

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OCT 25 2000

Ms. Kim Davis
RegWest Company
30856 Rocky Road
Greeley, CO 80631-9375

SUBJECT: Label Amendment
Enforcer P001
EPA File Symbol 40849-68
Enforcer P002-082797-RMP
EPA File Symbol 40849-72
Your Submissions Dated July 25 and September 15, 2000

Dear Ms. Davis,

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, are acceptable subject to the comments listed below.

1. Because MRIDs 44858201-04 and MRIDs 44874701-08 related to deltamethin, these studies can not be cited to support your permethin based products.
2. Under DIRECTIONS FOR USE, retain the "DO NOT USE ON CATS!" statement.

The Agency appreciates that spot-on flea and tick control products are popular among pet owners. However, due to the continued reports of incidents involving inadvertent exposure of cats to these products (either primarily through misuse or secondarily through interaction with a treated dog), we believe that further language and graphics should be added to existing and any future product labeling. For the above reasons, the Agency is considering the following labels changes to all product labeling of 45- 65% permethrin "spot-on" products:

3. On the front panel of the outside labeling, add 1) "Do Not Use on Cats" prominently displayed under the name of your product(s) and 2) an icon of a cat in a circle with a slash through it displayed on the front panel.
4. Under DIRECTIONS FOR USE, add the following statement, "Cats which actively groom

or engage in close physical contact with recently treated dogs may be at risk of serious harmful effect.”

5. Under DIRECTIONS FOR USE, following DO NOT USE ON CATS, add the following statement, “May be toxic and potentially fatal if applied to or ingested by cats.”
6. Include the statement “Do Not Use on Cats”, on the small vials in addition to the outside cardboard container and/or the icon discussed under 1).

We are aware that your above noted labels already incorporates some of these items. Although the Agency is currently considering these label changes, you are under no obligation to incorporate these at this time. We anticipate that a letter requesting these voluntary changes will be sent to all registrants of the > 40% permethrin spot-on products in the near future. Because we are reviewing your labels at this time, we wanted to ensure that you were aware of developing issues which may impact these labels in the near future.

7. Regarding the confidential statement of formula (CSFs) for EPA Reg. No. 40849-72, in order to correct a deficiency noted in the August 18, 2000 review of your submission requested a new alternative formulations being made part of the record, you submitted amended CSFs on September 15, 2000. These CSFs are acceptable. The following CSFs are now the CSFs of record:

Basic Formulation Dated: September 15, 2000

Alternative Formulation Dated: 1B, September 15, 2000; 1C, June 12, 2000

Stamped labeling for each of the above referenced products is enclosed for your records. If you have any questions regarding this action, please contact Linda Werrell Gerber, of my team, at (703) 308-8033.

Sincerely,



George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division

Enclosure

ENFORCER® P001

• Topical Flea and Tick Treatment for Dogs and Puppies

• **IMPORTANT! For use on Dogs and Puppies 6 Months of Age or Older; Do not use on Cats!**

No Cat Graphic

- For [Use on] Dogs and Puppies OVER 30 lbs. [0.06 fl. oz. (2 cc) applicator]
- For [Use on] Dogs and Puppies UNDER 30 lbs. [0.03 fl. oz. (1 cc) applicator]

- Kills and Repels Fleas and Ticks for up to 30 Days
- Kills and Repels the Deer Tick Which May Carry Lyme Disease
 - Kills Fleas Before They Lay Eggs

- Convenient, Pre-Filled Applicators
 - Easy and Convenient to Use

- 3 Month Supply [1 applicator = 1 month treatment]
 - 3 Month Flea & Tick Treatment
 - Once A Month Flea & Tick Treatment
 - Month 1 • Month 2 • Month 3

For Dogs of All Sizes:

3 Month treatment for dogs Over 30 pounds
6 Month treatment for dogs Under 30 pounds

ACTIVE INGREDIENT:

Permethrin [CAS #52645-53-1] 45%

OTHER INGREDIENTS 55%

Total: 100%

Keep Out of Reach of Children
CAUTION
See back panel for additional precautionary statements.

