

# 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<sup>®</sup> 2 in 1<sup>®</sup> Plus Long Lasting Collar for Cats, EPA Reg. No. 2596-63

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:

- 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 "Kittens" in the listed ABNs with "Kittens (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.

# Storage and Disposal section comment(s):

8. Revise the subsection header "Pesticide Disposal:" to read "Container Disposal:"

# Optional/Alternate Label Text section comment(s):

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

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

- 10. Revise all instances of the word "Kittens" or "(kittens)" to read "Kittens (Over 12 Weeks of Age)" or "(kittens over 12 weeks of age)"
- 11. Delete the 10<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*.

Sincerely Yours,

Richard J. Gebken

Product Manager (10)

Insecticide Branch

Registration Division (7505P)

Enclosure: Label stamped "Accepted with Comments"

EPA Reg. No.: 2596-63 MASTER LABEL

## Front Panel

# Hartz<sup>®</sup> 2 in 1<sup>®</sup> Plus Long Lasting Collar For Cats

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Alternate Brand Names
                                                                                             ACCEPTED
Hartz<sup>®</sup> 2 in 1<sup>®</sup> Flea & Tick Collar For Cats
                                                                                         In EPA Letter Dated:
(Hartz® 2 in 1® Collar with Rabon® Bright Pink for Cats)
                                                                             July 7, 2009
Under the Federal Insecticide, Fungicide
(Hartz<sup>®</sup> 2 in 1<sup>®</sup> Collar with Rabon<sup>®</sup> Bright Purple for Cats)
(Hartz® 2 in 1® Collar with Rabon® Bright Blue for Cats)
                                                                             and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:
(Hartz® 2 in 1® Collar with Rabon® Bright White for Cats)
(Hartz<sup>®</sup> 2 in 1<sup>®</sup> Collar with Rabon<sup>®</sup> Bright White for Kittens)
                                                                                         2596-63
(Hartz® 2 in 1® Collar with Rabon® Safety Snap for Cats)
(Hartz<sup>®</sup> 2 in 1<sup>®</sup> Collar Flea & Tick Collar with Rabon<sup>®</sup> Bright White for Cats)
(Hartz<sup>®</sup> 2 in 1<sup>®</sup> Collar Bright Pink for Cats)
(Hartz<sup>®</sup> 2 in 1<sup>®</sup> Collar Bright Purple for Cats)
(Hartz<sup>®</sup> 2 in 1<sup>®</sup> Collar Bright Yellow for Cats)
(Hartz® 2 in 1® Collar Bright Orange for Cats)
(Hartz<sup>®</sup> 2 in 1<sup>®</sup> Collar Bright Blue for Cats)
(Hartz<sup>®</sup> 2 in 1<sup>®</sup> Collar Bright Red for Cats)
(Hartz<sup>®</sup> 2 in 1<sup>®</sup> Collar Bright Silver for Cats)
(Hartz<sup>®</sup> 2 in 1<sup>®</sup> Collar Bright Gold for Cats)
(Hartz<sup>®</sup> Advanced Care<sup>®</sup> 2 in 1<sup>®</sup> Flea & Tick Collar for Cats)
(Hartz<sup>®</sup> Advanced Care<sup>®</sup> 2 in 1<sup>®</sup> Flea & Tick Collar for Kittens)
(Hartz®-Advanced Care® 2 in 1® Reflecting Flea & Tick Collar for Cats)
(Hartz®-Advanced Care® 2 in 1® Reflective Flea & Tick Collar for Cats)
(Hartz® Advanced Care® 2 in 1® Reflecting Flea & Tick Collar for Kittens)
(Hartz® Advanced Care® 2 in 1® Reflective Flea & Tick Collar for Kittens)
Hartz® In Control™ 5 Month Flea & Tick Collar for Cats
Hartz<sup>®</sup> In Control<sup>™</sup> 5 Month Flee & Tick Collar for Kittens
Hartz® In Control™ 5 Month Flea & Tick Collar for Cats & Kitten
ACTIVE INGREDIENT:
OTHER INGREDIENTS: 85.45%
CAUTION: Do not let children play with this collar. See (side) (and) (back) panel(s) for
additional precautionary statements.
NET CONTENTS: 1 (color designation) collar, NET WT. (range from 15g (0.53 oz.) to 17g
 (0.60 oz) depending on size of animal)
EPA Reg. No. 2596-63
 EPA Est. 2596-NJ-1
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EPA Reg. No.: 2596-63 MASTER LABEL

[Made in (the) U.S.A (by)]
©The Hartz Mountain Corporation
Secaucus, NJ 07094 (U.S.A)
(and St. Thomas, Ontario N5P-3W7 Canada)

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

### **Back Panel**

The (Hartz<sup>®</sup> 2 in 1<sup>®</sup> Flea & Tick Collar For Cats) (alternate brand name) (or) (this product) will kill ticks, including the Deer Tick, which may carry Lyme Disease, for five months under normal conditions.

