



WASHINGTON, D.C. 20460

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March 7, 1996

CERTIFIED MAIL

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

DVM Pharmaceuticals, Inc.  
c/o RegWest Company  
Greeley, CO 80632-2220

Attention: Ms. Kim Davis

Subject: Durakyl Pet Dip  
EPA Registration No. 41835-6  
Your amended application of January 15, 1994  
Recent Report of Incidents Involving Cats

The Agency originally registered this product on October 29, 1985. During the first 10 years of registration, the Agency received two reports of cats dying after treatment with this product. During this period, you reduced the dilution rate for cats from 1 oz to 1/2 oz of product per gallon of water. However, in 1996, we have already received one report of an incident involving a dead cat and expect to receive several additional reports in the next few weeks. In an effort to determine the extent of the problem and to take corrective action, you need to do the following things **within 30 days** of receipt of this letter.

1. Marketing Status of Product

According to our records, this product is still registered. The company has paid its 1996 Maintenance Fees and presumably is still actively marketing this product. Is this assessment true? Has the registrant voluntarily taken the product off the market anytime during the past five years?

2. Incidents Involving This Product

As required by 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Regulations (40 CFR 152.125), and PR Notice 92-1, you must submit to the Agency any adverse incidents associated with this product.

Have you noticed any increase in the numbers of incidents or changes in the profiles of incidents over the past 10 years? If so, what corrective action have you taken? Do you have any suggestions about changing the labeling text to reduce future incidents?



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contains at least 50% recycled fiber

### 3. Availability of Acute Toxicity Data

A review of the correspondence files for this product indicates that no acute toxicity data were ever submitted to support this product. Would you check with your supplier to determine if any such data exists for this formula. If so, submit the MRID numbers for the following studies:

- a. Acute Toxicity (Guideline No. 81-1)
- b. Acute Dermal Toxicity (81-2)
- c. Acute Inhalation Toxicity (81-3)
- d. Eye Irritation (81-4)
- e. Skin Irritation (81-5)
- f. Dermal Sensitization (81-6)

In addition, has your supplier conducted any domestic animal safety data on the formulation?

### 4. Revisions to Current Labeling

The last, stamped acceptable label for this product was dated August 10, 1990. You last submitted a revised label for this product on January 14, 1994. Since it was submitted as a Notification, we did not review it. We assume that the January 1994 version of your label is the one currently used. We have reviewed it here and are requiring a number of changes to insure maximum clarity to users, maximum safety to the users and pets, and compliance with current requirements. If you have additional suggestions to improve the label, let us know.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable provided that you make the following changes and submit one (1) copy to us before your ship product:

1. On the Front Panel, modify the text above the ingredient as follows:

Durakyl  
PET DIP

TO KILL FLEAS, TICKS AND LICE  
ON DOGS AND CATS  
(4 weeks or older)

2. Modify your "PRECAUTIONARY STATEMENTS" as follows:

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING

May be fatal if swallowed. Causes substantial but temporary eye injury. Harmful if absorbed through the skin. Causes skin irritation. Wear safety glasses. Do not get in eyes, on skin or on clothing. Avoid breathing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED: Call a physician or Poison Control Center. Do not give milk, cream or oily substances containing vegetable or animal fats. Drink large quantities of water. Avoid alcohol. Do not induce vomiting or give anything to an unconscious person. This product contains aromatic petroleum solvents. Aspiration may be a hazard.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF IN EYES: Flush with plenty of water. If irritation persists, get medical attention.

You current Environmental Hazards and Physical and Chemical Hazards statements are acceptable.

3. Revise your use directions as follows:

DIRECTIONS FOR USE

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

USE RESTRICTIONS: For use on dogs and cats, four (4) weeks or older, to control fleas, ticks, and lice.

MIXING DIRECTIONS: Depending upon the species and age of pet and the species of pest, dilute this product exactly according to the following table, using the enclosed measuring device:

		Dilution Rate of Product (Ounces of Product Per Gallon of Water)					
		DOGS			CATS		
		Puppies 4 Weeks Adults	Puppies Less Than 4 Weeks	Adults	Kittens 4 Weeks Adults	Kittens Less Than 4 Weeks	
FLEAS & LICE	1	1/2			1/2	1/4	DO NOT USE
TICKS	2	1			1/2	1/4	DO NOT USE

Note: Rarely, some animals, especially cats or older animals, may be more sensitive to this product. If an animal shows symptoms of distress (such as tremors, stiffness, or dilated eyes), immediately discontinue treatment, rinse the animal thoroughly with water, and take it and this bottle to veterinarian or animal hospital.