Net Contents: 3 - 0.06 fl. oz. (2 cc) applicators [dogs/puppies over 30 lbs.]
Net Contents 3 - 0.03 fl. oz. (1 cc) applicators [dogs/puppies under 30 lbs.]
Net Contents 6 - 0.03 fl. oz. (1 cc) applicators

ACCEPTED
with COMMENTS
in EPA Letter Dated:
OCT 25 2000

40849-68

EPA Reg. No. 40849-68

EPA Est. 40849-GA-1

Enforcer® P001
For Use on Dogs Over [Under] 30 lbs.

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS.
DO NOT USE ON CATS!

PRECAUTIONARY STATEMENTS
Hazards to Humans & Domestic Animals

CAUTION: Humans: Avoid contact with skin or clothing. Wash thoroughly with soap and water after handling. **Domestic Animals: DO NOT USE ON CATS!** Cats that actively groom or engage in close physical contact with recently treated dogs may be at risk of toxic exposure. Do not use on puppies less than six months of age. Consult a veterinarian before using this product on debilitated, aged, medicated, pregnant or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with a mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian IMMEDIATELY. In the event of an emergency, contact the National Animal Poison Control Center at (800) 345-4735.

First Aid

On Skin or Clothing:	<ul style="list-style-type: none"> • 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.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-241-5656 for emergency medical treatment.	

Environmental Hazards
This product is toxic to fish.

TREATMENT SCHEDULE			
Dosage: 1 tube every 30 days per dog.			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1st)	Third Treatment Date (30 Days From 2nd)

Reminder: I purchased P001 from: _____

DIRECTIONS FOR USE

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

This product [or product name] contains three monthly dosages, each 1 cc [2 cc]. This product [or product name] kills and repels fleas and ticks for up to 30 days. This product [or product name] kills and repels the Deer Tick which may carry Lyme Disease.

Graphics for Each Step

1. Remove one pre-filled applicator from package and hold in an upright position.
2. [Gently press cap to break the seal of the applicator.] Open applicator by carefully cutting the top of the tube.
3. [Carefully remove the cap.] Position the tip of the applicator on the dog's back between the shoulder blades.
For small dogs (under 30 lbs.): Apply half of the contents of the tube (0.5 cc) and proceed with steps 4 and 5.
For large dogs (over 30 lbs.): Apply the entire contents of the tube (1 cc) and proceed with steps 4 and 5.
4. **For small dogs (under 30 lbs.):** Invert the applicator to an upright position and move to the dog's hind quarters. Position the tip of the applicator at the base of the tail and apply the remaining contents of the tube (0.5 cc).
For large dogs (over 30 lbs.): Open another applicator (following directions provided in steps 1 and 2 above). Position the tip of the applicator at the base of the tail and apply the entire contents of the tube (1 cc).
 Do not reapply product for 30 days.

Although this product [or product name] is applied only between the shoulder blades and at the base of the tail, the dog's skin and hair oils carry the product over the entire body for protection against fleas and ticks. Do not bathe the dog for 5 days before or 5 days after treatment. This product [or product name] is most effective when used as part of a total flea and tick management program. Use other Enforcer products registered for residential area control of these pests in conjunction with this treatment. For additional control of fleas in and around the home use Enforcer Flea Spray for Yards Concentrate and Enforcer Flea Spray for Homes.

Storage and Disposal

Storage: Store in a cool, dry area in a location out of reach of children and pets. **Disposal:** Do not reuse empty applicator; wrap and discard in trash.

Copy: _____
Product Code: _____

Made in USA

Enforcer_® Products
a division of National Service Industries, Inc.
P.O. Box 1060
Cartersville, GA 30120-1060

Questions? Call (770) 386-0801, Monday through Friday, 9 am to 5 pm EST

{Note: The First Aid statements' grid format will be used if market label space permits; otherwise a paragraph format will be used.}

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