# READ ENTIRE LABEL BEFORE EACH USE: USE ONLY ON CATS:

### 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

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 and organophosphate and may cause cholinesterase inhibition. This product contains tetrachlorvinghos (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.

4/17/2009

MASTER LABEL

### **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.

Do not use on kittens under 12 weeks of age. Do not unroll collar until ready to use. Place the (Hartz® 2 in 1® Flea & Tick Collar For Cats) (alternate brand name) (or) (this product) (brand name) (collar) around the cat's neck, adjust to proper fit, and buckle in place. The collar must be worn loosely to allow for growth of the cat 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 cat'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, medicated, pregnant or nursing animals. 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 cat. 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 cats 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 cats 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 cat is out in the rain it is not necessary to remove the collar. The (Hartz® 2 in 1® Flea & Tick Collar For Cats) (alternate brand name) (or) (this product) (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.

For more information, call our flea and tick experts at 1 800 275 1414 weekdays, 9am 5pm E.S.T.

## 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 Hartz® 2 in 1® Plus Long Lasting Collar For Cats

EPA Reg. No.: 2596-63 MASTER LABEL

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

Long Term Protection

Continuous Protection against Fleas & Ticks

The active ingredient will work its way from the surface of the collar onto your pet's coat providing continuous protection against fleas and ticks

Kills for 5 months

Starts Killing (Fleas) (&) (and) (Ticks) (through contact) for (up to) (5) (Five) Months Starts Killing and (&) Repelling (Fleas) (&) (and) (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 (&) Repol (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 (5) (Five) Month(s) Protection

Starts Working (on)(through) Contact

Kills (&) (and) (Repels) Up to (5) (Five) Months

Kills (&) (and) (Repels) Ticks

Kills (&) (and) (Repels) Fleas

Kills (&) (and) (Repole) 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

# 4/17/2009

# NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

Bright (white) (pink) (purple) (blue) (yellow) (orange) (red) (silver) (gold)

Rabon<sup>®</sup> is the Hartz<sup>®</sup> trademark for tetrachlorvinphos

For Cats

For Kittens

Safety Snap

With Safety Snap

Fits necks to (8") (11")

Waterproof

Reflects Direct Light up to (200 ft.) (250 ft.) (300 ft.) (400 ft.) (500 ft.) (550 ft.) (600 ft.)

White Collar with Reflecting Technology

White Collar with Reflective Technology

Visible (in) (to) headlights

Important: Consumer-information and pet I.D. tag offer printed inside of package

Hartz®-Every Pet's Best Friend™

VISIT OUR WEBSITE www.hartz.com

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

Powder Action

Money back guarantee by Hartz

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation

[The (Hartz<sup>®</sup> 2 in 1<sup>®</sup> Reflecting Flea & Tick Collar for Cats (Kittens)] [Hartz<sup>®</sup> 2 in 1<sup>®</sup> Reflective Flea & Tick Collar for Cats (Kittens)] provides an added dimension of nighttime safety for you and your pet. The collar will reflect when light shines directly on the reflective strip.

For Cats (&) (and) Kittens

With deodorant

(Clean) (Fresh) (deodorant) scent

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

Safety (release) snap (buckle) (release) reduces risk of neck injury to your cat

EASY ACTIVATION - To activate collar, hold at each end ... STRETCH ... and it's ready (to

work) (to kill fleas & ticks) (for your cat to wear).

Water Resistant

(With) Safety (release) snap (buckle) (release)

Fits up to (range from 8" to 15") necks

For (cats) (and) (kittens) with necks up to (range from 8" to 15")

Hartz<sup>®</sup> (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<sup>®</sup> (brand name) products.

To learn more about treating current infestations and preventing future outbreaks please visit (our website) (at) (www.hartz.com)(www.hartzultraguard.com)

To learn more, visit (our website) (at) (www.hartz.com)(www.hartzultraguard.com)

(PLEASE)VISIT OUR WEBSITE (AT) (www.hartz.com) (www.hartzultraguard.com)

Hartz® (and other trademarks are trademarks) (is a trademark) of The Hartz Mountain Corporation