

US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (TS-767) WASHINGTON, DC 20460 NOTICE OF PESTICIDE: <input type="checkbox"/> REGISTRATION <input type="checkbox"/> Reregistration (Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)	EPA REGISTRATION NO. 41835-8	DATE OF ISSUANCE 6/5/89
	TERM OF ISSUANCE Until Reregistration	
	NAME OF PESTICIDE PRODUCT Durakyl II Flea and Tick Control Pet Spray	

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Dermatologic for Veterinary Medicine
 8785 W. 135th Terrace
 Miami, FL 33172

225344 / 161
18

NOTE: Changes in labeling formula 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 U.S. 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.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this 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 additionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Add the phrase "EPA Registration No. 41835-8" to your label before you release the product for shipment.
3. The following pertains to chemistry:
 - a. EPA Registration No. 1021-1141 is an incorrect Registration Number for permethrin. Please correct your Confidential Statement of Formula and resubmit.
 - b. Explain how you calculated the upper and lower limits if your volume of water fills up to 1000.
 - c. Please provide the chemical identity of all components, Material Safety Data Sheet, and CAS numbers of:
 - 1) Fragrance 38019, and
 - 2) PPG-12 - PPG-50 Lanolin.

BEST AVAILABLE COPY

ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL **DATE**
6/5/89

The suppliers may contact us directly referencing your EPA Registration Number in their response.

4. The Dermal Sensitization study is acceptable and is classified as follows: The acute inhalation study is also acceptable and is classified as:

<u>Study</u>	<u>Core Grade</u>	<u>Toxicity Category</u>
Dermal Sensitization	Guideline	Not a sensitizer
Acute Inhalation	Guideline	IV

5. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

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 constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosures

P.S. Delete the word "Natural" in the phrase synergized natural pyrethions. Word- or phrases implying safety of a pesticide product are not acceptable.

Immediately following the phrase Directions for Use add the misuse statement:

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

This statement should be set apart from the rest of the text in a separate paragraph.

DURAKYL II PET SPRAY

To Kill Fleas and Ticks on Dogs and Cats

ACTIVE INGREDIENTS	Percent by Weight
Fenmetin (1-(3-Phenoxypheyl)methyl (±) di-ene-3-(2,2-dichloroethyl)-2,2-dimethylcyclopropane-carboxylate)	0.100%
Pyrethrins	0.050%
N-Octyl bicycloheptene dicarboximide	0.500%
Inert Compounds	99.325%
TOTAL INGREDIENTS	100.000%

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
WARNING: May cause eye injury. Do not get in eyes or on clothing. Wash spray glasses during use. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Material is absorbed through skin. Avoid contact with skin. Do not spray on humans. Do not spray where food or drink is exposed. Do not spray in eyes, or on genitalia. Do not use on nursing puppies or kittens under 3 months old.

ENVIRONMENTAL HAZARDS: Keep out of lakes, streams or ponds. Do not contaminate water by cleaning of equipment or disposal of wastes.

STATEMENT OF PRACTICAL TREATMENT: If in eyes, flush with plenty of water and seek medical attention. If irritation develops or persists, get medical attention. If swallowed, drink one or two glasses of water and induce vomiting. If on skin, wash with soap and water. If irritation develops, get medical attention.

EPA REG NO. 41825 EPA EST NO. 43774F-G



DURAKYL II

PET SPRAY

To Kill Fleas and Ticks on Dogs and Cats
 Synergized Natural Pyrethrins with Fenmetin
 (See Panel to Left)

KEEP OUT OF REACH OF CHILDREN
WARNING

Net Contents: 16 FL. Oz.
 Product No. 9-541 REV 0688

DIRECTIONS FOR USE:
 TO KILL FLEAS AND TICKS ON DOGS AND CATS: Apply spray directly on animal around neck, along back, forelegs and on other areas where flea and/or tick infestation is common and insure good coverage. Hold spray from animal during application. Apply thoroughly. Do not spray in eyes, nose or mouth.

TO REDUCE REINFESTATION OF ANIMAL: Vacuum bedding and other nesting areas. Spray entire animal REPEAT AS OFTEN AS NECESSARY.

STORAGE AND DISPOSAL: Store in original container. Keep container and jar in clean, cool, dry place.

