

1007-97

12/18/2013

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

EPA Registration Number:
1007-97

Date of Issuance:
DEC 18 2013

Term of Issuance:
Conditional

Name of Pesticide Product:
LA Combo for Dogs

NOTICE OF PESTICIDE:

Registration
 Reregistration

(Under FIFRA as amended)

Name and Address of Registrant (include ZIP Code):
Zoetis
7000 Portage Road, KZO 300-403 SW
Kalamazoo, MI 49001

Note: Changes in labeling 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 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.

Registration is in no way to be construed as an endorsement or recommendation of this product by the 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 **conditionally** registered in accordance with FIFRA sec. 3(c)(7)(A), provided that:

- 1. This registration is 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. Only one basic confidential statement of formula will be on file for this product at any one time; no alternate formulations or minor formulation amendments will be submitted or approved for this product.
- 3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning January 1, 2014.

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: Katlin Keller).

Signature of Approving Official:
Debra Alexander for
Richard Gebken Product Manager
Insecticide Branch/Registration Division (7505P)

Date:
December 18, 2013

Enclosure

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, 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. You must submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data, and submit acceptable responses required for reregistration of your product under FIFRA section 4.
 6. You revise the EPA Registration Number to read: "EPA Registration No. "EPA Reg. No. 1007-97" on page 1 of the label.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

Two copies of the finished labeling must be submitted prior to releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A copy of your label stamped "Accepted" is enclosed for your records.

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Front Panel

[Note to reviewer: [brackets] indicate optional and/or alternate text]

| |
|--|
| ACCEPTED |
| DEC 18 2013 |
| Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide Registered under EPA Reg. No. 1007-97 |

LA Combo for Dogs

Single spot application for control of fleas and ticks ONLY on dogs and puppies 9 weeks of age and older, and
 [11 to 20 lbs.]
 [22 to 33 lbs.]
 [34 to 50 lbs.]
 [51 to 66 lbs.]

Net Contents: X fl oz [Y- X fl oz tubes]

[3] [Three] [6] [Six]

[0.033 fl oz (1.0 ml) tubes]

[0.067 fl oz (2.0 ml) tubes]

[0.101 fl oz (3.0 ml)(1.0 mL+2.0 mL) tubes]

[0.135 fl oz (4.0 ml) tubes]

| | |
|----------------------------|---------------|
| ACTIVE INGREDIENTS: | % w/w |
| Demiditraz | 14.4 |
| Fipronil | 4.8 |
| OTHER INGREDIENTS | 80.8 |
| TOTAL | 100.00 |

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

[Refer to [side][back][other] panel for First Aid and Precautionary Statements]

READ ENTIRE LABEL BEFORE USE

For control of fleas (*Ctenocephalides* sp.) on dogs and puppies 9 weeks of age and older. *LA Combo for Dogs* is a convenient single spot application that provides control of existing flea and brown dog tick and American dog tick infestations, and protects against reinfestation. It may also be used to prevent infestation in flea free dogs and puppies 9 weeks of age and older taken into a flea-contaminated environment.

Kills fleas that may cause flea allergy dermatitis.

Kills and controls the following ticks:

- Brown dog ticks (*Rhipicephalus sanguineus*), which can transmit *Ehrlichia canis*
- American dog ticks (*Dermacentor variabilis*), which can transmit Rocky Mountain Spotted Fever

A single dose of *LA Combo for Dogs* is effective for up to 6 weeks in controlling fleas and up to 4 weeks for brown dog ticks and American dog ticks. Apply a single dose prior to exposure. Monthly application is recommended for effective control of fleas and ticks and to prevent reinfestation. Do not apply more than once monthly.

[1.5 cm X 1.5 cm cat prohibition icon in box at lower right hand corner of front panel in yellow with black images, or similar]

[side panel]

- Stops infestations of fleas, brown dog ticks and American dog ticks
- Prevents reinfestation of fleas, brown dog and American dog ticks
- Up to 6 weeks of flea control with a single treatment
- Kills the fleas that may cause flea allergy dermatitis
- Up to 4 weeks of control of brown dog ticks and American dog ticks with a single treatment
- Kills brown dog ticks and American dog ticks that may transmit canine ehrlichiosis or Rocky Mountain Spotted Fever
- Convenient and easy to use applicator
- Waterproof
- Effective on indoor or outdoor dogs
- [Available only from a licensed veterinary professional] **[note to reviewer: this voluntary statement will only be used when the product is marketed through veterinarians]**

Side Effects: Monitor your dog after application. Side effects may include salivation, signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea may be reported. If these or other side effects occur, consult your veterinarian or Zoetis at 1-888-963-8471.

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.

[1.5 cm x 1.5 cm cat prohibition icon in yellow with black images and text located at lower right corner of panel]

PRECAUTIONARY STATEMENTS

CAUTION

Hazards to Humans

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Hazards to Domestic Animals

For external use only. For use on dogs only. **DO NOT USE ON ANY ANIMALS OTHER THAN DOGS.** Do not use on puppies younger than 9 weeks of age. Certain medications can interact with pesticides. Consult a veterinarian before using this product on aged, debilitated, medicated, pregnant or nursing animals. Sensitivities may occur after using ANY pesticide product for pets. If skin irritation, change in behavior, vomiting or diarrhea is observed and persists after the use of the product, call your veterinarian immediately. For further product information, call 1-888-963-8471.

