

2596-62

07/07/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460-0001

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

July 7, 2009

Ms. Heather Masch,  
Regulatory Affairs Associate  
The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, NJ 07094-3688

**Subject: Amended Labeling, Response to PR Notices 2001-1 & 2007-4  
Hartz® 2 in 1® Plus Long Lasting Collar for Dogs, EPA Reg. No. 2596-62  
Your Submission Dated April 22, 2009**

Dear Ms. Masch:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with the following label revision provision(s):

General Statements:

1. Delete all text throughout the label marked with "strikethrough."
2. Delete all repellency claims throughout this label, since tetrachlorvinphos is not a repellent.

Alternate Brand Name (ABN) section comment(s):

3. To facilitate inclusion of language from the tetrachlorvinphos RED, revise all instances of the word "Puppies" in the listed ABNs with "Puppies (Over 12 Weeks of Age)"
4. Delete the newly added ABNs. Control claims are prohibited without supporting efficacy (product performance) data.

Ingredient Statement comment(s):

5. As per Chapter VII, Section 4.6 of the Agency's LRM, within the text immediately following the Ingredient Statement, revise the shaded language to read: "See back panel for additional precautionary statements." since this statement should only appear on the back panel of this label.

Precautionary Statements section, Hazards to Humans and Domestic Animals subsection comment(s):

6. To facilitate inclusion of language from the tetrachlorvinphos RED, replace the 4<sup>th</sup> sentence with: "This product may cause skin sensitization reactions in certain individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Do not treat (use on) animals less than twelve (12) weeks of age."

First Aid Statement section, Hotline Number subsection comment(s):

7. Replace 2<sup>nd</sup> sentence in this section with: "For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414." It is important to note that the "1-800-275-1414" number listed must be available twenty-four (24) hours per day, seven (7) days per week for answering and responding to any medical emergencies or health concerns.

Directions for Use section comment(s):

- 8. Revise the 1<sup>st</sup> sentence of the 2<sup>nd</sup> paragraph to read: "Do not use on puppies less than 12 weeks of age."
- 9. In the 2<sup>nd</sup> sentence of the 3<sup>rd</sup> paragraph, replace the words "... puppies at least 6 weeks old" with "... puppies over 12 weeks of age."

Optional/Alternate Label Text section comment(s):

- 10. Delete all repellency claims throughout this section of the label, since tetrachlorvinphos is not a repellent.

Storage and Disposal section comment(s):

- 11. Revise the subsection header "**Pesticide Disposal:**" to read "**Container Disposal:**"

Non-Pesticide Related Claims and Other Optional Text section comment(s):

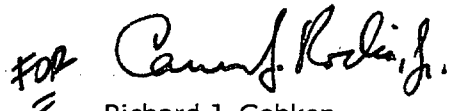
- 12. Revise all instances of the word "Puppies" or "(puppies)" to read "Puppies (Over 12 Weeks of Age)" or "(puppies over 12 weeks of age)"
- 13. Delete the 6<sup>th</sup> non-pesticide related claim, since it is an implied safety claim.

Should you wish to add/retain a reference to the company's website on your label, please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not be substantially differ from those claims approved through the registration process. Therefore, should the Agency find, or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

If you have any questions about this label review, please contact Mr. Carmen J. Rodia, Jr. at (703) 306-0327 or via e-mail at [Rodia.Carmen@epa.gov](mailto:Rodia.Carmen@epa.gov).

Sincerely Yours,



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

Enclosure: Label stamped "Accepted with Comments"

Front Panel

**Hartz® 2 in 1® Plus Long Lasting Collar For Dogs**

Alternate Brand Names

- Hartz® 2 in 1® Flea & Tick Collar For Dogs
- Hartz® 2 in 1® Flea & Tick Collar For Large Dogs
- Hartz® 2 in 1® Flea & Tick Collar For Puppies

- ~~Hartz® In Control™ 5 Month Flea & Tick Collar for Dogs~~
- ~~Hartz® In Control™ 5 Month Flea & Tick Collar for Puppies~~
- ~~Hartz® In Control™ 5 Month Flea & Tick Collar for Dogs & Puppies~~
- ~~Hartz® In Control™ 5 Month Flea & Tick Collar for Large Dogs~~

ACCEPTED  
With COMMENTS  
In EPA Letter Dated:  
July 7, 2009  
Under the Federal Insecticide, Fungicide  
and Rodenticide Act, As amended, for the  
pesticide Registered under EPA Reg. No:  
**2596-62**

**ACTIVE INGREDIENT:**

Tetrachlorvinphos (CAS # 22248-79-9) ..... 14.55%

**OTHER INGREDIENTS:** ..... 85.45%

**TOTAL** ..... 100.00%

**CAUTION:** Do not let children play with this collar. See back panel for ingredient statement, precautionary statement, and directions for use. See (side) (and) (back) panel(s) for additional precautionary statements.

