

68451-1

7/17/2009

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JUL 17 2009

Ms Heather R. Bjornson
Intervet Inc.
29160 Intervet Lane
Millsboro, DE 19966

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

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 June 9, 2009 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
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
 Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

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# 13	
5. Name and Address of Applicant (Include ZIP Code) Intervet Inc. 29160 Intervet Lane Millsboro, DE 19966 <input 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. <u>NOTIFICATION</u> Product Name <u>JUL 17 2009</u>	

Section - II

Amendment - Explain below. Final printed labels in response to Agency letter dated _____
 Resubmission in response to Agency letter dated _____ "Me Too" Application.
 Notification - Explain below. Other - Explain below.

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

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 type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input 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
 Label Container

4. Size(s) Retail Container

5. Location of Label Directions

6. Manner in Which Label is Affixed to Product
 Lithograph Paper glued Stenciled Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Heather R. Bjornson, hbjornson@tsgusa.com	Title Regulatory Assistant	Telephone No. (Include Area Code) (202) 828-8945
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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.

2. Signature
Heather R. Bjornson

3. Title
Regulatory Assistant to Intervet Inc.

4. Typed Name
Heather R. Bjornson

5. Date
June 9, 2009

6. Date Application Received (Stamped)



United States
Environmental Protection Agency
 Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

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# 13	
5. Name and Address of Applicant (Include ZIP Code) Intervet Inc. 29160 Intervet Lane Millsboro, DE 19966 <input 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"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

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

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 PR Notice 98-10 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:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
				<input checked="" type="checkbox"/> Glass	<input type="checkbox"/> Paper
				Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 collar, 0.9 oz.		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph Paper glued Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Heather R. Bjornson, hbjornson@tsgusa.com	Title Regulatory Assistant	Telephone No. (Include Area Code) (202) 828-8945
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 	3. Title Regulatory Assistant to Intervet Inc.	
4. Typed Name Heather R. Bjornson	5. Date July 7, 2009	

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WASHINGTON

1150 18th Street, N.W.
Suite 1000
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

June 9, 2009

Kimberly Nesci
Registration Division (7504P)
Office of Pesticide Products
U.S. 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 Notice 2007-4

SACRAMENTO

712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

Dear Ms. Nesci:

Technology Sciences Group, Inc., on behalf of Intervet Inc., submits the enclosed notification to update the label per PR Notice 2007-4 and to make additional minor text revisions. You will find the following in support of this notification:

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

Please do not hesitate to contact me with any questions and/or concerns.

CANADA

275 Slater Street
Suite 900
Ottawa, Ontario
K1P 5H9
Telephone 613 247-6285
Fax 613 236-3754

Sincerely,

Heather R. Bjornson
Regulatory Assistant to Intervet Inc.
Direct dial: (202) 828-8945
e-mail: hbjornson@tsgusa.com

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 of 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.

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NOTIFICATION

JUL 17 2009

DELTAMETHRIN 4% COLLAR

FLEA & TICK COLLAR FOR DOGS

Kills Fleas and Ticks for up to 6 Months
LONG LASTING PROTECTION FOR UP TO 6 MONTHS
Kills Ticks (*including deer ticks which may carry Lyme disease*)
ALSO KILLS FLEAS

ACTIVE INGREDIENT:	Percentage by Weight
Deltamethrin	4.0%
INERT INGREDIENTS	<u>96.0%</u>
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

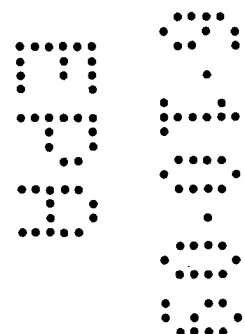
EPA Reg No. 68451-1

EPA Est. No. 68451-FRA-1

NET CONTENTS: 1 Collar
NET WT. 0.9 oz

Distributed by:
Intervet Inc.
405 State Street
Millsboro, DE 19966

Product of France



Deltamethrin 4% Collar (EPA Reg. No. 68451-1)
June 4, 2009

7/8

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.

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 For incidents involving ANIMALS, call 1-800-548-2423 Have the product container of label with you when calling a poison control center or doctor, or going for treatment.</p>	

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.

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

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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: Store in original, unopened container, away from children. 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

Universal Product Code Number (Bar Code)

Product if France

