



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

August 11, 2009

Mr. Robert Rosenwasser, Director, Regulatory Affairs The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688

Subject:

Amended Labeling, Response to EPA Letter Dated July 7, 2009

Hartz[®] 2 in 1[®] Plus Long Lasting Collar for Cats, EPA Reg. No. 2596-63

Your E-Mail Submission Dated August 4, 2009

Dear Mr. Rosenwasser:

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):

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

1. To facilitate inclusion of language from the tetrachlorvinphos RED, insert the following sentence immediately preceding the existing 4th sentence: "This product may cause skin sensitization reactions in certain individuals."

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 <u>Rodia.Carmen@epa.gov</u>.

Sincerely Yours,

Product Manager (10)

Insecticide Branch

Registration Division (7505P)

Enclosure: Label stamped "Accepted with Comments" 002596-00063 p418329

Hartz[®] 2 in 1[®] Plus Long Lasting Collar For Cats

Alternate Brand Names Hartz[®] 2 in 1[®] Flea & Tick Collar For Cats (Hartz[®] 2 in 1[®] Collar with Rabon[®] Bright Pink for Cats) (Hartz[®] 2 in 1[®] Collar with Rabon[®] Bright Purple for Cats) (Hartz[®] 2 in 1[®] Collar with Rabon[®] Bright Blue for Cats) (Hartz[®] 2 in 1[®] Collar with Rabon[®] Bright White for Cats) (Hartz[®] 2 in 1[®] Collar with Rabon[®] Bright White for Kittens [over 12 weeks of age]) (Hartz[®] 2 in 1[®] Collar with Rabon[®] Safety Snap for Cats) (Hartz[®] 2 in 1[®] Collar Flea & Tick Collar with Rabon[®] Bright White for Cats) (Hartz[®] 2 in 1[®] Collar Bright Pink for Cats) (Hartz[®] 2 in 1[®] Collar Bright Purple for Cats) (Hartz[®] 2 in 1[®] Collar Bright Yellow for Cats) (Hartz[®] 2 in 1[®] Collar Bright Orange for Cats) (Hartz[®] 2 in 1[®] Collar Bright Blue for Cats) (Hartz[®] 2 in 1[®] Collar Bright Red for Cats) (Hartz[®] 2 in 1[®] Collar Bright Silver for Cats) (Hartz[®] 2 in 1[®] Collar Bright Gold for Cats) Hartz[®] In Control[™] 5 Month Flea & Tick Collar for Cats
Hartz[®] In Control[™] 5 Month Flea & Tick Collar for Kittens (over 12 weeks of age) Hartz[®] In Control[™] 5 Month Flea & Tick Collar for Cats & Kittens (over 12 weeks of age) ACTIVE INGREDIENT: OTHER INGREDIENTS: 85.45%

CAUTION: Do not let children play with this collar. See (back) panel 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

Made [in (the) U.S.A.] by The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094 (U.S.A.) With COMMENTS
In EPA Letter Dated:
August 11, 20

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

2596-63

EPA Reg. No.: 2596-63 **MASTER LABEL**

7/24/2009

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 Do not treat (use on) animals less than twelve (12) weeks of age.

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. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414.

Note to Physicians and Veterinarians: 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.

Do not use on kittens under 12 weeks of age. Do not unroll collar until ready to use. Place the (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

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EPA Reg. No.: 2596-63 MASTER LABEL

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 (brand name) (collar) may be worn with a regular collar.

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.

Container 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

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 to Kill (Fleas) (&) (and) (Ticks) (through contact) for (up to) (5) (Five) Months

Kills (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 to Kill (Fleas) (&) (and) (Ticks) on contact for (up to) (5) (five) months

(5) (Five) Month(s) Protection

Starts Working (on)(through) Contact

Kills Up to (5) (Five) Months

Kills Ticks

Kills Fleas

Kills fleas and ticks

Kills 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

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Hartz[®] 2 in 1[®] Plus Long Lasting Collar For Cats

EPA Reg. No.: 2596-63 MASTER LABEL

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

For Cats

For Kittens (Over 12 weeks of age)

Safety Snap

With Safety Snap

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

[The (Hartz[®] 2 in 1[®] Reflecting Flea & Tick Collar for Cats (Kittens)] [Hartz[®] 2 in 1[®] 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 (Over 12 weeks of age)

With deodorant

(Clean) (Fresh) (deodorant) scent

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 over 12 weeks of age) with necks up to (range from 8" to 15")

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) (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