



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

Zep Commercial Sales & Service, A Unit of Zep Inc.
c/o Melinda Pritchett
1310 Seaboard Industrial Blvd.
Atlanta, GA 30318

AUG 30 2010

Subject: Notification of Additional Alternate Unit Packaging/Use Directions [Label Amendment]
Enforcer P002-082797-RMP
EPA Reg. No. 40849-72
Your Submission Dated May 6, 2010
Decision No: 435776

Dear Ms. Pritchett:

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 conditions of registration and label 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. Per the March 17, 2010 meeting with registrants of spot-on pet products, this registration is now time-limited and expires two years from the date this product is first released for shipment.

You must provide the Agency with a projected release for shipment date within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected release for shipment date until an actual release for shipment date is provided in writing.

2. Please consider limiting the formulations of this product to one basic confidential statement of formula. The Agency may require this in the future and no additional alternate formulations or minor formulation amendments will be approved for this product in the future.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning January 1, April 1, July 1, or October 1, whichever date most closely follows the date this product is first released for shipment.

Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kimberly Nesci).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
Product name (brand name)
Lot #
Where purchased: internet, store, or veterinarian
Active Ingredient(s)
Weight range for product

Date on which incident occurred. (mm/dd/yyyy)
State in which the incident occurred. (standard 2 letter abbreviation)
Registrant case #

Species: dog, cat, other (specify)
Breed: (as reported by pet owner)
Age: months or years
Sex: M, F, or neutered
Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other
Body System: neurological, dermatological, GI, respiratory, ocular, other
Major signs noted with separate column for each sign, using standard terminology
Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no
Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
Any known precondition
EPA Severity Code: death, major, moderate, minor
Outcome: died, recovered, still treated, unknown

4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- All incidents should be reported including all minor dermal and ocular irritation reports.
- Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.

- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
 - A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
 - A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
 - A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
 - Table showing number of incidents for each dog breed.
 - Table showing number of incidents in dogs for each clinical sign.
 - Table showing number of incidents in dogs for each organ system.
 - Report aggregate incidents, but do not combine moderate and minor incidents.
5. For consistency throughout the label, correct the weight ranges in the Use Directions and Application tables to reflect the following:
- For dogs weighing 29 pounds or less,
 - For dogs weighing 30 pounds to 59 pounds,
 - For dogs weighing 60 pounds or greater.
6. In the third bullet on page 1, add the word “supply” after “3 months.”
7. In the fourth bullet on page 1 and in the “Note: DO NOT APPLY...” statement on page 3, delete “Intended.”
8. On page 1, since the front page has package labeling for use on dogs 29 pounds or less, replace the alternate word bracket in the ninth bullet containing “[Number] Convenient, Pre-filled Applicators” with “[Three, 3].”
9. On page 2, add “supply” after “[3 months]” in the sentence under the Directions for Use.
10. On page 2 under Physical or Chemical Hazards, the word “Combustible” must be listed as required text, rather than optional text.

11. On page 2 under Precautionary Statements, add a “.” and two spaces after “Animals.” In the Hazards to Humans & Domestic Animals.
12. On page 2 in the Hazards to Humans & Domestic Animals, bold the word “ANY” in the sentence “Sensitivities may occur...”
13. On page 2 in the First Aid box, remove the brackets and “(if space available)” statement from the last bullet, since this is required language and must appear on the label.
14. For clarity and consistency throughout the label, always include the statement “six months and older” wherever “Puppies” are referenced.
15. To ensure that this product is only used on dogs, change the word “Pet’s” to “Dog’s” in the Treatment Schedule table on page 2 of the label.
16. In order for the Treatment Schedule table on page 2 to be consistent with the alternate use directions, either:
 - delete “Dosage: 1 tube every 30 days per dog” and leave the table as is, or
 - delete “Dosage: 1 tube every 30 days per dog” and insert a new column for the consumer to write the dosage (e.g., how many applicators are needed) for the respective dog(s).
17. Move the appropriate Monthly Application chart from page 6 to page 2, closer to the Treatment Schedule table so that the consumer may clearly see and note what the appropriate application for the dog is.
18. For clarity, replace the words “first month’s” with “an” in the first statement of the Alternate Packaging Directions on pages 3 through 6.
19. In the Storage and Disposal box on page 3, remove the alternate language in brackets and update the Pesticide Disposal and Container Handling statement (per 40 CFR part 156.140) to read as follows:

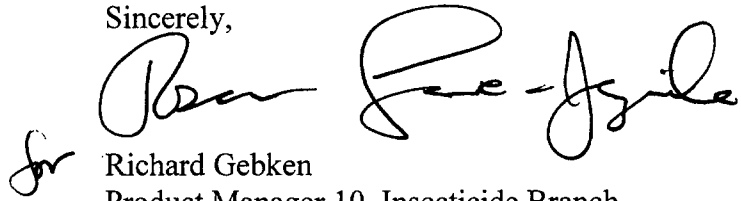
“Pesticide Disposal and Container Handling: Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling if available.
If partly filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.”
20. On page 4 in the Alternate Language for dogs “Over 30 lbs,” change all references to read “Weighing 30 pounds to 59 pounds.”
21. On page 5 for Alternate Language for Dogs up to 60 lbs, change the reference to read “Weighing 30 pounds to 59 pounds.”

