

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

September 8, 2015

Mr. Lance Hemsarth Senior Director, Research and Development The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094-3688

Subject: Label Amendment – Response to Agency Initiated Action Dated May 13, 2015

Product Name: Hartz® 2 in 1® Flea & Tick Pump for Dogs II

EPA Registration Number: 2596-125 Application Date: May 13, 2015 Decision Number: 504967

#### Dear Hemsarth:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act 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 FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list 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 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 the EPA's Office of Enforcement and Compliance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Mr. Carmen J. Rodia, Jr. by phone at (703) 306-0327, or via email at <u>Rodia.Carmen@epa.gov</u>.

Sincerely,

Richard Gebken Product Manager 10

Invertebrate & Vertebrate Branch 2

Office of Pesticide Programs

Enclosure

MASTER LABEL BASED ON 1/28/2011 EPA STAMPED APPROVED LABEL

# Hartz® 2 in 1® Flea & Tick Pump for Dogs II

#### Alternate Brand Names

Hartz<sup>®</sup> UltraGuard<sup>TM</sup> Flea & Tick Spray for Dogs Hartz<sup>®</sup> Advanced Care<sup>TM</sup> 2 in 1<sup>®</sup> Flea & Tick Dog Spray Hartz<sup>®</sup> 2 in 1<sup>®</sup> Flea & Tick Dog Spray

# ACCEPTED

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2596-125

A CORNER		TRICIN	****	WIND TOWN
ACT	IVE:	INGR	ил	ENT:

Tetrachlorvinphos	1.08%
OTHER INGREDIENTS	98.92%
TOTAL	100.00%

#### KEEP OUT OF REACH OF CHILDREN

#### CAUTION:

See (back) (side) panel(s) for additional precautionary statements.

**NET CONTENT** fl. oz. ( ml)

EPA Reg. No. 2596-125

EPA Est. No.

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

Note: Optional/alternate text in parentheses or brackets

MASTER LABEL BASED ON 1/28/2011 EPA STAMPED APPROVED LABEL

# READ ENTIRE LABEL BEFORE EACH USE USE ONLY ON DOGS

## PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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

Do not apply to pets (puppies) less than twelve (12) weeks old. Consult a veterinarian before using this product on debilitated, aged, 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. Do not use near birds, fish or foodstuffs. If used on pregnant or nursing dogs, do not retreat until the puppies are at least 12 weeks old. Do not use this product simultaneously or within 30 days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides or chemicals. However, flea and tick collars may be immediately replaced after use.

#### FIRST AID

This product contains tetrachlorvinphos (an organophosphate) which is a cholinesterase inhibitor.

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. You may also contact 1-800-275-1414 for emergency medical treatment information twenty-four (24) hours per day, seven (7) days per week.

**Note to Physicians and Veterinarians**: This product contains an organophosphate and may cause cholinesterase inhibition. 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.

Note: Optional/alternate text in parentheses or brackets

#### DIRECTIONS FOR USE

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

#### 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.
- Rub spray into animal's coat. For longhaired dogs, ruffle fur to allow the spray to reach skin.
- 4. After 10 minutes, dry dog 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.

Recommended dosage: Spray 25-30 strokes for a small dog (e.g. Terrier). Spray 30-40 strokes for a medium dog (e.g. Spaniel). Spray 40-70 strokes for a large dog (e.g. Labrador). More spray may be needed for longhaired dogs.

#### STORAGE AND DISPOSAL

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

Pesticide Storage: Store 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.

## OPTIONAL/ALTERNATE LABEL TEXT

Kills and repels fleas and ticks

Fast acting

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

Kills fleas within 10 minutes

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

(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

Kills (and repels) (fleas) (ticks)

(Starts) Killing (through) contact

Kills (through) contact

Flea and tick control

Keep flea and ticks off your pet

Note: Optional/alternate text in parentheses or brackets

6/8/2015

### MASTER LABEL BASED ON 1/28/2011 EPA STAMPED APPROVED LABEL

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

Deodorizing

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

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

For full precautions and directions for use, peel (back) here.

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)

Visit (our website)

Note: Optional/alternate text in parentheses or brackets