



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

APR 15 2003

Ms. April Hawkes
Enforcer Products
P.O. Box 1060
Cartersville, GA 30120

Subject: Amendment Removing Pre-/Post-Treatment Bathing Interval and Adding
Alternate Language for Dogs of All Sizes (3-Pack)
Enforcer P002-082797-RMP
EPA Registration Number: 40849-72
Your Submission Dated October 2, 2002 as Amended by Email April 14, 2003

Dear Ms. Hawkes:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments below. Two (2) copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy of the label is enclosed for your records.

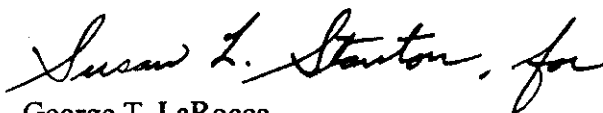
1. The ingredient statement is generally required on the front panel. If the size or form of the package makes it impractical to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere [40 CFR 156.10(g)(2)]. Your label indicates that the ingredient statement may appear on either the front or back panel, a change you made by notification on September 27, 1999. Such a change cannot be made by notification. Instead, you must submit a request to amend the label and include an explanation as to why it is not practical to place the ingredient statement on the front panel. Generally, EPA will not approve alternate placements of the ingredient statement to accommodate pictures, graphics or other marketing claims not required by FIFRA.
2. The statements near the beginning of the Directions for Use regarding the toxicity of this product to cats are complete and acceptable. Some of these statements (or modified versions of these statements) also appear in the Hazards to Humans & Domestic Animals section. The cat precautionary statements should be grouped together in one location. Accordingly, you should delete the following statements from the Hazards section: "Do not use on cats" and "Cats that actively groom or engage in close physical contact with recently treated dogs may be at risk of toxic exposure". If you would rather include the cat precautions in the Hazards section, you may do so, but the statements should appear

in a separate paragraph and must be revised to read as they currently do in the Directions for Use:

“DO NOT USE ON CATS! May be toxic and potentially fatal if applied to or ingested by cats. Cats that actively groom or engage in close physical contact with recently treated dogs may be at risk of serious harmful effects.”

If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely,



George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division (7505C)

Enclosure

3 2 8

ENFORCER®
P002-082797-RMP

- Topical Flea & Tick Treatment for Dogs and Puppies six months and older
- Contains [With] Precor®, Vigren® [Insect Growth Regulator (IGR)] or FGR[®] (Flea Growth Regulator)
- Prevents Flea Eggs from Developing into Biting Adults for up to 30 Days [3 Months]
- **IMPORTANT! [Intended] 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 Under 30 lbs. [0.03 fl. oz. (1 cc) applicator]
 - Kills and Repels Fleas, Ticks and Mosquitoes for up to 30 Days
 - Kills Fleas Before they Lay Eggs
 - Kills Flea Eggs to Prevent Reinfestation
 - [Number] 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 and Mosquito Treatment
 - 3 Month treatment for dogs under 30 pounds
 - Month 1 • Month 2 • Month 3

ACCEPTED
with COMMENTS
In EPA Letter Dated:
APR 15 2003

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
40849-72**

(Front or Back Panel)

ACTIVE INGREDIENTS:	
Permethrin [CAS #52645-53-1].....	45%
(s)-Methoprene [CAS #65733-16-6].....	3%
OTHER INGREDIENTS:	<u>52%</u>
Total	100%

Keep Out of Reach of Children
CAUTION
See back panel for [Ingredients and] additional precautionary statements.

Net Contents: 3 - 0.03 fl. oz. (1 cc) applicators [dogs/puppies under 30 lbs.]
[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples*]

EPA Reg. No. 40849-72

EPA Est. 40849-GA-1

**READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS OR PUPPIES.
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 1-800-345-4735.**

First Aid

If 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.] (if space available)
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 [1-800-950-4783 or 1-800-766-7661 or a Poison Control Center] for emergency medical treatment, Monday – Friday, 9am-5pm EST.	

