

2596-86

11/4/2010

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 4, 2010

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

Subject: Amended Labeling; Addition of New EPA Establishment Number & Deletion of Use on Cats Hartz® 2 in 1® Flea & Tick Dip for Dogs with Pyrethrin, EPA Reg. No. 2596-86 Your Submission Dated September 16, 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):

General Statement:

1. Please note that the affected main active and alternate brand names for this product have been changed to specify use only on dogs. Revise the main active brand name for this product to read "Hartz® 2 in 1® Flea & Tick Dip for Dogs with Pyrethrins."

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

2. In order to facilitate inclusion of language from the acute toxicology review completed for this application, revise this subsection to read "CAUTION: Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse."

Environmental Hazards Statement section comment(s):

3. In order to facilitate inclusion of required language from the REDs for pyrethrins, piperonyl butoxide and MGK® 264 insecticide synergist (updated label tables for pyrethrins/piperonyl butoxide/MGK 264 insecticide synergist combination products), revise this section to read:

"ENVIRONMENTAL HAZARDS

This product is toxic to aquatic organisms, including fish and invertebrates. Drift and run-off may be hazardous to aquatic organisms in water adjacent to treated areas. This product may contaminate water through run-off. This product has a potential for run-off for several months or more after application. Poorly draining soils and soils with shallow water tables are more prone to produce run-off that contains this product.

This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.

Do not apply directly to water, to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash-waters or rinsate. See Directions of Use for additional precautions and requirements."

First Aid Statement section comment(s):

4. In order to facilitate inclusion of language from the acute toxicology review completed for this application, revise the "If swallowed:" statement to read "If swallowed: Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person."

Directions for Use section comment(s):

5. In order to facilitate inclusion of required language from the REDs for pyrethrins, piperonyl butoxide and MGK® 264 insecticide synergist (updated label tables for pyrethrins/piperonyl butoxide/MGK 264 insecticide synergist combination products), insert the following new subsection immediately following the statement starting with "It is a violation of federal law to use ..." as follows:

USE RESTRICTIONS
<ul style="list-style-type: none"> • Apply this product only as specified on this label. • Do not contaminate food or feedstuffs with this concentrate or dip. • Do not apply this product to cats or kittens. • Do not apply to pets (puppies) less than 12 weeks old. • Consult a veterinarian before applying this product on medicated, debilitated, aged, pregnant, or nursing animals. • Sensitivities 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 apply more than 1 time per day.

6. Revise the existing statement "**USE ONLY ON DOGS**" to read "**USE ONLY ON DOGS AND PUPPIES OLDER THAN 12 WEEKS OF AGE.**"

Storage and Disposal Statement section comment(s):

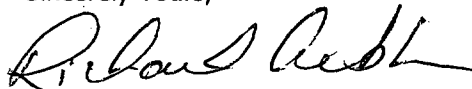
7. Revise the existing "**Pesticide Storage:**" subsection to read "**Pesticide Storage:** Keep this product in its tightly closed original container when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals."

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 (7504P)

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Hartz® 2 in 1® Flea & Tick Dip for Dogs with Pyrethrin

9/16/10

EPA Reg. No.: 2596-86

MASTER LABEL BASED ON 10/7/08 EPA STAMPED APPROVED LABEL

Hartz® 2 in 1® Flea & Tick Dip for Dogs with Pyrethrin

Alternate Brand Names

Hartz® UltraGuard™ Flea & Tick Dip for Dogs

Hartz® Advanced Care™ 2 in 1® Flea & Tick Dip

Hartz® 2 in 1® Flea & Tick Dip

ACCEPTED
With COMMENTS
In EPA Letter Dated:

November 4, 2010

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

2596-86

ACTIVE INGREDIENTS:

Pyrethrins.....0.33%

Piperonyl butoxide, technical*.....0.67%

N-octyl bicycloheptene dicarboximide.....1.11%

OTHER INGREDIENTS97.89%

TOTAL 100.00%

*Equivalent to 0.54% (butylcarbityl)(6-propylpiperonyl) ether and 0.13% related compounds. Contains petroleum distillate.

KEEP OUT OF REACH OF CHILDREN

CAUTION

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

NET CONTENT ___ fl. oz. (___ ml)

EPA Reg. No. 2596-86

EPA Est. No. 2596-NJ-01 = BL

EPA Est. No. 11525-IL-001 = BB

See lot # for EPA Est. No.

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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Do not apply to puppies less than 12 weeks old. Consult a veterinarian before using this product on medicated, debilitated, aged, pregnant, or nursing animals. Sensitivities 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.

USER SAFETY RECOMMENDATIONS

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic organisms, including fish and invertebrates. Do not contaminate water when disposing of equipment, wash water or rinsate. See Directions for Use for additional precautions and requirements.

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. You may also contact 1-800-275-1414 for emergency medical treatment information.

Note to Physician: Contains petroleum distillate. Vomiting may cause aspiration pneumonia.

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic organisms, including fish and invertebrates. Do not contaminate water when disposing of equipment, wash water or rinsate. See Directions for Use for additional precautions and requirements.

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Hartz® 2 in 1® Flea & Tick Dip for Dogs with Pyrethrin

9/16/10

EPA Reg. No.: 2596-86

MASTER LABEL BASED ON 10/7/08 EPA STAMPED APPROVED LABEL

PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame.

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

MUST BE DILUTED (*Note: may also appear on front panel*)

1. Dilute 4 ounces of this product with 1 gallon of water.
2. Dip animal into solution, making sure hair is thoroughly wet to the skin.
3. The area around the ears should be sponged thoroughly. Avoid contact of material with eyes and mouth of animal.
4. Do not rinse.
5. Towel dry.
6. Repeat weekly (if necessary)

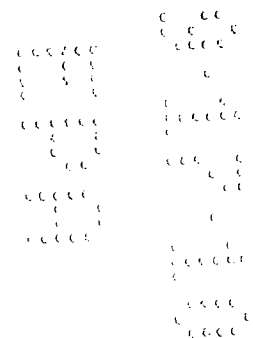
Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing or medicated animals. Sensitivity may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

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.



6096

Hartz® 2 in 1® Flea & Tick Dip for Dogs with Pyrethrin

9/16/10

EPA Reg. No.: 2596-86

MASTER LABEL BASED ON 10/7/08 EPA STAMPED APPROVED LABEL

OPTIONAL/ALTERNATE LABEL TEXT

Kills Fleas

Kills Ticks

Kills Fleas and Ticks

Kills fleas and ticks, including the Deer tick, which may carry Lyme disease

Kills Deer ticks, which may carry Lyme disease

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

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

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

For Dogs

Concentrated- Makes (x) gallons

Concentrated- Makes three gallons

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

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

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) (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)