

80490-3

11/05/2008

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



OFFICE OF
PREVENTION, PESTICIDES,
AND TOXIC SUBSTANCES

NOV - 5 2008

Bosco Wang
Fort Dodge Animal Health
PO Box 5366
Princeton, NJ 08543-5366

Dear Dr. Wang:

Subject: Submission of revised label
ProMeris for Cats
EPA Registration No. 80490-3
Your submission dated June 16, 2008

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable with the following comments:

- Immediately after the statement "*ProMeris® for cats* can be used on pregnant and lactating cats," add the following statement: "Do not use on lactating/nursing cats until at least 5 days after delivery."

A stamped copy is enclosed for your records. Submit two copies of your final printed labeling before you release the product for shipment. If you have any questions, please Julie Chao at (703) 308-8735 or chao.julie@epa.gov.

Regards,

A handwritten signature in black ink, appearing to read "John Hebert".
John Hebert
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

ACCEPTED
With COMMENTS
In EPA Letter Dated:

NOV - 5 2008

Under the Federal Insecticide, Fungicide
and Rodenticide Act, As amended, for the
pesticide Registered under EPA Reg. No:

80490-3

ProMeris® for cats



Fort Dodge Animal Health
A division of Wyeth

of control of fleas by blocking gated sodium channels.

Benefits of ProMeris® for cats include:

- Stops and controls infestations of fleas
- Prevents reinfestation of fleas
- Long-lasting control for up to 7 weeks
- Mode of action - voltage dependent sodium channel blocker
- Kills fleas that may cause flea allergy dermatitis
- Convenient and easy to use applicator
- Available only from a licensed veterinary professional

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For external use on cats and kittens 8 weeks of age and older*. DO NOT USE ON ANY ANIMALS OTHER THAN CATS.

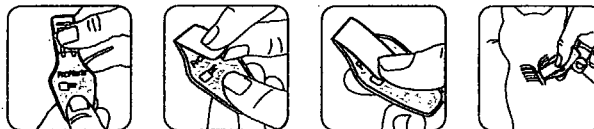
PACKAGING

ProMeris® for cats is available in two packaging presentations for different body weights of cats or kittens 8 weeks of age and older (see table below). Each package contains three or six individual applicator tubes to provide monthly treatments. The cat body weight limits and product volume sizes are specified on individual labels of cartons, foil pouches and applicators.

Package Size	Cat Size (lb)	Fl. oz/applicator
S	Small cats* less than 9	0.027
L	Large cats 9 and over	0.054

*Use the Small Cat applicator for all kittens between 8 weeks and 6 months of age

HOW TO APPLY



1. Remove one applicator from the foil pouch.
2. Hold applicator upright for three seconds to avoid splash when opening.
3. Use two hands to hold both ends of applicator with printed side facing the user and narrow end pointing upward and away from the user.
4. To open, bend the tip of applicator towards the user and break along the fracture line.
5. Do not squeeze applicator when opening. Avoid touching applicator opening.
6. Fold tip back against the printed side of applicator. Hold applicator in one hand using thumb to hold tip back against the printed side of applicator.
7. Push the open tip through cat's hair coat onto cat's skin below the back of the head. Squeeze applicator to apply the entire contents to the cat's skin. Do not apply on the surface of cat's hair coat. Avoid contact with treated area until dry.
8. Avoid allowing the product to come in contact with your skin.
9. Place empty applicator in trash.

STORAGE AND DISPOSAL

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

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Storage:

Store in a cool dry place.

Container Disposal:

If empty: Do not reuse 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.

FIRST AID FOR HUMANS

Have the product applicator, carton or this product label with you when contacting a poison control center or medical professional. If in eyes, hold eyes open and rinse with water for 15 to 20 minutes. If contact lens is present, remove contact lens after the first five minutes of rinsing, then continue rinsing eyes. Call a poison control center or doctor for treatment advice.

PRECAUTIONARY STATEMENTS

Hazards to Humans

Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

Hazards to Domestic Animals

For external use only. FOR USE ON CATS ONLY. Do not use on kittens younger than 8 weeks of age. Care should be taken to apply as directed to minimize the chance of accidental ingestion by the cat. Exposure or ingestion may result in temporary salivation; this response should disappear without treatment. Correct application of the product will reduce the chances of oral exposure. Certain medications can interact with pesticides. Consult a veterinarian before using this product on aged, debilitated or medicated animals. Individual sensitivities, while rare, may occur after the use of any pesticide product. 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-PROMERIS (1-888-776-6374).

Physical and Chemical Hazards

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

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 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.

Fort Dodge Animal Health
P.O. Box 25945
Overland Park, KS 66225

MADE IN ITALY

EPA Reg. No. 80490-3
EPA Est. No. 81052-ITA-001

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ProMeris®
for cats



Fort Dodge Animal Health

Single spot application for control of fleas on cats and kittens 8 weeks of age and older.

ACTIVE INGREDIENT:

Metaflumizone (CAS No. 139968-49-3)18.53%
OTHER INGREDIENTS81.47%
TOTAL100.00%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

READ ENTIRE LABEL BEFORE USE

For control of fleas (*Ctenocephalides* sp.) on cats and kittens 8 weeks of age and older. ProMeris® for cats is a convenient single spot application that provides control of existing flea infestations, and protects against reinfestation. It may also be used to prevent infestation in flea-free cats and kittens 8 weeks of age and older taken into a flea-contaminated environment. Kills fleas that may cause flea allergy dermatitis. ProMeris® for cats can be used on pregnant and lactating cats.

A single dose of ProMeris® for cats is effective for up to 7 weeks in controlling fleas. Apply a single dose prior to exposure. Reapplication at monthly intervals may be appropriate depending upon the level of flea challenge and animal sensitivities (i.e. flea allergy dermatitis). Do not apply more than once monthly.

ProMeris® for cats contains the active ingredient, metaflumizone, which provides a high level

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