**NET CONTENTS:** 1 (color designation) collar, NET WT. (range from 19g (0.68 oz.) to 32g (1.15 oz.) depending on size of animal)

EPA Reg. No. 2596-62

EPA Est. 2596-NJ-1

Made [in (the) U.S.A.] by  
The Hartz Mountain Corporation  
400 Plaza Drive  
Secaucus, NJ 07094 (U.S.A.)

SIDE, TOP, or BOTTOM PANELS

Hartz 2 in 1 Flea & Tick Collar [for (large) dogs (puppies) with necks to (15") 26" (23") (26")]

Unconditional money back guarantee by Hartz

To activate collar, hold at each end...STRETCH...it's ready to work

Powder Action

(purple)(red)(blue) white collar

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BACK PANEL

Kills fleas and ticks common to dogs, including Rocky Mountain Wood Tick, carrier of Rocky Mountain Spotted Fever and the Deer Tick, which may carry Lyme Disease

**ACTIVE INGREDIENT:** \_\_\_\_\_

Tetrachlorvinphos (CAS # 22248-79-9) ..... 14.55%

**OTHER INGREDIENTS:** ..... 85.45%

**TOTAL** ..... 100.00%

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

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION:** Harmful if swallowed or absorbed through skin. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

**FIRST AID** — Contains an organophosphate that inhibits cholinesterase.

**If Swallowed:** 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 doctor. Do not give anything by mouth to an unconscious person.

**If On Skin Or Clothing:** 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:** 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.

Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment. You may also contact 1-800-275-1414 for emergency medical treatment information.

**Note to Physicians and Veterinarians:** This product contains an organophosphate and may cause cholinesterase inhibition. This product contains tetrachlorvinphos (an organophosphate), which is a cholinesterase inhibitor. Cholinergic symptoms may include salivation, miosis, incoordination, muscle fasciculation and/or weakness, vomiting and diarrhea. Atropine is antidotal. 2-PAM may be effective as an adjunct to atropine. Call 1-800-275-1414 or your local Poison Control Center for further information.

**DIRECTIONS FOR USE**

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

**REMOVE COLLAR FROM PACKAGE, UNROLL, AND STRETCH TO ACTIVATE INSECTICIDE GENERATOR.** As the collar begins to work, a fine white powder will appear on the surface.

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Do not use on puppies under 6 weeks of age. Do not unroll collar until ready to use. Place the (brand name) (collar) around the dog's neck, adjust to proper fit, and buckle in place. The collar must be worn loosely to allow for growth of the dog and to permit the collar to move about the neck. Generally, a properly fitted collar is one that, when fastened, will snugly slide over the dog's head. Leave 2 or 3 inches on the collar for extra adjustment and cut off and dispose of extra length.

Consult a veterinarian before using this product on debilitated, aged, or medicated animals. If used on pregnant or nursing dogs, do not replace collar until the puppies are at least 6 weeks old. Sensitivities may occur after using ANY pesticide product for pets. Some animals may become irritated by any collar if it is applied too tightly. If this occurs, loosen the collar. If irritation continues, remove the collar from the dog. If signs of sensitivity occur, remove the collar and bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Do not use this product on dogs simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. However, flea & tick collars may be immediately replaced (with new collars).

This collar is intended for use only as an insecticide generator. The collar will begin to kill fleas and ticks immediately. Its full protection against harder to kill ticks will be built up within a few days after being placed on the pet. For continuous flea and tick protection under normal conditions replace the collar every 5 months. Under conditions where dogs are exposed to severe flea or tick infestations it may be necessary to replace more frequently, however, do not replace the collar more frequently than every 4 months. 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. The (brand name) (collar) may be worn with a regular collar.

