	45.00%
OTHER INGREDIENT	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 PRECAUTIONARY STATEMENTS
READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

Star Business Products, Inc.,
262 West Washington Street,
Ridgeland, MS 39157

EPA Registration No. 75257-R
EPA Establishment No.

Each tube provides 1 month protection
Package contains a two [2], three [3],
four [4], twelve [12] months supply
(as applicable)

ACCEPTED
with COMMENTS
In EPA Letter Dated
MAR 15 2004
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
75257-1

NET CONTENTS

- 3 x 1½ cc applicators
- 3 x 3 cc applicators
- 3 x 6 cc applicators
- 12 x 1½ cc applicators

4/6

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

CAUTION

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. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

DO NOT USE ON CATS. Cats which actively groom or engage in close physical contact with recently treated dogs may be at risk of serious harmful effects. 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 using 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.

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 do so 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, if present, after first 5 minutes, then continue rinsing eyes.
- 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.

ENVIRONMENTAL HAZARDS

This product is extremely toxic to fish. Do not apply directly to water. Do not contaminate water when cleaning equipment or disposing of equipment washwaters.

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 or disposal.

PESTICIDE STORAGE:

Store in 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:

Do not reuse empty container. Place in trash.

DIRECTIONS FOR USE

It is a violation of Federal law 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 FOR DOGS as follows by gently squeezing the applicator.
- Part dog's hair between the shoulder blades.
- Apply the 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 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 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 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 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 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 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.

WARRANTY

Star Business Products, Inc., warrants that this product conforms to the chemical description on the label. Star Business Products, 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. Star Business Products, 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.

