

68451-1

4/15/2010

1027



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

APR 15 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Ms Patricia A. Sheehy, MS
Intervet Inc.
56 Livingston Avenue, R-3-3153G
Roseland, New Jersey 07068

Subject: Label Notification(s) for Pesticide Registration Notice 2007-4 and 98-10
Storage & Disposal and other changes

Dear Registrant:

The Agency is in receipt of your Application(s) for Pesticide Notification under Pesticide Registration Notice (PRN) 2007-4 and 98-10 dated February 23, 2010 for:

EPA Registration 68451-1 Deltamethrin 4% Collar

The Registration Division (RD) has conducted a review of this request for applicability under PRN 2007-4 and 98-10, and finds that the label change(s) requested falls within the scope of PRN-2007-4 and 98-10. The label has been date-stamped "Notification" and will be placed in our records.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on nonrefillable containers. The code may appear either on the label (and can be added by non-notification/PR Notice 98-10) or durably marked on the container itself.

If you have any questions, please contact me directly at 703-305-6249 or Banza Djapao of my staff at 703-305-7269.

Sincerely,

Linda Arrington *for*
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

 United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 68451-1	2. EPA Product Manager Kimberly Nesci	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Deltamethrin 4% Collar	PM# PM # 13	
5. Name and Address of Applicant (Include ZIP Code) Intervet Inc. 56 Livingston Avenue, R-3-3153G Roseland, New Jersey 07068 <input checked="" type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Other - Explain below.
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NOTIFICATION

APR 15 2010

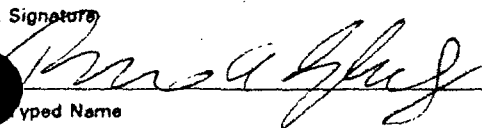
Explanation: Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION OF DELTAMETHRIN 4% COLLAR PER PR NOTICE 98-10. Notification of label changed per PR Notice 2007-4 and to make minor text changes. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 10001 to willfully make any false and misleading statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR § 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt No. per container	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1-collar net wgt 0.9 oz	
5. Location of Label Directions <input checked="" type="checkbox"/> On carton		6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other carton label - <i>ink jet</i>	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Patricia A. Sheehy, M.S.	Title Manager, Regulatory Affairs	Telephone No. (Include Area Code) (862) 245-3551
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature  Typed Name Patricia A. Sheehy, M.S.		3. Title Manager, Regulatory Affairs
		5. Date 3-25-10 resubmission of application to 2-23-2010 Notification

Patricia A. Sheehy
Manager, Regulatory Affairs

February 23, 2010

Kimberly Nesci
Registration Division (7504P)
Office of Pesticide Products
US. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

**RE: Deltamethrin 4% Collar (EPA Reg. No. 68451 -1)
Notification per PR Notices 98-10 and 2007-4**

Dear Ms. Nesci:

Following my conversation with Melody Banks this morning Intervet Inc has removed the statements previously submitted in our December 22, 2009 notification that do not fall within the scope of PR Notice 98-10 and PR Notice 2007-4 related to vector borne diseases. Intervet Inc is providing the enclosed notification to update the label per PR Notices 98-10 and 2007-4.

Notification of Deltamethrin 4% Collar per PR Notice 98-10. "This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA".

Notification of label changed per PR Notice 2007-4 and to make minor text changes. "This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false and misleading statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR § 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA".

Please find the following documents attached in support of this notification:

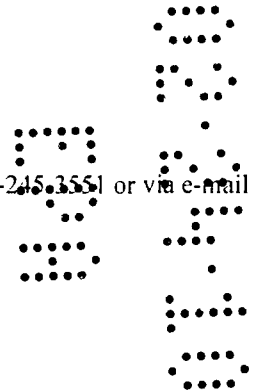
- 1) Notification application form,
- 2) One highlighted version of the revised label, and
- 3) One clean version of the revised label.

If you have any questions or comments regarding this submission, please contact me at 862-245-3551 or via e-mail at patricia.sheehy@sp.intervet.com

Sincerely


Patricia A. Sheehy, M.S.
Manager, Regulatory Affairs

enclosures



DELTAMETHRIN 4% COLLAR FLEA & TICK COLLAR FOR DOGS

Alternate Brand Names:

SCALIBOR® Flea and Tick Collar for Dogs
SCALIBOR® Flea & Tick Collar for Dogs

SCALIBOR® Collar with Deltamethrin
SCALIBOR® Collar with 4% Deltamethrin

SCALIBOR® Dog Collar for Flea and Tick Control
SCALIBOR® Dog Collar for Flea & Tick Control

SCALIBOR® Long Lasting Collar for Dogs
SCALIBOR® Full Season Collar for Dogs

SCALIBOR® Deltamethrin Collar for Dogs

SCALIBOR® Collar for Dogs

SCALIBOR® 6-Month Collar for Dogs
SCALIBOR® 6-Month Flea and Tick Collar for Dogs
SCALIBOR® 6-Month Flea & Tick Collar for Dogs

SCALIBOR® Protector Band for Dogs

SCALIBOR® Six Month Collar for Dogs
SCALIBOR® Six Month Flea and Tick Collar for Dogs
SCALIBOR® Six Month Flea & Tick Collar for Dogs