#### APPLICATION DIRECTIONS:

Apply directly to animal as a spray, sponge-on or a wash until skin is wet. Avoid contact with eyes, nose, mouth, or wounds. Do not rinse. After [insert number if applicable] minutes, dry with cloth or paper towels. Do not apply more than once every [insert number] weeks.

4. What is the purpose of the following sentence:

Keep diluted liquid away from light.

We would not expect the product to break down that fast or assume that users would storage diluted product. Therefore, we are recommending that the sentence be dropped from your label.

**BEST AVAILABLE COPY**

5. Modify your Storage and Disposal statements as follows:

STORAGE AND DISPOSAL

Storage: Store only in original container, in a dry place inaccessible to children and pets.

Disposal: Do not reuse empty container. Rinse thoroughly. Securely wrap in newspaper and discard in trash.

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 the amended labeling constitutes acceptance of these conditions.

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

Sincerely yours,



Robert A. Forrest  
Product Manager (14)  
Insecticide-Rodenticide Branch  
Registration Division (H7504C)

Enclosures: 1. Stamped Label  
2. A-79 Enclosure

cc: 1. Ms. Deanna Pfann  
9901 Pinelake Drive  
Houston, TX 77055

2. Mr. James Redd  
EPA Region 6  
1445 Ross Ave.  
12th Floor Suite 1200  
Dallas, TX 75202-2733

Peacock WP#8:A:\Rotenone\41835-6.MAR:305-5407,-6600:3/7/96



# PET DIP

TO KILL FLEAS, TICKS AND LICE  
ON DOGS AND CATS

### ACTIVE INGREDIENTS:

Rotenone	1.1%
Other Associated Resins	2.2%
Pyrethrins	0.8%
<b>INERT INGREDIENTS</b>	<b>95.9%</b>
	<b>100.0%</b>

**PRECAUCION AL CONSUMIDOR:** Si usted no lee ingles, no use este producto has que la etiqueta le haya sido explicada ampliamente.  
**TRANSLATION: TO THE USER:** If you cannot read English, do not use this product until the label has been fully explained to you.

Keep Out of Reach of Children

### WARNING

See back panel for additional precautionary statements

Net Contents: 4 Fl. Oz. (8 Tbs.)



**DVM Pharmaceuticals, Inc. (Dist.)**  
Miami/Florida/33172

REGISTERED  
EPA COMMENTS  
of EPA Letter Dated

MAR 0 / 1996

Under the Federal Insecticide, Fungicide, and Rodenticide Act, this product is registered under the Act.

41835-6

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS & DOMESTIC ANIMALS

**WARNING:** Harmful if swallowed or absorbed through the skin. Avoid breathing vapors or spray mist. Avoid contact with skin and eyes. **DO NOT USE ON PUPPIES OR KITTENS LESS THAN 4 WEEKS OLD.**

#### STATEMENT OF PRACTICAL TREATMENT

**If Swallowed:** Call a physician or poison control center. Do not induce vomiting. This product contains aromatic petroleum solvent. Aspiration may be a hazard.  
**If In Eyes or On Skin:** Flush with plenty of water. Get medical attention if irritation persists.

#### ENVIRONMENTAL HAZARDS

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

#### PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or open flame. Flash point minimum 120°F.

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Keep diluted spray away from light.

Apply directly to animal as a spray, sponge on or a wash. Dip until animal's skin is wet. Do not rinse. Avoid contact with eyes, nose or mouth of animals.

**ON DOGS: DO NOT USE MORE THAN 1 OUNCE PER GALLON ON PUPPIES. FOR FLEAS AND LICE,** dilute DuraKyl Pet Dip at the rate of 1 oz. (2 Tbs.) per 1 gallon of water. **FOR TICKS,** dilute DuraKyl Pet Dip at the rate of 2 ounces (4 Tbs.) per 1 gallon of water.

**ON CATS: ON ADULT ANIMALS, DO NOT USE MORE THAN 1/2 OUNCE PER GALLON. FOR FLEAS, TICKS AND LICE,** dilute 1/2 ounce (1 Tbs.) DuraKyl Pet Dip in 1 gallon of water.

**STORAGE:** Store in original container in a cool, dry place (preferably locked) inaccessible to children and pets and away from heat or open flame. **DISPOSAL:** Do not reuse empty container. Wrap container and put in trash.

EPA Reg. No. 41835-6  
EPA Est. No. 62478-FL-01

Product No. 6-560  
REV 0893