[Note: First Aid statement paragraph format may be used if space is limited]

Environmental Hazards
This product is toxic to fish.

Physical or Chemical Hazards
Do not use or store near heat or open flame.

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)

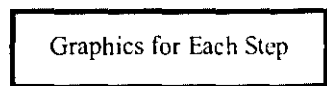
Reminder: I purchased P002-082797-RMP from: _____

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] prevents eggs from developing into adult fleas for up to 30 days [3 months]. This product [or product name] also kills and repels ticks and mosquitoes for up to 30 days.

Do Not Use on Cats!

May be toxic and potentially fatal if applied to or ingested by cats. Cats that actively groom or engage in close physical contact with recently treated dogs may be at risk of serious harmful effects.



[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples*]

5 7 8

1. Remove pre-filled applicator(s) from package and hold in an upright position.
2. [Gently press cap to break the seal of the applicator.] [Simply twist 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. Apply half of the contents of the tube (0.5 cc) and proceed with steps 4 and 5.
4. Invert the applicator to an upright position and move to the dog's hindquarters. Position the tip of the applicator at the base of the tail and apply the remaining contents of the tube (0.5cc).
5. **Do not reapply product for 30 days.**

[Alternate Packaging Directions]

1. Bend at perforation and tear off first month's applicator.
2. Hold applicator upright and snap tip back, away from face and body.

Note: DO NOT APPLY this product [or product name] to cats. These flea drops are intended for dogs only!

Although this product [or product name] is applied only between the shoulder blades and at the base of the tail [and in the middle of the back (over 60 lbs)], the dog's skin and hair oils carry the product over the entire body for protection against fleas, ticks and flea eggs. 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 [product names] 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: If empty: Do not reuse this container [empty applicator]. Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

[Disposal: Do not reuse this container [empty applicator]. Place in trash or offer for recycling if available. Never place unused product down any indoor or outdoor drain.]

Copy: _____
Product Code: _____

Made in USA

ENFORCER® PRODUCTS,
A division of Acuity Specialty Products Group, Inc.
P.O. Box 1060
Cartersville, GA 30120-1060
www.enforcer.com

Questions? Call (770) 386-0801, Monday through Friday, 9 am to 5 pm EST
[In case of emergency or for product use information, call (phone number) or visit our Web site: (URL)]

[Alternate Language for dogs Over 30 lbs] [E]

[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples*]

For [Use on] Dogs and Puppies Over 30 Lbs. [0.03 fl. Oz. (1 cc) applicator]

3 Month treatment for dogs Over 30 pounds

3 Month Supply [2 applicators = 1 month treatment]

Net Contents: 6 – 0.03 fl. Oz. (1 cc) applicators

1. Remove pre-filled applicator(s) from package and hold in an upright position.
2. [Gently press cap to break seal of the applicator.] [Simply twist 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. Apply the entire contents of the tube (1 cc) and proceed with steps 4 and 5.
4. 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).
5. Do not reapply product for 30 days.

[Alternate Packaging Directions]

1. Bend at perforation and tear off first month's applicator.
2. Hold applicator upright and snap tip back, away from face and body.

[Alternate Language for dogs over 60 lbs] [W]

[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples*]

4 Month Supply [1 applicator = 1 month treatment]

Net Contents: 4 – 3cc applicators

1. Remove pre-filled applicator(s) from package and hold in an upright position.
2. [Gently press cap to break seal of the applicator.] [Simply twist cap to break the seal of the applicator.] Open applicator by carefully cutting the top of the tube.
3. Position the tip of the applicator at the base on the dog's neck. Apply 1/3 of the contents of the applicator.
4. Invert the applicator to an upright position and move to the middle of the dog's back. Apply 1/3 of the remaining contents of the applicator.
5. Invert the applicator to an upright position and move to the base of the dog's tail. Apply the remaining 1/3 of the contents of the applicator.
6. Do not reapply product for 30 days.

