



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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

February 9, 2011

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

Subject:

Amended Labeling; Response to SAL Dated September 1, 2010, Addition of Aloe-Related Marketing Claims, and Addition of New EPA Establishment Number Hartz® Rabon® Spray with Methoprene Pump Formulation, EPA Reg. No. 2596-140 Your Submissions Dated September 9, 2010 & November 8, 2010

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):

Directions for Use section comment(s), page 3 of 6:

1. Revise the 8th enumerated claim to read "Be sure to treat the animal's bedding and surroundings (other areas) with a product registered for these uses, such as Hartz (brand name) line (products)."

Optional/Alternate Label Text section comment(s), bottom of page 5 of 6:

- Within the paragraph found the end of this section, make the following changes:
 - On the 4th line of this paragraph, replace the word "flea" with the word "fleas."
 - On the 5th line of this paragraph, replace the word "products" with the word "produce," and replace the word "flea" with the word "fleas."
 - On the 6th line of this paragraph, replace the words "pre adult" with the word "pre-adults."
 - Revise the last sentence to read "(this product) (alternative brand name) is designed to kill adult fleas, flea eggs and flea larvae; therefore, breaking the flea life cycle]"

Non-Pesticide Related Claims and Other Optional Text section comment(s), page 6 of 6:

3. Revise the 17th claim to read "For (dogs) (cats) (pupples over 12 weeks of age) (kittens over 12 weeks of age)"

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

Richard J. Ğebken

Product Manager (10)

Insecticide Branch

Registration Division (7504P)

Enclosure: Label stamped "Accepted with Comments"
002596-00140 D440420 & D440144

EPA Reg. No.: 2596-140

MASTER LABEL BASED ON 9/1/10 EPA STAMPED APPROVED LABEL

Hartz® Rabon® Spray with Methoprene Pump Formulation

Alternate Brand Names
Hartz® UltraGuard PlusTM Flea & Tick Spray for Dogs
Hartz® UltraGuard PlusTM Flea & Tick Spray for Cats
Hartz® Advanced CareTM 3 in 1 Dog Spray
Hartz® Advanced CareTM 3 in 1 Cat Spray
Hartz® 3 in 1 Dog Spray
Hartz® 3 in 1 Cat Spray
Hartz® InControl Flea & Tick Dog Spray
Hartz® InControl Flea & Tick Cat Spray

With COMMENTS
In EPA Letter Dated:
February 9, 2011
Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:

2596-140

Hartz® Rabon® Spray with Methoprene Pump Formulation

Tetrachlorvinphos	1.08%
[S]-Methoprene	
OTHER INGREDIENTS	<u>98.85%</u>
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See (back) (side) panel(s) for (ingredient) (and) additional precautionary statements. [Ingredient statement on the back of 8 fl oz bottle only]

NET CONTENT: ____fl. oz. (___ml)

EPA Reg. No. 2596-140

EPA Est. No.

Made (in the USA) by The Hartz Mountain Corporation, 400 Plaza Drive, Sccaucus, NJ 07094

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MASTER LABEL BASED ON 9/1/10 EPA STAMPED APPROVED LABEL

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 hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Do not use on (puppies) (kittens) (puppies or kittens) less than twelve (12) weeks old. Do not spray in eyes. To prevent harm to you or your pet, read entire label before use. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or medicated animals. Sensitivity may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

ENVIRONMENTAL HAZARDS: This product is toxic to aquatic invertebrates. Using it in a manner other than that described by this label could result in harm to aquatic invertebrates.

FIRST AID

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.

If swallowed •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.

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 pesticide product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-275-1414 twenty-four (24) hours per day, seven (7) days per week.

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) a Poison Control Center for further information.

(Remember to always read each product label and follow directions carefully.)

EPA Reg. No.: 2596-140

MASTER LABEL BASED ON 9/1/10 EPA STAMPED APPROVED LABEL

DIRECTIONS FOR USE

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

READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON (DOGS) (CATS) (DOGS OR CATS)

SHAKE WELL BEFORE USE:

- 1. Hold bottle upright about 6 inches from pet.
- 2. Spray lightly until the tips of the pet's hair are moist. Keep spray out of pet's eyes.
- 3. Rub spray into animal's coat. For longhaired (dogs) (cats), ruffle fur to allow the spray to reach skin.
- 4. After 10 minutes, dry (dog) (cat) with towel.
- 5. Comb and brush coat.
- 6. Repeat once a week.
- 7. If you see a tick, spray it directly.
- 8. Use on bedding and other areas as needed.

STORAGE AND DISPOSAL

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

Pesticide Storage: Do not store near heat or open flame. Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

Container Handling: 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.