FIRST AID [FOR HUMANS]

| | |
|---|---|
| IF SWALLOWED | <ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or medical professional. • Do not give anything to an unconscious person. |
| IF IN EYES | <ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice |
| Have the product container or label with you when contacting a poison control center or medical professional. | |

Physical and Chemical Hazards

Combustible. Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For external use only on dogs and puppies 9 weeks of age and older. DO NOT USE ON ANY ANIMALS OTHER THAN DOGS. Do not allow your dog to ingest this product.

[Only for small dogs weighing 11 to 20 [lbs.][pounds] Do not apply to dogs weighing less than 11 lbs.

[For cartons containing 0.033 [fl oz][fluid ounces] applicator tubes.]

Snap open applicator tube. Part the dog's hair at the base of the neck in front of the shoulder blades. Slowly empty the [0.033 [fl oz][fluid ounces] vial by squeezing gently to ensure direct application to the skin.]

[Only for medium dogs weighing 22 to 33 [lbs.][pounds]

[For cartons containing 0.067 [fl oz][fluid ounces] applicator tubes.]

Snap open applicator tube. Part the dog's hair at the base of the neck in front of the shoulder blades. Slowly empty the [0.067 [fl oz][fluid ounces] vial by squeezing gently to ensure direct application to the skin.]

[Only for intermediate dogs weighing 34 to 50 [lbs.][pounds]

[For cartons containing 0.033 fl oz and 0.067 [fl oz][fluid ounces] applicator tubes.]

Snap open one applicator tube of 0.033 [fl oz][fluid ounces] and one of 0.067 [fl oz.][fluid ounces] Part the dog's hair at the base of the neck in front of the shoulder blades. Slowly empty one vial of each size [0.033 [fl oz][fluid ounces] and 0.067 [fl oz][fluid ounces] by squeezing gently to ensure direct application to the skin. Apply one vial at a time.]

[Only for large dogs weighing 51 to 66 [lbs.][pounds]. Do not double dose dogs larger than 66 [lbs.][pounds].

[For cartons containing 0.135 [fl oz][fluid ounces] applicator tubes.]

Snap open applicator tube. Part the dog's hair at the base of the neck in front of the shoulder blades. Slowly empty the [0.135 [fl oz][fluid ounces] vial by squeezing gently to ensure direct application to the skin.]

[PACKAGING

LA Combo for Dogs is available in four packaging presentations for different body weights of dogs and puppies 9 weeks of age and older weighing 11 pounds or more only (see table below). Each package for Small dogs, Medium dogs, Intermediate dogs and Large dogs contains three or six individual applicator tubes to provide monthly treatments. The dog body weight limits and product volume sizes are specified on individual labels of cartons, foil pouches and applicators.]

[Each package for Intermediate-sized dogs contains a set of [three] [or] [six] individual small applicator tubes (0.033 fl oz) and medium applicator tubes (0.051 fl oz). Apply one of each size tube for dogs in this weight range. All other weight ranges only apply one tube.]

Package Dog Size (lbs) Fl. oz/applicator [table optional]

| | Body weight in pounds | | Volume |
|-------------------|-----------------------|------|---------|
| | Low | High | Fl. Oz. |
| Small dogs | 11 | 20 | 0.033 |
| Medium dogs | 22 | 33 | 0.067 |
| Intermediate dogs | 34 | 50 | 0.101* |
| Large dogs | 51 | 66 | 0.135 |

*one 0.033 oz (1 mL) tube plus one 0.067 oz (2 mL) tube

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

Pesticide Storage: Store in a cool dry place.

Container Disposal:

If empty: Non-refillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available.

If partly filled:

Call your local solid waste agency for disposal instruction. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND DISCLAIMER

Directions for use of this product are based upon tests believed to be reliable. The use of this product being beyond control of the seller, no guarantee, express or implied, is made as to the effects of such use or the results to be obtained if not used in accordance with printed directions and established safe practice. To the extent consistent with applicable law, buyer's exclusive remedy and seller's exclusive liability for any and all claims, losses, damages or injuries resulting from the use or handling of this product, whether or not based in contract, negligence, strict liability in tort or otherwise shall be limited, at the seller's option, to replacement of, or the repayment of the purchase price for, the quantity of product with respect to which damages are claimed.

[MADE IN ITALY]

[Manufactured by]

[Manufactured for]

Zoetis Inc.
333 Portage Street
Kalamazoo, MI 49007

EPA Reg. No. 1007- 97
EPA Est. No. 81052-ITA-001

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[Text on foil pouch:]

Cut along line and peel foil back.

LA Combo

Demiditraz 14.4% w/w,

Fipronil 4.8% w/w

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for additional directions

Cat prohibition icon

EPA Reg. No. 1007-97

Only for dogs 9 weeks & older, and

[11 to 20 lbs]

[22 to 33 lbs]

[34 to 50 lbs]

[51 to 66 lbs]

[Text on tube:]

LA Combo

EPA Reg. No. 1007-97

Only for dogs 9 weeks and older, and

[11 to 20 lbs]

[22 to 33 lbs]

[34 to 50 lbs]

[51 to 66 lbs]

Demiditraz 14.4% w/w,

Fipronil 4.8% w/w

[0.033 fl oz tube]

[0.067 fl oz tube]

[0.101 fl oz one 0.033 oz (1 mL) tube plus one 0.067 oz (2 mL) tube]

[0.135 fl oz tube]