[Alternate Packaging Directions]

1. Bend at perforation and tear off first month's applicator.
2. Hold applicator upright and snap tip back, away from face and body.

[Alternate Language for dogs up to 60 lbs] [W]

[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples*]

4 Month Supply [1 applicator = 1 month treatment]

Net Contents: 4 – 2cc applicators [dogs/puppies 31-60 lbs]

Net Contents: 4 – 1 cc applicators [dogs/puppies less than 30 lbs]

1. Remove pre-filled applicator(s) from package and hold in an upright position.
2. [Gently press cap to break seal of the applicator.] [Simply twist cap to break the seal of the applicator.] Open applicator by carefully cutting the top of the tube.
3. Position the tip of the applicator on the dog’s back between the shoulder blades. Apply half of the contents of the applicator.
4. Invert the applicator to an upright position and move to the dog’s hindquarters. Position the tip of the applicator at the base of the tail and apply the remaining contents of the applicator.
5. Do not reapply product for 30 days.

[Alternate Packaging Directions]

1. Bend at perforation and tear off first month’s applicator.
2. Hold applicator upright and snap tip back, away from face and body.

[Alternate Language for dogs of all sizes] [E]

[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples*]

For [Use on] Dogs of All Sizes [0.03 fl oz. (1 cc) applicator]:

6 Month treatment for dogs Under 30 pounds [1 applicator = 1 month treatment]

3 Month treatment for dogs 30 to 59 pounds [2 applicators = 1 month treatment]

2 Month treatment for dogs Over 60 pounds [3 applicators = 1 month treatment]

Drop 1	Drop 2	Drop 3	Drop 4	Drop 5	Drop 6
--------	--------	--------	--------	--------	--------

Net Contents: 6 – 0.03 fl. Oz. (1cc) applicators

[Alternate Language for dogs of all sizes] [E]

[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples*]

For [Use on] Dogs of All Sizes [0.03 fl oz. (1 cc) applicator]:

3 Month treatment for dogs Under 30 pounds [1 applicator = 1 month treatment]

1.5 Month treatment for dogs 30 to 59 pounds [2 applicators = 1 month treatment]

1 Month treatment for dogs Over 60 pounds [3 applicators = 1 month treatment]

Drop 1	Drop 2	Drop 3
--------	--------	--------

Net Contents: 3 – 0.03 fl. Oz. (1cc) applicators

[Alternate Language for dogs of all sizes] [W]

[Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. See end of label for examples*]

Net Contents: 50 – 1cc applicators

1. Remove pre-filled applicator(s) from package and hold in an upright position.
2. [Gently press cap to break the seal of the applicator.] [Simply twist cap to break the seal of the applicator.] Open applicator by carefully cutting the top of the tube. [Carefully remove the cap.]
3. Apply as directed below.
4. Do not reapply product for 30 days.

[Alternate Packaging Directions]

1. Bend at perforation and tear off first month’s applicator.
2. Hold applicator upright and snap tip back, away from face and body.

8 7 8

MONTHLY [product name] APPLICATION

Application By Weight	# of 1cc Tubes	Where to Apply
Dogs up to 29 pounds	One tube	½ tube at base of neck ½ tube at base of tail
Dogs 30 to 59 pounds	Two tubes	1 tube at base of neck 1 tube at base of tail
Dogs 60 pounds +	Three tubes	1 tube at base of neck 1 tube in middle of back 1 tube at base of tail

[*Alternate applicator sizes permissible as long as dosage/ratios are maintained the same. Examples:]

DOG WEIGHT	SIZE	WHERE TO APPLY
Less than 15 lbs.	1cc	½ at neck, ½ at tail
16-30 lbs.	1cc	½ at neck, ½ at tail
31-60 lbs.	2cc	½ at neck, ½ at tail
Greater than 60 lbs.	3cc	1/3 at neck, 1/3 at mid-back, 1/3 at tail