NOTIFICATION

APR 15 2010

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	96.0%
Total	100.0%

CAUTION: Do Not Let Children Play With This Collar

See Insert or Side Panel for additional Precautionary Statements

See Back for additional Precautionary Statements

Adjustable – One Size Fits All

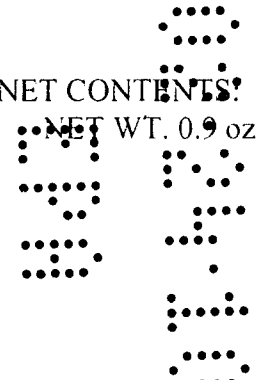
EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar

NET WT. 0.9 oz

Distributed by:
Intervet Inc.
Roseland, NJ 07068



Product of France

5097

Deltamethrin 4% Collar
EPA Reg. No: 68451-1

page: 2 of 4
revision date: 02-23-10

**READ ENTIRE LABEL BEFORE EACH USE
USE ONLY ON DOGS**

Deltamethrin 4% Collar provides full season, up to 6 months protection against fleas and ticks

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION:

Do not open protective pouch until ready to use. Do not let children play with this collar.

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

Do not use on puppies under 12 weeks. Consult a veterinarian before using this product on debilitated, aged, pregnant, medicated, or nursing animals. Sensitivities may occur after using ANY pesticide products for pets. If signs of sensitivity occur, remove collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

This collar is intended for use only as an insecticide generator and is not to be taken internally by man or animals. Applying other pesticides on the dog may not be necessary while the collar is being worn.

FIRST AID	
If swallowed	<ul style="list-style-type: none"> • Call 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 the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
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 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 eye. • Call a poison control center or doctor for treatment advice.
<p>For incidents involving HUMANS, call 1-800-680-9206</p> <p>For incidents involving ANIMALS, call 1-800-548-2423</p> <p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment.</p>	

Deltamethrin 4% Collar
EPA Reg. No: 68451-1

page: 3 of 4
revision date: 02-23-10

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

Deltamethrin 4% Collar, containing deltamethrin insecticide, has been specially formulated using patented insecticide-release technology. Maximum effectiveness may not occur for 2-3 weeks after collar placement. Fleas (*Ctenocephalides sp.*) on the dog will be killed and ones which are present in the dog's environment that may appear on your pet will be killed. Collar will also kill ticks for up to 6 months. Collar will kill ticks including Brown dog tick (*Rhipicephalus sanguineus*), American dog tick (*Dermacentor variabilis*), and deer ticks (*Ixodes scapularis* and *Ixodes pacificus*) which may carry the Lyme disease. This collar should be worn continuously. Reapply a new collar every 6 months.

Place the collar around dog's neck, buckle and adjust for proper fit. Cut off approximately 2 inches from the buckle and dispose of excess length by wrapping in newspaper and placing in trash. The collar must be worn loosely so that two fingers may be placed between collar and dog's neck. Living and rest areas of pet must also be treated with appropriate pest control measures to ensure control of pests. Wetting will not impair the collar's effectiveness or the pet's protection. If the dog goes swimming or is out in the rain, it is not necessary to remove the collar.

Deltamethrin 4% Collar may be used in addition to a lead or constraint collar. Use only one Deltamethrin 4% Collar at a time.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store this product in a cool, dry place away from children and pets.

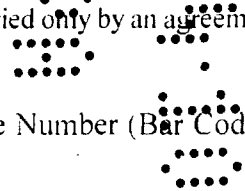
Pesticide and Container Disposal: Do not reuse container or used collar. Dispose of in trash.

IMPORTANT NOTICE: DISCLAIMER

Read "IMPORTANT NOTICE: DISCLAIMER" before buying or using. If terms are not acceptable, return at once unopened. To the extent consistent with applicable law, INTERVET INC. warrants only that the product conforms to the chemical description on the label and is reasonably fit for the purpose stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions or under abnormal conditions, or under conditions not reasonably foreseeable to INTERVET INC., and user assumes the risk of any such use. To the extent consistent with applicable law, INTERVET INC. MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OR FITNESS FOR A PARTICULAR PURPOSE OR OF MERCHANTABILITY. In no case shall INTERVET INC. be liable for consequential, special, indirect or incidental damages resulting from the use or handling of this product. The foregoing conditions of sale and warranty can be varied only by an agreement in writing signed by a duly authorized representative of INTERVET INC.

Part No. xxxxx
Product of France

Universal Product Code Number (Bar Code)



Deltamethrin 4% Collar
EPA Reg. No: 68451-1

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OPTIONAL/ALTERNATE LABEL TEXT

Kills Fleas and Ticks for up to 6 Months

Long lasting protection for up to 6 months

Continuous protection

Kills Ticks (*including deer ticks which may carry Lyme disease*)

Kills Ticks (which may carry Rocky Mountain Spotted Fever)

Also kills fleas

Kills fleas

(Deltamethrin 4% Collar) (alternate brand name) may be useful for dogs susceptible to Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause Flea Allergy Dermatitis (FAD)

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anemia.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause bartonellosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may transmit tapeworms.

The successive feeding activity of fleas on dogs may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). (Deltamethrin 4% Collar) (alternate brand name kills fleas and may reduce the incidence of FAD

Kills ticks

(Deltamethrin 4% Collar) (alternate brand name) kills ticks that may cause babesiosis.

(Deltamethrin 4% Collar) (alternate brand name) kills fleas that may cause anaplasmosis.

Patented insecticide-release technology

Wetting will not impair the collar's effectiveness or the pet's protection

Not affected by water

Water resistant