- 22. On page 5 for Alternate Language for Dogs up to 60 lbs, move “Net Contents: 4 - 1 cc applicators [dogs/puppies less than 30 pounds]” from this section and create a new section for “Alternate Language for “Dogs 29 pounds or less” to reflect this packaging’s net contents.

- 23. At the bottom of page 5 for the second set of Alternate Language for Dogs of All Sizes for the packaging containing three applicators, the line starting with “1.5 month treatment for dogs...” must be deleted because this can be misinterpreted/misleading to the user.

If EPA determines that future mitigation measures are necessary for all pet spot-on products, the Agency will inform registrants, and if needed, EPA may take regulatory action. If you have any questions regarding this action, please contact Rosanna Louie at (703) 308-0037.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard Gebken". The signature is written in a cursive style with a large initial "R".

Richard Gebken
Product Manager 10, Insecticide Branch
Registration Division (7505P)

Enclosure:

- Enforcer P002-082797-RMP label, Stamped *Accepted with Comments*

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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:**

AUG 30 2010
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
40849-72

(Front or Back)

ACTIVE INGREDIENTS:

Permethrin [CAS #52645-53-1].....	45%
(s)-Methoprene [CAS #65733-16-6].....	3%

OTHER INGREDIENTS:	52%
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 (E), 2724-TX-1 (C)

**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 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

[Combustible.] 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 1 st)	Third Treatment Date (30 Days From 2 nd)

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

DIRECTIONS FOR USE

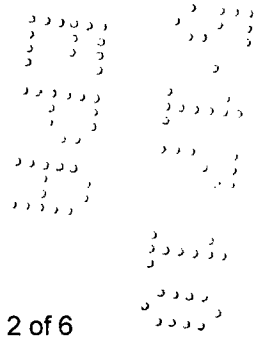
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

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.

Graphics for Each Step



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

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.

[Alternate Packaging Directions]

1. Remove pre-filled applicators from package and hold in an upright position.
2. Bend at perforation and tear off a single applicator.
3. Hold applicator upright (away from face and body) and snap tip back.
4. Apply as directed below.

Do not reapply product for 30 days

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.

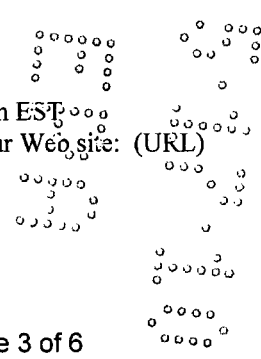
[Disposal: Do not reuse this container [empty applicator]. Place in trash or offer for recycling if available. Never place unused product down any indoor or outdoor drain.]

Copy: _____
Product Code: _____

Made in USA

Zep Commercial Sales & Service
A Unit of Zep Inc.
1310 Seaboard Industrial Blvd.
Atlanta, GA 30318
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 Website: (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 Packaging Directions]

1. Remove pre-filled applicators from package and hold in an upright position.
2. Bend at perforation and tear off a single applicator.
3. Hold applicator upright (away from face and body) and snap tip back.
4. Apply as directed below.

Do not reapply product for 30 days

[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*]

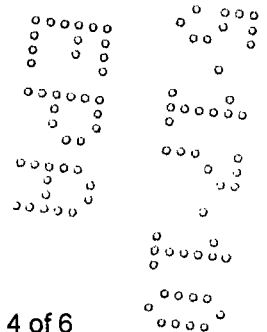
4 Month Supply [1 applicator = 1 month treatment]

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 1/2 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 Packaging Directions]

1. Remove pre-filled applicators from package and hold in an upright position.
2. Bend at perforation and tear off a single applicator.
3. Hold applicator upright (away from face and body) and snap tip back.
4. Apply as directed below.

Do not reapply product for 30 days

[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 Packaging Directions]

1. Remove pre-filled applicators from package and hold in an upright position.
2. Bend at perforation and tear off a single applicator.
3. Hold applicator upright (away from face and body) and snap tip back.
4. Apply as directed below.

Do not reapply product for 30 days

[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]

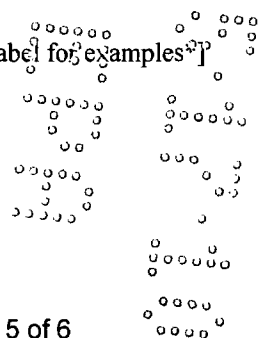
1.5 Month treatment for dogs 30 to 59 pounds [2 applicators = 1 month treatment]

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.

[Alternate Packaging Directions]

1. Remove pre-filled applicators from package and hold in an upright position.
 2. Bend at perforation and tear off a single applicator.
 3. Hold applicator upright (away from face and body) and snap tip back.
 4. Apply as directed below.
- Do not reapply product for 30 days

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