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EPA Reg. No.: 2596-140

MASTER LABEL BASED ON 9/1/10 EPA STAMPED APPROVED LABEL

OPTIONAL/ALTERNATE LABEL TEXT

Flea and tick (spray) (killer)

Kills (adult) fleas and ticks for [(7) (seven) days] [(1) (one) week]

Kills (fleas) (+) (and) (•) (ticks) for [(7) (seven) days] [(1) (one) week]

Kills fleas, ticks, and lice

Prevents reinfestation and flea build-up for 1 (one) month

Kills insects, which reduces the incidence of itching and scratching

Contains an insect growth regulator

Prevents (flea) eggs (ova) (ovum) from hatching for [(1) (one) month] (28 days) (4 weeks)

Kills flea eggs (and larvae) for (1) (one) month (28 days) (4 weeks)

Kill (flea eggs) (+) (and) (•) (flea larvae) for (1) (one) month (28 days) (4 weeks)

Kills hatching eggs (ova) (ovum)

Repellent

Repels fleas and ticks

Kills and repels (adult) fleas and ticks

Fast-acting

Kills fleas in 10 minutes

Actually prevents fleas and ticks from living on your pet

Breaks the flea and tick life cycle

Kills all stages of the flea (life cycle)

Kills (Fleas) (&) (and) (Ticks) (through contact)

Kills (Fleas) (&) (and) (Ticks)

(Immediately) starts to kill (Fleas) (&) (and) (Ticks) (through contact)

Kills fleas which may cause (flea bite anemia)(flea allergy dermatitis)

Kills fleas that may transmit (tapeworm)

(Plus) kills (keeps killing) pre-adult flea stages (too)

Breaks the flea life cycle

(Plus) Kills (fleas) (and) (ticks) and pre-adult fleas (before they grow into biting adults)

(Plus) Kills fleas and ticks and (continues to protect against) (prevents) pre-adult fleas from

(changing) (growing) (developing) into biting adults

(Plus) Prevents infestation by halting the flea reproductive cycle.

(Plus) halts the flea life cycle by killing flea eggs (and flea larvae)

One step to treat and prevent

One step to treat existing problem and prevent future infestations

(Plus) Provides protection against future infestations

Treats & (and) Prevents in one step

(Plus) Prevents Fleas Eggs (and flea larvae) from hatching for (1 month) (28 days) (4 weeks)

(Plus) Kills flea eggs (and flea larvae) helping to prevent re-infestations

(Plus) Kills (flea eggs) (and flea larvae) before they hatch

Helps prevent flea re-infestation for (1 month) (28 days) (4 weeks)

(Plus) Stops fleas from multiplying

(Plus) Protects against pre-adult fleas

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Kills (3 stages) of (tick) (the tick) life cycle

(Plus) kills (adult ticks) (larvae) (and) (&) (nymphs)

Kills (pre-adult) ticks

Kills (and Prevents) (Flea Eggs) (and) (Flea Larvae) for (one month)(4 weeks)(28 days)

Kills and repels (fleas) (ticks) (flea eggs) (flea larvae) for (1 month) (28 days) (4 weeks)

Kills (fleas) (ticks) (flea eggs) (flea larvae) for (1 month) (28 days) (4 weeks)

(Starts) killing (through) contact

Kills (through) contact

Controls flea and tick infestations on dogs

Flea and tick control

(one product) kills (fleas) (ticks) plus flea eggs (flea larvae)

Flea egg and flea larvae treatment

Kills all stages of the flea life cycle

Controls (kills) fleas, ticks round -the-clock for up to (1 month) (28 days) (4 weeks)

Controls flea (population growth) (infestation)

Focused on breaking the flea life cycle

Controls flea infestation where it starts

Active ingredient (specifically) targeting flea eggs and flea larvae – stopping their ability to mature and infest your home

Help prevent flea re-infestation for (1 month) (28 days) (4 weeks)

X Day Protection

(This product) (alternate brand name) contains [(both) (an adulticide to kill adult fleas and ticks) and an insect growth regulator (IGR) to kill fleas eggs before they hatch] [an insecticide which kills adult fleas and ticks and an insect growth regulator which prevents flea eggs and flea larvae from maturing into adults] (Adult flea spend virtually all of their time on your pet, but they products eggs which drop off the pet and develop in the environment) [once flea are apparent on your pet, there can already be an infestation of their pre adult stages in your home. (this product) (alternative brand name) is designed to kill both the adult flea and flea eggs and flea larvae, thereby breaking the flea life cycle]

Hartz®Rabon® Spray wit..... Aethoprene Pump Formulation

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NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

Conditions and Restores Shine

(Deep) (Rich) Conditioning

With (Conditioning) Aloe

Moisturizing Aloe

Aloe Relief

With Aloe to (Condition) (&) (Restore Shine)

With Soothing Aloe

Contains (Soothing) Aloe

(With) (Contains) Aloe to (Nourish) (&) (Moisturize)

(Calming) Aloe

Gentle Aloe

(With)(Contains) Aloe to (Calm) (&) (Soothe) (Skin)

(With) (Contains) Aloe to (Nourish) (&) (Moisturize) (Skin)(&)(Coat)

(With)(Contains) Aloe to sooth (irritated) (flea-bitten) skin

Visit (our website) (www.hartz.com) (www.hartzultraguard.com) (www.hartzincontrol.com)

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

For (dogs) (cats) (puppies) (kittens)

Fine mist spray

Water-based formula

Contains a conditioner

Conditioning formula

With deodorant

Direct treatment

Patented formula

For more information, call our experts at xxx-xxx-xxxx

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.

As with all flea and tick products, they are most effective when used as part of a total program aimed at reducing fleas and ticks in the (dog's) (cat's) (pet's) environment

A single female flea can lay [an average of] 25 eggs per day [on average]

Complete your preventative program with products that kill both adult and pre-adult fleas.

(Complete your defense against fleas with) (two) ingredients targeted at (killing fleas) (breaking the life cycle)

Be sure to treat the animal's bedding and surroundings with product registered for these uses, such as Hartz (brand name) line (products)