**STORAGE AND DISPOSAL**

~~Storage: Store at room temperature.~~

~~Disposal: Do not use empty pouch. Place in trash or offer for recycling if available.~~

**STORAGE AND DISPOSAL**

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

~~**Pesticide Storage:** Store this product in a cool, dry place that is inaccessible to children.~~

~~**Pesticide Disposal:** If empty: Nonrefillable container. Do not reuse or refill this container.~~

~~Offer for recycling if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.~~

~~For more information (or in case of emergency) call (our) (flea and tick) (experts) (at) 1-800-275-1414 (weekdays, 9am-5pm E.S.T.)~~

OPTIONAL/ALTERNATE LABEL TEXT

(with Rabon)  
(Long term protection)  
(Kills for 5 months)  
Kills fleas and ticks common to dogs, including Rocky Mountain Wood Tick, carrier of Rocky Mountain Spotted Fever and the Deer Tick, which may carry Lyme Disease  
Starts Killing (Fleas) (&) (and) (Ticks) (through contact) for (up to) (5) (Five) Months  
Starts Killing and (&) Repelling (Fleas) (&) (Ticks) (through contact) for (up to) (5) (Five) Months  
Starts to Kill (Fleas) (&) (and) (Ticks) (through contact) for (up to) (5) (Five) Months  
Starts to Kill and (&) Repel (Fleas) (&) (and) (Ticks) (through contact) for (up to) (5) (Five) Months  
Kills (Fleas) (&) (and) (Ticks) (through contact) for (up to) (5) (Five) Months  
Kills and (&) Repels (Fleas) (&) (and) (Ticks) through contact for (up to) (5) (Five) Months  
Starts Killing (Fleas) (&) (and) (Ticks) on contact for (up to) (5) (five) months  
Starts Killing and (&) Repelling (Fleas) (&) (and) (Ticks) on contact for (up to) (5) (five) months  
Starts to Kill (Fleas) (&) (and) (Ticks) on contact for (up to) (5) (five) months  
Starts to Kill and (&) Repel (Fleas) (&) (and) (Ticks) on contact for (up to) (5) (five) months  
(Five) (5) Month(s) Protection  
Starts Working (on)(with) Contact  
Kills (&) (and) (Repels) Up to (5) Months  
Kills (&) (and) (Repels) Ticks  
Kills (&) (and) (Repels) Fleas  
Kills (&) (and) (Repels) fleas and ticks  
Kills (&) (and) (Repels) fleas and ticks (for) up to (5) (five) months  
(Long Term) (5-Month) (Continuous) Protection (against fleas and ticks)  
(Controls)(Kills)(fleas)(and)(&)(ticks) round-the-clock for (up to)(5)(five) months

**NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT**

(with Deodorant)

[Bright (Purple) (Red) (Blue) (White)]

(purple)(red)(blue) white collar

Unconditional money back guarantee by Hartz

To activate collar, hold at each end...STRETCH...it's ready to work

Powder Action

Hartz Every Pet's Best Friend

Visit our website [www.hartz.com](http://www.hartz.com)

(Important: Consumer information and pet I.D. tag offer printed on inside of package.)

Made in the U.S.A. by

©The Hartz Mountain Corporation, Secaucus, NJ 07094

For Dogs

For Puppies

For Dogs (&) (and) Puppies

With deodorant

(Clean) (Fresh) (Deodorant) scent

~~Powerful Results When You Need (it)(them)~~

EASY ACTIVATION - To activate collar, hold at each end... STRETCH... and it's ready (to work) (to kill fleas & ticks) (for your dog to wear)

Water resistant

Fits up to (range from 15" to 26") necks

For (dogs) (and) (&) (puppies) with necks up to (range from 15" to 26")

Hartz® (brand name) products are designed to complement each other in an integrated program for flea (and)(&) tick management. To assure proper treatment, we recommend use of only Hartz® (brand name) products.

To learn more about treating current infestations and preventing future outbreaks please visit our website ([www.hartz.com](http://www.hartz.com))([www.hartzultraguard.com](http://www.hartzultraguard.com))

To learn more visit (our website) (at) ([www.hartz.com](http://www.hartz.com))([www.hartzultraguard.com](http://www.hartzultraguard.com))

(PLEASE) VISIT OUR WEBSITE (AT) ([www.hartz.com](http://www.hartz.com))([www.hartzultraguard.com](http://www.hartzultraguard.com))

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