WARRANTY STATEMENT: Our recommendations are based upon tests believed to be realistic. The use of the contents of the manufacturing, no guarantee is made as to the effects of such of the results to be obtained with diseases or established side products. The purchaser assumes liability for injury or damage, resulting from combination with other medicines.

Formulated and distributed by
DVM DERMATOLOGICS FOR VETERINARIANS
 Miami, FL 33172

Conditional Registration Application
 Durakyl Flea & Tick Control Pet Spray
 EPA File Symbol 41835-I

BEST AVAILABLE COPY

ACCEPTED
 with COMMENTS
 in EPA Letter Dated:
 JUN - 5 1989

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

15, 2, 3

The suppliers may contact us directly referencing your EPA Registration Number in their response.

4. The Dermal Sensitization study is acceptable and is classified as follows: The acute inhalation study is also acceptable and is classified as:

<u>Study</u>	<u>Core Grade</u>	<u>Toxicity Category</u>
Dermal Sensitization	Guideline	Not a sensitizer
Acute Inhalation	Guideline	IV

5. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

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 constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Enclosures

P.S. Delete the word "Natural" in the phrase synergized natural pyrethions. Words or phrases implying safety of a pesticide product are not acceptable.

Immediately following the phrase Directions for Use add the misuse statement:

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

This statement should be set apart from the rest of the text in a separate paragraph.

BEST AVAILABLE COPY

BEST AVAILABLE COPY

DURAKYL II PET SPRAY

To Kill Fleas and Ticks on Dogs and Cats

ACTIVE INGREDIENTS	Percent by Weight
Fenmethrin (O-Phenacyloxyphenyl)methyl (z)-cis-trans-3-(2,2-dichloroethyl)-2,2-dimethylcyclopropane-carboxylate	0.100%
Pyrethrins	0.050%
N-Octyl bicycloheptane dicarbamate	0.500%
Residual Carcinogens	0.225%
INERT INGREDIENTS	99.125%
	100.000%

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

WARNING: May cause eye injury. Do not get in eyes or on clothing. Wear safety glasses during use. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Hazardous if absorbed through skin. Avoid contact with skin. Do not spray on animals. Do not spray where food or drink is exposed. Do not spray in face, eyes, or on genitalia. Do not use on nursing puppies or kittens under 3 months old.

ENVIRONMENTAL HAZARD: Keep out of lakes, streams or ponds. Do not contaminate water by cleaning or equipment or disposal of wastes.

STATEMENT OF PRACTICAL TREATMENT: If in eyes, flush with plenty of water and seek medical attention. If in skin develops or persists, get medical attention. If swallowed, drink one or two glasses of water and induce vomiting. If on skin, wash with soap and water. If in contact develop, get medical attention.

EPA REG NO 41835-

EPA EST NO 43774L-0



To Kill Fleas and Ticks on Dogs and Cats

Synergized Natural Pyrethrins with Fenmethrin
(See Panel to Left)

**KEEP OUT OF REACH OF CHILDREN
WARNING**

Net Contents: 16 Fl. Oz.

Product No. 9-541

REV 0588

DIRECTIONS FOR USE:

TO KILL FLEAS AND TICKS ON DOGS AND CATS AND IN SPRAY: Spray on animal around neck, along back, forelegs and on other areas where flea and tick infestation is most likely to occur. Hold spray nozzle close to animal and insure good coverage. Hold animal in every inch animal during application. Apply until thoroughly moist. Do not spray in eyes, nose or mouth. **TO REDUCE REINFESTATION OF ANIMAL:** Thoroughly groom and give medicated comb. Spray every week or REPEAT AS OFTEN AS NECESSARY.

STORAGE AND DISPOSAL: Store at temperatures above 32 degrees. Wrap container and put in trash container.

WARRANTY STATEMENT: Our recommendations are based upon tests believed to be realistic. The use of this product is the responsibility of the user. The manufacturer does not warrant the effects of such use or the results to be obtained. It is not to be used in conjunction with other insecticides or acaricides, including injury or damage, resulting from its combination with other products.

Formulated and distributed by
DVM DERMATOLOGICS FOR VETERINARIANS
Miami, FL 33172

Additional Registration Application
DuraKyl Flea & Tick Control Pet Spray
A File Symbol 41835-I

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN - 5 1989

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

41835-I